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DELTA REPORT

10-K

AEMD - AETHLON MEDICAL INC

10-K - MARCH 31, 2024 COMPARED TO 10-K - MARCH 31, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	2516
CHANGES	232
DELETIONS	1079
ADDITIONS	1205

REFINITIV

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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 March 31, 2023 2024

OR

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER 001-37487

Aethlon Medical, Inc.

(Exact name of registrant as specified in its charter)

NEVADA	13-3632859
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11555 Sorrento Valley Road, Suite 203 San Diego, California (Address of principal executive office)	92121 (Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: ((619) 619) 941-0360

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE EXCHANGE ACT:

TITLE OF EACH CLASS	TRADING SYMBOL	NAME OF EACH EXCHANGE ON WHICH REGISTERED
COMMON STOCK, $0.001 PAR VALUE	AEMD	NASDAQ CAPITAL MARKET

SECURITIES REGISTERED UNDER SECTION 12(g) OF THE EXCHANGE ACT:
NONE
(TITLE OF CLASS)

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 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 pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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 No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant as of September 30, 2022 September 29, 2023 (the last trading day of the registrant's most recently completed second quarter) was approximately $13.2 5.5 million, computed by reference to the closing sale price of the common stock of $0.58 $2.258 per share on the Nasdaq Capital Market on September 30,

2022 September 29, 2023. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the common stock of the registrant outstanding as of June 26, 2023 June 25, 2024 was 24,771,367 13,899,725.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission, or SEC, pursuant to Regulation 14A in connection with the registrant's 2023 2024 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days following the end of the registrant's fiscal year ended March 31, 2023 March 31, 2024.

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CAUTIONARY NOTICE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the safe harbor created by those sections.

We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements and are based upon our current expectations, beliefs, estimates and projections, and various assumptions, many of which, by their nature, are inherently uncertain and beyond our control. Such statements, include, but are not limited to, statements contained in this Annual Report relating to our business, business strategy, products and services we may offer in the future, the timing and results of future regulatory filings, the timing and results of future clinical trials, and capital outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statement of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward looking statements include, but are not limited to, a decline in general economic conditions nationally and internationally; the ability to protect our intellectual property rights; competition from other providers and products; risks in product development; inability to raise capital to fund continuing operations; changes in government regulation; the ability to complete capital raising transactions, and other factors (including the risks contained in Item 1A of this Annual Report under the heading "Risk Factors") relating to our industry, our operations and results of operations and any businesses that may be acquired by us. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, we undertake no obligation to and do not intend to update any of the forward-looking statements to conform these statements to actual results.

SUMMARY RISK FACTORS

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" in Part I of this Annual Report and should be carefully considered, together with other information in this Annual Report and our other filings with the SEC before making investment decisions regarding our securities.

- We have incurred significant losses and expect to continue to incur losses for the foreseeable future.
- We will require additional financing to sustain our operations, achieve our business objectives and satisfy our cash obligations, which may dilute the ownership of our existing stockholders.
- We have limited experience in identifying and working with large-scale contracts with medical device manufacturers; manufacture of our devices must comply with good manufacturing practices in the United States.
- Delays, interruptions or the cessation of production by our third-party suppliers of important materials or delays in qualifying new materials, has and may continue to prevent or delay our ability to manufacture our Hemopurifier.
- Our Hemopurifier technology may become obsolete.
- If we fail to comply with extensive regulations of U.S. and foreign regulatory agencies, the commercialization of our products could be delayed or prevented entirely.
- If we are unable to regain compliance with the listing requirements of the Nasdaq Capital Market, our common stock may be delisted from the Nasdaq Capital Market, which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.
- As a public company with limited financial resources undertaking the launch of new medical technologies, we may have difficulty attracting and retaining executive management and directors.
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- We plan to expand our operations, which may strain our resources; our inability to manage our growth could delay or derail implementation of our business objectives.
- Our success is dependent in part on our executive officers.
- Delays in successfully commencing or completing our planned clinical trials could jeopardize our ability to obtain regulatory approval. approval and sustain our operations.

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PART I

ITEM 1. BUSINESS

Unless otherwise indicated or the context otherwise requires, references to the "Company", "Aethlon", "we", "us" and "our" refer to Aethlon Medical, Inc.

Overview and Corporate History

Aethlon Medical, Inc., or Aethlon, the Company, we or us, is Overview

We are a medical therapeutic company focused on developing products to treat cancer and life-threatening infectious diseases. The Aethlon the Hemopurifier, is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. infections and for use in organ transplantation. In cancer, human studies, 164 sessions with 38 patients, the Hemopurifier is designed was safely utilized and demonstrated the potential to deplete remove life-threatening viruses. In pre-clinical studies, the presence of circulating tumor-derived Hemopurifier has demonstrated the potential to remove harmful exosomes that and exosomal particles from biological fluids, utilizing its proprietary lectin-based technology. This action has potential applications in cancer, where exosomes and exosomal particles may promote immune suppression seed the spread of and metastasis, and inhibit the benefit of leading cancer therapies. in life-threatening infectious diseases. The U.S. Food and Drug Administration, or FDA, has designated the Hemopurifier as a "Breakthrough Device" for two independent indications:

- the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes or exosomal particles have been shown to participate in the development or severity of the disease; and

- the treatment of life-threatening viruses that are not addressed with approved therapies.

Oncology

We believe the Hemopurifier can may be a substantial advance advancement in the treatment of patients with advanced and metastatic cancer through the clearance of its design to bind to and remove harmful exosomes and exosomal particles that promote the growth and spread of tumors through multiple mechanisms. tumors. In October 2022, we formed a wholly-owned subsidiary in Australia to initially conduct oncology-related clinical research, then seek regulatory approval and commercialize our Hemopurifier in Australia. We are currently working with our new contract research organization, or CRO, on preparations to conduct a clinical trial in Australia in patients with solid tumors, including head and neck cancer, and gastrointestinal cancers and other cancers.

On October 4, 2019, the FDA approved our Investigational Device Exemption, or IDE, application to initiate an Early Feasibility Study, or EFS, of the Hemopurifier in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda). The primary endpoint for the EFS, designed to enroll 10 to 12 subjects at a single center, is safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. This clinical trial, initially conducted at the UPMC Hillman Cancer Center in Pittsburgh, PA, or UPMC, treated two patients. Due to lack of further patient enrollment, we and UPMC terminated this trial.

In January 2023, we entered into an agreement with North American Science Associates, LLC, or NAMSA, a world leading MedTech medical technology CRO offering global end-to-end development services, to oversee our planned clinical trials investigating the Hemopurifier for oncology indications. Pursuant to the agreement, NAMSA will agreed to manage our planned clinical trials of the Hemopurifier for patients in the United States and Australia with various types of cancer tumors.

We anticipate recently completed an *in vitro* binding study of relevant oncology targets, to provide pre-clinical evidence to support our trial design and translational endpoints. Our study indicated positive results from this study, providing evidence that the initial our Hemopurifier removes extracellular vesicles, or EVs, from plasma. This translational study provides pre-clinical evidence to support our planned phase 1 safety, feasibility and dose-finding clinical trials will begin of our Hemopurifier in Australia. patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment, such as Keytruda® or Opdivo®. In addition to an interested initial trial site in India, we had three interested sites in Australia that were awaiting our completion of this *in vitro* binding study. We added the data from this study to our Clinical Investigator Brochure and submitted that brochure to the Ethics Committee of Royal Adelaide Hospital in Australia and in June 2024, we received approval for our proposed phase 1 oncology trial from the Ethics Committee from Royal Adelaide Hospital. We are currently in the process of applying to the Ethics Committees of the two additional interested clinical trial sites in Australia and the site in India.

Life-Threatening Viral Infections

We also believe that the Hemopurifier can be part of the broad-spectrum treatment of life-threatening highly glycosylated, or carbohydrate coated, viruses that are not addressed with an already approved treatment. In small-scale or early feasibility human studies, the Hemopurifier has been used in the past to treat individuals infected with human immunodeficiency virus, or HIV, hepatitis-C and Ebola.

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Additionally, *in vitro*, the Hemopurifier has been demonstrated to capture Zika virus, Lassa virus, MERS-CoV, cytomegalovirus, Epstein-Barr virus, Herpes simplex virus, Chikungunya virus, Dengue virus, West Nile virus, smallpox-related viruses, H1N1 swine flu virus, H5N1 bird flu virus, Monkeypox virus and the reconstructed Spanish flu virus of 1918. In several cases, these studies were conducted in collaboration with leading government or non-government research institutes.

We believe the Hemopurifier can be part of the treatment of severe SARS-CoV-2 viremia/COVID-19, or COVID-19, cases. COVID viremia is detected in approximately 34% of patients and is associated with severity, requirement for intensive care unit, or ICU, stay, development of multi-organ failure and poor outcomes. EVs and exosomal miRNAs may play a role in the spread of infection as well as ongoing inflammation, development of coagulopathy and lung injury. Our proprietary *Galanthus nivalis* agglutinin, or GNA, affinity resin has been shown to bind multiple clinically relevant SARS-CoV-2 variants. Furthermore, studies have demonstrated *in vitro* removal of seven SARS-CoV2 variants (104 PFU/mL) in phosphate buffered saline passed over a column of GNA affinity resin (1g) three times, with capture efficiencies between 53% and 89%.

On June 17, 2020, the FDA approved a supplement to our open Investigational Device Exemption, or IDE, for the Hemopurifier in viral disease to allow for the testing of the Hemopurifier in patients with SARS-CoV-2/COVID-19, or COVID-19, in a New Feasibility Study. new feasibility study. That study was designed to enroll up to 40 subjects at up to 20 centers in the United States. Subjects had were to have an established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU and have acute lung injury and/or severe or life-threatening disease, among other criteria. Endpoints for this study, in addition to safety, included reduction in circulating virus, as well as clinical outcomes (NCT # 04595903). In January 2021, the Hemopurifier was used to treat a viremic patient, under our emergency use approval, with a predicted risk of mortality of 80% and the Hemopurifier was able to reduce the patient's SARS-CoV-2 plasma viral load by 58.4%. In June 2022, the first patient in this study was enrolled and completed the Hemopurifier treatment phase of the protocol. Due to the lack of COVID-19 patients in the ICUs of our trial sites, we terminated this study in 2022. However, our IDE for this indication remains open, as we have an active COVID-19 trial in India and wish to preserve the option of enrolling patients if the situation with COVID-19 changes.

Under Single Patient Emergency Use regulations, the Company Aethlon has treated two patients with COVID-19 with the Hemopurifier, in addition to the COVID-19 patient treated with our Hemopurifier in our COVID-19 clinical trial discussed above.

We currently are experiencing previously reported a disruption in our Hemopurifier supply, as our then existing supply of Hemopurifiers expired on September 30, 2022, and, also as previously disclosed, we are dependent on FDA approval of qualified suppliers to manufacture our Hemopurifier. We recently completed final testing in order to begin manufacturing Hemopurifiers at our new manufacturing facility in San Diego, California for use in planned U.S. clinical trials, using GNA from our current supplier. In April 2024, we received a notice of approval from the FDA for our IDE supplement to add our San Diego manufacturing facility and we now are able to manufacture Hemopurifiers at this site. We also have sufficient Hemopurifiers on hand for use in our planned Australia and India oncology trials. Our intended transition to a new supplier for galanthus nivalis agglutinin, or GNA, a component of our Hemopurifier, is continues to be delayed as we work with the FDA for approval of our supplement to our IDE, which is required to make this manufacturing supplier change.

In October 2022, we launched a wholly owned subsidiary in Australia, formed We are working with the FDA to conduct clinical research, seek regulatory approval and commercialize qualify this second supplier of our Hemopurifier in that country. The subsidiary will initially focus on oncology trials in Australia. GNA.

We also obtained Ethics Review Board, ethics review board, or ERB, approval from and entered into a clinical trial agreement with Medanta Medicity Hospital, a multi-specialty hospital in Delhi NCR, India, for a COVID-19 clinical trial at that location. One patient has completed participation in the Indian COVID-19 study. The relevant authorities in India have accepted the use of the Hemopurifiers made with the GNA from our new supplier.

In May 2023, we also received ERB approval from the Maulana Azad Medical College, or MAMC, for a second site for our clinical trial in India to treat severe COVID-19. MAMC was established in 1958 and is located in New Delhi, India. MMAC MAMC is affiliated with the University of Delhi and is operated by the Delhi government.

We also recently announced now have two sites in India for this trial with the Medanta Medicity Hospital and Maulana Azad Medical College, or MAMC. One patient has been treated to date; however, we have been informed by our CRO that we also have begun investigating the use of our Hemopurifier a new COVID-19 subvariant was detected in India recently. Our COVID-19 trial in India remains open in the organ transplant setting. Our objective is event that there are COVID-19 admissions to confirm the ICUs at our sites in India.

Organ Transplantation

Additionally, based on preclinical data with acellular kidney perfusates, we believe that the Hemopurifier has potential applications in our translational studies, organ transplantation. We are investigating whether the Hemopurifier, when incorporated into a machine perfusion organ preservation circuit, can remove harmful viruses, exosomes, RNA molecules, cytokines, chemokines and exosomes other inflammatory molecules from harvested recovered organs. We initially are focused on recovered kidneys from deceased donors. We have previously demonstrated the removal of multiple viruses and exosomes and exosomal particles from buffer solutions, *in vitro*, utilizing a scaled-down version of our Hemopurifier. This Hemopurifier and believe this process potentially may could reduce transplantation complications following transplantation of the harvested organ, which can include viral infection, delayed by improving graft function, reducing graft rejection, maintaining or improving organ viability prior to transplantation, and rejection. We believe this new approach could be additive to existing technologies that currently are in place to increase potentially reducing the number of viable organs kidneys rejected for transplant.

Previously, we were the majority owner of Exosome Sciences, Inc., or ESI, a company formed to focus on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases, and thus consolidated ESI in our consolidated financial statements. For more than four years, the primary activities of ESI were limited to the payment of patent maintenance fees and applications. In September 2022, the Board of Directors of ESI and we, as the majority stockholder of ESI, approved the dissolution of ESI.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we plan to market and sell the Hemopurifier. Some of our patents may expire before FDA approval or approval in a foreign country, if any, is obtained. However, we believe that certain patent applications and/or other patents issued to us more recently will help protect the proprietary nature of the our Hemopurifier treatment technology.

In addition to the foregoing, we are monitoring closely the impact of inflation, recent bank failures and the war between Russia and Ukraine and the military conflicts in Ukraine Israel and the surrounding areas, as well as related political and economic responses and counter-responses by various global factors on our business. Given the level of uncertainty regarding the duration and impact of these events on capital markets and the U.S. economy, we are unable to assess the impact on our timelines and future access to capital. The full extent to which inflation, recent bank failures and the war in Ukraine ongoing military conflicts will impact our business, results of operations, financial condition, clinical trials and preclinical research will depend on future developments, as well as the economic impact on national and international markets that are highly uncertain.

We incorporated On March 10, 1999, Aethlon, Inc., a California corporation, Hemex, Inc., a Delaware corporation and the accounting predecessor to Aethlon, Inc., and Bishop Equities, Inc., a publicly traded Nevada corporation, completed an Agreement and Plan of Reorganization structured to result in Nevada on March 10, 1999. Bishop Equities, Inc.'s acquisition of all of the outstanding common stock of Aethlon, Inc. and Hemex, Inc. Under the plan's terms, Bishop Equities, Inc. issued shares of its common stock to the stockholders of Aethlon, Inc. and Hemex, Inc. such that Bishop Equities, Inc. then owned 100% of each company. Upon completion of the transaction, Bishop Equities, Inc. was renamed Aethlon Medical, Inc. Our executive offices are located at 11555 Sorrento Valley Road, Suite 203, San Diego, California 92121. Our telephone number is (619) 941-0360. Our website address is www.aethlonmedical.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report.

The Mechanism of the Hemopurifier

The Hemopurifier is an affinity hemofiltration device designed for the single-use removal of harmful exosomes and life-threatening viruses from the human circulatory system. In the United States, the Hemopurifier is classified as a combination product whose regulatory jurisdiction is the Center for Devices and Radiological Health, or CDRH, the branch of FDA responsible for the premarket approval of all medical devices.

In our current applications, our Hemopurifier can be used on the established infrastructure of continuous renal replacement therapy, or CRRT, and dialysis instruments located in hospitals and clinics worldwide. It could also potentially be developed as part of a proprietary closed system with its own pump and tubing set, negating the requirement for dialysis infrastructure. Incorporated within the Hemopurifier is a protein called a lectin, that aids in binding exosomes and viruses.

The initial development of the Hemopurifier was focused on viral infections. In non-clinical bench experiments using a laboratory version of the Hemopurifier, performed in Company labs as well as in multiple other outside labs, including the Centers for Disease Control and Prevention, or CDC, the United States Army Medical Research Institute of Infectious Diseases, or USAMRIID, Battelle Memorial Research Institute and others, we have demonstrated that a miniature version of the Hemopurifier can bind and clear multiple different glycosylated viruses. These viruses include HIV, HCV, Dengue, West Nile, multiple strains of influenza, Ebola, Chikungunya, smallpox, monkeypox, multiple herpes viruses, a MERS-CoV related pseudovirus and others.

Initial clinical trials on the Hemopurifier were conducted overseas on dialysis patients with HCV, with a subsequent EFS conducted in the United States under an FDA approved IDE.

On March 13, 2017, we concluded an FDA-approved EFS under an IDE in end stage renal disease patients on dialysis who were infected with HCV. The study was conducted at DaVita MedCenter Dialysis in Houston, Texas. We reported that there were no device-related adverse events in enrolled subjects who met the study inclusion-exclusion criteria. We also reported that an average capture of 154 million copies of HCV (in International Units, I.U.) within the Hemopurifier during four-hour treatments. Prior to this approval, we collected supporting Hemopurifier data through investigational human studies conducted overseas.

SARS-CoV-2/COVID-19

SARS-COV-2, the causative agent of COVID-19 is a member of the coronavirus family, which includes the original SARS virus, SARS-CoV, and the MERS virus. SARS-CoV-2, like all coronaviruses, is glycosylated. This suggests that the Hemopurifier could potentially clear it from biologic biological fluids, including blood.

On June 17, 2020, the FDA approved a supplement to our open IDE for the Hemopurifier in viral disease to allow for the testing of the Hemopurifier in patients with SARS-CoV-2/COVID-19 in a New Feasibility Study. That study was designed to enroll up to 40 subjects at up to 20 centers in the United States. Subjects had to have an established laboratory diagnosis of COVID-19, be admitted to an ICU, and have acute lung injury and/or severe or life threatening life-threatening disease, among other criteria. Endpoints for this study, in addition to safety, include reduction in circulating virus, as well as clinical outcomes (NCT # 04595903). In June 2022, the Company completed the treatment protocol for its first patient in this study.

In September 2021, we entered into an agreement with a leading global CRO to oversee our U.S. clinical studies investigating the Hemopurifier for critically ill COVID-19 patients. Due to lack of COVID-19 patients in the ICUs of our trial sites, we terminated this study in 2022.

Under Single Patient Emergency Use regulations, we have also treated two patients with COVID-19 with the Hemopurifier, in addition to the COVID-19 patient treated with our Hemopurifier in our COVID-19 clinical trial discussed above. We published a manuscript reviewing case studies covering those two Single Patient Emergency Use treatments entitled “Removal of COVID-19 Spike Protein, Whole Virus, Exosomes and Exosomal microRNAs by the Hemopurifier® Lectin-Affinity Cartridge in Critically Ill Patients with COVID-19 Infection.”

The manuscript described the use of the Hemopurifier for a total of nine sessions in two critically ill COVID-19 patients. The first case study demonstrated the improvement in the patient who was a SARS-COV-2 positive COVID-19 present at entry to the hospital, with associated coagulopathy, or CAC, lung injury, inflammation, and tissue injury despite the absence of demonstrable COVID-19 viremia at the start of treatment at Day 22 and having demonstrated strong viremia earlier in the patient’s disease cycle, suggesting that the significant removal of exosomes contributed to the patient’s recovery. This patient received eight Hemopurifier treatments without complications and eventually was weaned from a ventilator and was discharged from the hospital.

The second patient case study demonstrated in vivo removal of SARS-CoV-2 virus from the blood stream of an infected patient. This patient completed a six-hour Hemopurifier treatment without complications and subsequently was placed on continuous renal replacement therapy, or CRRT. The patient ultimately expired three hours after being placed on CRRT because of the advanced stage of the patient's disease.

In May 2022, we announced the publication of a pre-print manuscript featuring data that demonstrated Aethlon's our proprietary GNA affinity resin was able to bind seven clinically relevant SARS-CoV-2 variants in vitro, including the Delta and Omicron variants. Viral capture efficiency with the GNA affinity resin ranged from 53% to 89% for all variants tested. The GNA affinity resin is a key component of the Aethlon Hemopurifier®. Hemopurifier. The manuscript is titled "Removal of Clinically Relevant SARS-CoV-2 Variants by An Affinity Resin Containing Galanthus nivalis Agglutinin" and was published in bioRxiv.

We previously commissioned Battelle Memorial Institute in 2008 to run a monkeypox virus, or MPV, in vitro study using a mini-Hemopurifier. This study demonstrated that high concentrations of MPV (approximately 35 thousand cpu/ml) were rapidly depleted from cell culture fluids when circulated through the Hemopurifier. The study data indicated that the Hemopurifier removed 44 percent of infectious MPV in the first hour of testing, 82 percent after six hours, and 98 percent after 20 hours. The studies were conducted in triplicate and data verification was provided by real-time polymerase chain reaction.

The Hemopurifier – Clinical Trials Conducted Overseas in Viral Infections

EBOLA Virus

In December of 2014, *Time Magazine* named the Hemopurifier a "Top 25 Invention" as the result of treating an Ebola-infected physician at Frankfurt University Hospital in Germany. The physician was comatose with multiple organ failure at the time of treatment with the Hemopurifier. At the American Society of Nephrology Annual Meeting, Dr. Helmut Geiger, Chief of Nephrology at Frankfurt University Hospital reported that the patient received a single 6.5 hour Hemopurifier treatment. Prior to treatment, viral load was measured at 400,000 copies/ml. Post-treatment viral load reported to be at 1,000 copies/ml. Dr. Geiger also reported that 242 million copies of Ebola virus were captured within the Hemopurifier during treatment. The patient ultimately made a full recovery. Based on this experience, the Company filed an Expanded Access protocol with the FDA to treat Ebola virus infected patients in up to ten centers in the United States and a corresponding protocol was approved by HealthCanada. These protocols remain open allowing Hemopurifier treatment to be offered to patients presenting for care in both countries. In 2018, we applied for and were granted the FDA designated the Hemopurifier as a Breakthrough Designation by the FDA Device "… for the treatment of life-threatening viruses that are not addressed with approved therapies."

Hepatitis C Virus (HCV)

Prior to FDA approval of the IDE feasibility study, we conducted investigational HCV treatment studies at the Apollo Hospital, Fortis Hospital and the Medanta Medicity Institute in India. In the Medanta Medicity Institute study, 12 HCV-infected individuals were enrolled to receive three six-hour Hemopurifier treatments during the first three days of a 48-week peginterferon+ribavirin treatment regimen. The study was conducted under the leadership of Dr. Vijay Kher. Dr. Kher's staff reported that Hemopurifier therapy was well tolerated and without device-related adverse events in the 12 treated patients.

Of these 12 patients, ten completed the Hemopurifier-peginterferon+ribavirin treatment protocol, including eight genotype-1 patients and two genotype-3 patients. Eight of the ten patients achieved a sustained virologic response, which is the clinical definition of treatment cure and is defined as undetectable HCV in the blood 24 weeks after the completion of the 48-week peginterferon+ribavirin drug regimen. Both genotype-3 patients achieved a sustained virologic response, while six of the eight genotype-1 patients achieved a sustained virologic response, which defines a cure of the infection.

Hemopurifier - Human Immunodeficiency Virus (HIV)

In addition to treating Ebola and HCV-infected individuals, we also conducted a single proof-of-principle treatment study at the Sigma New Life Hospital in an AIDS patient who was not being administered HIV antiviral drugs. In the study, viral load was reduced by 93% as the result of 12 Hemopurifier treatments (each four hours in duration) that were administered over the course of one month.

The Hemopurifier in Cancer

Our primary focus in recent years has been on the evaluation of the Hemopurifier in cancer, where we have previously shown in non-clinical studies and in a COVID-19 emergency use patient that it is capable of clearing exosomes, which are subcellular particles that are secreted by both normal and malignant cells. Tumor derived exosomes, have been shown in multiple laboratories to be critical components in the progression of cancers. They can mediate resistance to chemotherapy, resistance to targeted agents such as trastuzumab (Herceptin), metastasis and resistance to the newer immuno-oncology agents, such as pembrolizumab (Keytruda). Based on these observations and data, in November 2019 the FDA granted us a second Breakthrough Designation "…for the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease."

U.S. GOVERNMENT CONTRACTS

We did not recognize revenue from government contracts in the fiscal year ended March 31, 2024. We have recognized revenue under the following government contracts/grants over contract/grant in the past two years: fiscal year ended March 31, 2023:

Phase 2 Melanoma Cancer Contract

On September 12, 2019, the National Cancer Institute, or NCI, part of the National Institutes of Health, or NIH, awarded to us an a SBIR Phase II Award Contract, for NIH/NCI Topic 359, entitled “A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring”, or the Award Contract. The Award Contract amount was $1,860,561 and, as amended, ran for the period from September 16, 2019 through September 15, 2022.

The work performed pursuant to this Award Contract was focused on melanoma exosomes. This work followed from our completion of a Phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018, as described below. Following on the Phase I work, the deliverables in the Phase II program involved the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

The Award Contract ended on September 15, 2022 and we presented the required final report to the NCI. As the NCI completed its close out review of the contract, we recognized as revenue the $574,245 previously recorded as deferred revenue on our December 31, 2022 balance sheet.

Subaward with University statement of Pittsburgh

In December 2020, we entered into a cost reimbursable subaward arrangement with the University of Pittsburgh in connection with an NIH contract entitled "Depleting Exosomes to Improve Responses to Immune Therapy in HNNCC." Our share of the award was $256,750. We did not record revenue related to this subaward in operations for the fiscal year ended March 31, 2023. We recorded $64,467of revenue related to this subaward in the fiscal year ended March 31, 2022.

In October 2022, we agreed with the University of Pittsburgh to terminate the subaward arrangement, effective as of November 10, 2022, since it related to our clinical trial in head and neck cancer in which the University of Pittsburgh was unable to recruit patients. There are no provisions in the subaward arrangement requiring repayment of cash received for work completed through November 10, 2022.

Research and Development Costs

A substantial portion of our operating budget is used for research and development activities. The cost of research and development, all of which has been charged to operations, amounted to approximately $2,745,000 $2,520,000 and $2,341,000 $2,745,000 in the fiscal years ended March 31, 2023 March 31, 2024 and 2022, 2023, respectively.

Intellectual Property

We currently own or have license rights to a number of U.S. and foreign patents and patent applications and endeavor to continually improve our intellectual property position. We consider the protection of our technology, whether owned or licensed, to the exclusion of use by others, to be vital to our business. While we intend to focus primarily on patented or patentable technology, we also rely on trade secrets, unpatented property, know-how, regulatory exclusivity, patent extensions and continuing technological innovation to develop our competitive position. We also own certain trademarks.

Our success depends in large part on our ability to protect our proprietary technology, including the Hemopurifier product platform, and to operate without infringing the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success also depends, in part, on our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products or processes, obtain licenses or cease sales of products or certain activities.

To protect our proprietary medical technologies, including the Hemopurifier product platform and other scientific discoveries, we have a portfolio of over 50 46 issued patents and pending applications worldwide. We currently have five issued U.S. patents and 32 24 issued patents in countries outside of the United States. In addition, we have thirteen 17 patent applications pending worldwide related to our Hemopurifier product platform and other technologies. We are seeking additional patents on our scientific discoveries.

It is possible that our pending patent applications may not result in issued patents, that we will not develop additional proprietary products that are patentable, that any patents issued to us may not provide us with competitive advantages or will be challenged by third parties and that the patents of others may prevent the commercialization of products incorporating our technology. Furthermore, others may independently develop similar products, duplicate our products or design around our patents. U.S. patent applications are not immediately made public, so it is possible that a third party may obtain a patent on a technology we are actively using.

There is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or unenforceable. For many of our pending applications, patent interference proceedings may be instituted with the U.S. Patent and Trademark Office, or the USPTO, when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the USPTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delays in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. Third parties can file post-grant proceedings in the USPTO, seeking to have issued patent invalidated, within nine months of issuance. This means that patents undergoing post-grant proceedings may be lost, or some or all claims may require amendment or cancellation, if the outcome of the proceedings is unfavorable to us. Post-grant proceedings are complex and could result in a reduction or loss of patent rights. The institution of post-grant proceedings against our patents could also result in significant expenses.

Patent law outside the United States is uncertain and in many countries, is currently undergoing review and revisions. The laws of some countries may not protect our proprietary rights to the same extent as the laws of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition. Outside of the United States, we currently have pending patent applications or issued patents in Europe, India, Russia, Canada, Japan, Singapore and Hong Kong.

In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. It is possible that others could independently develop or otherwise acquire substantially equivalent technology, somehow gain access to our trade secrets and proprietary technological expertise or disclose such trade secrets, or that we may not successfully ultimately protect our rights to such unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Patents

The following table lists our issued patents and patent applications, including their ownership status: status, including relevant patent term adjustments (PTA), which is a process of extending the term of a U.S. patent:

Patents Issued in the United States

PATENT #	**PATENT NAME**	ISSUANCE DATE	OWNED OR LICENSED	EXPIRATION DATE
9,707,333	Extracorporeal removal of microvesicular particles	7/18/17	Owned	1/6/29
9,364,601	Extracorporeal removal of microvesicular particles	6/14/16	Owned	10/2/ 5/30/29 as terminal disclaimer filed over 8,288,172
8,288,172	Extracorporeal removal of microvesicular particles	10/16/12	Owned	3/09/27 05/30/29 (with 813 days Patent Term Adjustment (PTA))
7,226,429	Method for removal of viruses from blood by lectin affinity hemodialysis	6/5/07	Owned	1/20/24 25 (with 366 days PTA)
10,022,483	Method for removal of viruses from blood by lectin affinity hemodialysis	7/17/18	Owned	1/20/ 8/8/24 (with 201 days PTA)

Patent Applications Pending in the United States

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
16/415,713	Affinity capture of circulating biomarkers	5/17/19	Owned
17/301,666	Method for removal of viruses from blood by lectin affinity hemodialysis	4/09/21	Owned
16/459,220	Methods and compositions for quantifying exosomes	7/01/19	Owned
17/918,085	Devices and methods for treating a coronavirus infection and symptoms thereof	10/10/22	Owned
18/700571	Devices and methods for treating a viral infection and symptoms thereof	04/11/24	Owned

Foreign Patents

PATENT #	PATENT NAME	ISSUANCE DATE	OWNED OR LICENSED	EXPIRATION DATE
2353399	Method for removal of viruses from blood by lectin affinity hemodialysis (Russia)	4/27/09	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Belgium)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Ireland)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Italy)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Great Britain)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (France)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Germany)	7/17/13	Owned	1/20/24
2516403	Method for removal of viruses from blood by lectin affinity hemodialysis (Canada)	8/12/14	Owned	1/20/24
2591359	Methods for quantifying exosomes (Germany)	3/01/17	Owned	7/07/31
2591359	Methods for quantifying exosomes (France)	3/01/17	Owned	7/07/31
2591359	Methods for quantifying exosomes (Great Britain)	3/01/17	Owned	7/07/31
2591359	Methods for quantifying exosomes (Spain)	3/01/17	Owned	7/07/31
2644855	Extracorporeal removal of microvesicular particles (Canada)	11/19/19	Owned	1/20/24 3/09/27
3061952	Extracorporeal removal of microvesicular particles (Canada)	7/19/22	Owned	1/20/24 3/09/27
1993600 502019000055563	Extracorporeal removal of microvesicular particles (Germany)	4/24/19	Owned	1/20/24 3/09/27
1993600	Extracorporeal removal of microvesicular particles (Switzerland)	4/24/19	Owned	1/20/24 3/09/27
1993600	Extracorporeal removal of microvesicular particles (Spain)	4/24/19	Owned	1/20/24 3/09/27
1993600	Extracorporeal removal of microvesicular particles (France)	4/24/19	Owned	1/20/24 3/09/27
1993600	Extracorporeal removal of microvesicular particles (Great Britain)	4/24/19	Owned	1/20/24 3/09/27
1993600 502019000055563	Extracorporeal removal of microvesicular particles (Italy)	4/24/19	Owned	1/20/24 3/09/27
1993600	Extracorporeal removal of microvesicular particles (Netherlands)	4/24/19	Owned	1/20/24 3/09/27
1993600	Extracorporeal removal of microvesicular particles (Sweden)	4/24/19	Owned	1/20/24 3/09/27
1126138	Extracorporeal removal of microvesicular particles (Hong Kong)	6/19/20	Owned	1/20/24 3/09/27
3517151	Extracorporeal removal of microvesicular particles (Switzerland)	4/21/21	Owned	1/20/24 3/09/27
3517151 60 2007 061 082.6	Extracorporeal removal of microvesicular particles (Germany)	4/21/21	Owned	1/20/24 3/09/27
3517151	Extracorporeal removal of microvesicular particles (Denmark)	4/21/21	Owned	1/20/24 3/09/27
3517151 2880460	Extracorporeal removal of microvesicular particles (Spain)	4/21/21	Owned	1/20/24 3/09/27
3517151	Extracorporeal removal of microvesicular particles (France)	4/21/21	Owned	1/20/24 3/09/27
3517151	Extracorporeal removal of microvesicular particles (Great Britain)	4/21/21	Owned	1/20/24 3/09/27
3517151	Extracorporeal removal of microvesicular particles (Ireland)	4/21/21	Owned	1/20/24 3/09/27
3517151	Extracorporeal removal of microvesicular particles (Netherlands)	4/21/21	Owned	1/20/24 3/09/27
3517151	Extracorporeal removal of microvesicular particles (Sweden)	4/21/21	Owned	1/20/24 3/09/27

Pending Foreign Patent Applications

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
8139/DELNP/2008	Extracorporeal removal of microvesicular particles (exosomes) (India)	**3/9/07**	**Owned**
2939652	Brain specific exosome based diagnostics and extracorporeal therapies (Canada)	**8/12/06**	**Owned**
2021256402	Devices and methods for treating a coronavirus infection and symptoms thereof (Australia)	**10/16/22**	**Owned**
3178687	Devices and methods for treating a coronavirus infection and symptoms thereof (Canada)	**9/29/22**	**Owned**
21788894.0	Devices and methods for treating a coronavirus infection and symptoms thereof (Europe)	**10/26/22**	**Owned**
62023077768.7	Devices and methods for treating a coronavirus infection and symptoms thereof (Hong Kong)	**08/17/23**	**Owned**
297109	Devices and methods for treating a coronavirus infection and symptoms thereof (Israel)	**10/26/ 6/22**	**Owned**
2023-505809	Devices and methods for treating a coronavirus infection and symptoms thereof (Japan)	**10/12/22**	**Owned**
11202253625T	Devices and methods for treating a coronavirus infection and symptoms thereof (Singapore)	**9/29/22**	**Owned**
11202253625T	Devices and methods for treating a viral infection and symptoms thereof (Australia)	**04/12/24**	**Owned**
2024-522200	Devices and methods for treating a viral infection and symptoms thereof (Japan)	**04/12/24**	**Owned**
11202402448W	Devices and methods for treating a viral infection and symptoms thereof (Singapore)	**04/11/24**	**Owned**
11202402448W	Devices and methods for treating a viral infection and symptoms thereof (Canada)	**4/11/2024**	**Owned**
11202402448W	Devices and methods for treating a viral infection and symptoms thereof (Europe)	**4/23/2024**	**Owned**

Pending International Patent Applications

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
PCT/US2022/077885 US2024/015614	Devices Removal of exosomes, ectosomes, mirnas, circulating nucleic acids, and methods for treating a viral infection and symptoms thereof particles with	10/11/22**2/13/24**	**Owned**

Trademarks

APPLICATION NAME	FILING DATE	OWNED OR LICENSED
TAUSOME	7/24/2015	Owned
SANSAGITTA	7/8/2021	Owned
HEMOSAGITTA	1/13/2021	Owned

Trademarks

In addition to the Tausome, Sansagitta and Hemosagitta trademarks noted in the above table, we also have trademark registrations in the United States for Hemopurifier and Aethlon Medical, Inc., and obtained a trademark registration in India for Hemopurifier. We also have common law trademark rights in Aethlon ADAPT™ and ELLSA™.

Licensing and Assignment Agreements

On November 7, 2006, we executed an assignment agreement with the London Health Science Center Research, Inc. under which an invention and related patent rights for a method to treat cancer were assigned to us. The invention provides for the "Extracorporeal removal of microvesicular particles" for which the U.S. Patent and Trademark Office granted a patent (Patent No.8,288,172) in the United States as of October 2012. The agreement provided for an upfront payment of 53 six shares of unregistered common stock and a 2% royalty on any future net sales of all products or services, the sale of which would infringe in the absence of the assignment granted under this agreement. We are also responsible for paying certain patent application and filing costs. Under the assignment agreement, we own the patents until their respective expirations. Under certain circumstances, ownership of the patents may revert to the London Health Science Center Research, Inc. if there is an uncured substantial breach of the assignment agreement.

Industry & Competition

The industry for treating infectious disease and cancer is extremely competitive, and companies developing new treatment procedures face significant capital and regulatory challenges. As our Hemopurifier is a clinical-stage device, we have the additional challenge of establishing medical industry support, which will be driven by treatment data resulting from human clinical studies. Should our device become market cleared by the FDA or the regulatory body of another country, we may face significant competition from well-funded pharmaceutical organizations. Additionally, we would likely need to establish large-scale production of our device in order to be competitive. We believe that our Hemopurifier is a first-in-class therapeutic candidate and we are not aware of any affinity hemofiltration device being market cleared in any country for the single-use removal of circulating viruses or tumor-derived exosomes. Our competitors include blood filters produced by Exthera Medical Corporation.

Government Regulation

The Hemopurifier is subject to regulation by numerous regulatory bodies, primarily 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, storage, distribution, advertising and promotion, and post-marketing surveillance reporting of medical devices. As the primary mode of action of the Hemopurifier is attributable to the device component of this combination product, the CDRH has primary jurisdiction over its premarket development, review and approval. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as issuance of warning letters, import detentions, civil monetary penalties and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution.

FDA's Pre-market Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States will require either a prior 510(k) clearance, unless it is exempt, or a pre-market approval from the FDA. Generally, if a new device has a predicate that is already on the market under a 510(k) clearance, the FDA will allow that new device to be marketed under a 510(k) clearance; otherwise, a premarket approval, or PMA, is required. Medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the general controls of the Federal Food, Drug and Cosmetic Act, such as provisions that relate to: adulteration; misbranding; registration and listing; notification, including repair, replacement, or refund; records and reports; and good manufacturing practices. Most Class I devices are classified as exempt from pre-market notification under section 510(k) of the FD&C Act, and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA. Class II devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls include performance standards, post market surveillance, patient registries and guidance documents. A manufacturer may be required to submit to the FDA a pre-market notification requesting permission to commercially distribute some Class II devices. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. A Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA. However, there are some Class III devices for which FDA has not yet called for a PMA. For these devices, the manufacturer must submit a pre-market notification and obtain 510(k) clearance in orders to commercially distribute these devices. The FDA can also impose sales, marketing or other restrictions on devices in order to assure that they are used in a safe and effective manner. We believe that the Hemopurifier will be classified as a Class III device and as such will be subject to PMA submission and approval.

Pre-market Approval Pathway

A pre-market approval application must be submitted to the FDA for Class III devices for which the FDA has required a PMA. The pre-market approval application process is much more demanding than the 510(k) pre-market notification process. A pre-market approval application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction reasonable evidence of safety and effectiveness of the device.

After a pre-market approval application is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days to review a filed pre-market approval application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device.

Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision making process. In addition, the FDA may conduct a preapproval inspection of the manufacturing facility to ensure compliance with the Quality System Regulation, or QSR. The agency also may inspect one or more clinical sites to assure compliance with FDA's regulations.

Upon completion of the PMA review, the FDA may: (i) approve the PMA which authorizes commercial marketing with specific prescribing information for one or more indications, which can be more limited than those originally sought; (ii) issue an approvable letter which indicates the FDA's belief that the PMA is approvable and states what additional information the FDA requires, or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Emergency Use Authorizations, or EUAs, are granted by FDA in public health emergencies but allow use of the authorized device only during the period of the respective public health emergency, and do not change the requirement to ultimately seek PMA approval after the authorization period has ended.

Clinical Trials

Clinical trials are almost always required to support pre-market approval and are sometimes required for 510(k) clearance. In the United States, for significant risk devices, these trials require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients at specified study sites. During the trial, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting and recordkeeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and recordkeeping requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of human research subjects. The FDA or the IRB at each site at which a clinical trial is being performed may withdraw approval of a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and effectiveness of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

Ongoing Regulation by the FDA

Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
- corrections and removal reporting regulations, which require that manufactures report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a risk to health; and
- post market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Some changes to an approved PMA device, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new PMA or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMAs.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in processing submissions or applications for new products or modifications to existing products;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

The Medical Device Reporting laws and regulations require us to provide information to the FDA when we receive or otherwise become aware of information that reasonably suggests our device may have caused or contributed to a death or serious injury as well as a device malfunction that likely would cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits an approved device from being marketed for off-label use. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product's labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

Healthcare Regulation

In addition to the FDA's restrictions on marketing of pharmaceutical products, the U.S. healthcare laws and regulations that may affect our ability to operate include: the federal fraud and abuse laws, including the federal anti-kickback and false claims laws; federal data privacy and security laws; and federal transparency laws related to payments and/or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals. Many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. For example, states have anti-kickback and false claims laws that may be broader in scope than analogous federal laws and may apply regardless of payor. In addition, state data privacy laws that protect the security of health information may differ from each other and may not be preempted by federal law. Moreover, several states have enacted legislation requiring pharmaceutical manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, report information related to drug pricing, require the registration of sales representatives, and prohibit certain other sales and marketing practices. These laws may adversely affect our sales, marketing and other activities with respect to any product candidate for which we receive approval to market in the United States by imposing administrative and compliance burdens on us.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, particularly any sales and marketing activities after a product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, among other things, reduced and/or limited Medicare reimbursement to certain providers and imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions. However, the 2020 federal spending package permanently eliminated, effective January 1, 2020, this ACA-mandated medical device tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by two percent through fiscal year 2032. These reductions may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. In July 2021, the Biden Administration released an executive order, "Promoting Competition in the American Economy," which contained provisions relating to prescription drugs. On September 9, 2021, in response to this executive order, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

Legislation could be adopted in the future that limits payments for our products from governmental payors. It is possible that additional governmental action will be taken to address the COVID-19 pandemic. In addition, commercial payors such as insurance companies, could adopt similar policies that limit reimbursement for medical device manufacturers' products.

Coverage and Reimbursement

In both the U.S. and international markets, the use of medical devices is dependent in part on the availability of reimbursement from third-party payors, such as government and private insurance plans. Healthcare providers that use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services. Should our Hemopurifier or any other products under development be approved for commercialization by the FDA, any such products may not be considered cost-effective, reimbursement may not be available in the United States or other countries, if approved, and reimbursement may not be sufficient to allow sales of our future products on a profitable basis. The coverage decisions of third-party payors will be significantly influenced by the assessment of our future products by health technology assessment bodies. If approved for use in the United States, we expect that any products that we develop, including the Hemopurifier, will be purchased primarily by medical institutions, which will in turn bill various third-party payors for the health care services provided to patients at their facility. Payors may include the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program and works in partnership with state governments to administer Medicaid, other government programs and private insurance plans. The process involved in applying for coverage and reimbursement from CMS is lengthy and expensive. Further, Medicare coverage is based on our ability to demonstrate that the treatment is "reasonable and necessary" for Medicare beneficiaries. Even if products utilizing our Aethlon Hemopurifier technology receive FDA and other regulatory clearance or approval, they may not be granted coverage and reimbursement by any payor, including by CMS. Many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies and amounts. However, no uniform policy for coverage and reimbursement for medical devices exists among third-party payors in the United States. Therefore, coverage and reimbursement can differ significantly from payor to payor.

Manufacturing

To date, Historically, manufacturing of our Hemopurifier occurs occurred in collaboration with a contract manufacturer based in California under current Good Manufacturing Practice, or cGMP, regulations promulgated by the FDA. Our contract manufacturer is registered with the FDA. To date, our manufacture of the Hemopurifier has been limited to quantities necessary to support our clinical studies.

In May 2024, the FDA approved the use of our own manufacturing facility to manufacture Hemopurifiers.
Our costs of compliance with federal, state and local environmental laws have been immaterial to date.

Sources and Availability of Raw Materials and the Names of Principal Suppliers

Our Hemopurifiers were previously assembled by Aethlon personnel in a cGMP manufacturing facility provided by Life Science Outsourcing, Inc, or LSO. Currently, we are in the process of bringing our manufacturing operations in-house. Aethlon personnel assemble the various components of the Hemopurifier with materials from our various suppliers, which are purchased and released by Aethlon. Specifically, the Hemopurifier contains three critical components with limited available suppliers. The GNA lectin is sourced from Vector Laboratories Inc. and also is available from other suppliers. We currently are experiencing a disruption in our Hemopurifier supply, as our existing supply of Hemopurifiers expired on September 30, 2022, and as previously disclosed, we are dependent on FDA approval of qualified suppliers to manufacture our Hemopurifier. Our intended transition from Vector Laboratories to a new supplier for GNA is delayed as we work with the FDA for approval of our supplement to our IDE, which is required to make this manufacturing change. The base cartridge on which the Hemopurifier is constructed is sourced from Medica S.p.A and we are dependent on the continued availability of these cartridges. Although there are other suppliers, the process of qualifying a new supplier takes time and regulatory approvals must be obtained. We currently purchase the diatomaceous earth from Janus Scientific, Inc., as the distributor; however, the product is manufactured by Imerys Minerals Ltd. There potentially are other suppliers of this product, but as with the cartridges, qualifying and obtaining required regulatory approvals takes time and resources.

Sales and Marketing

We do not currently have any sales and marketing capability. With respect to commercialization efforts in the future, we intend to build or contract for distribution, sales and marketing capabilities for any product candidate that is approved. From time to time, we have had and are having strategic discussions with potential collaboration partners for our product candidates, although no assurance can be given that we will be able to enter into one or more collaboration agreements for our product candidates on acceptable terms, if at all.

Product Liability

The risk of product liability claims, product recalls and associated adverse publicity is inherent in the testing, manufacturing, marketing and sale of medical products. We have limited clinical trial liability insurance coverage. It is possible that future insurance coverage may not be adequate or available. We may not be able to secure product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any liability for mandatory damages could exceed the amount of our coverage. A successful product liability claim against us could require us to pay a substantial monetary award. Moreover, a product recall could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other future product candidates.

Employees

As of June 26, 2023 June 25, 2024, we had 15 14 full-time employees and no part-time employees. All of our employees are located in the United States. We do intend to hire additional employees. We utilize, whenever appropriate, consultants in order to conserve cash and resources.

We believe our employee relations are good. None of our employees are represented by a labor union or are subject to collective-bargaining agreements.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below as well as the other information in this Annual Report before deciding to invest in or maintain your investment in our company. The risks described below are not intended to be an all-inclusive list of all of the potential risks relating to an investment in our securities. Any of the risk factors described below could significantly and adversely affect our business, prospects, financial condition and results of operations. Additional risks and uncertainties not currently known or that are currently considered to be immaterial may also materially and adversely affect our business. As a result, the trading price or value of our securities could be materially adversely affected and you may lose all or part of your investment.

Risks Relating to Our Financial Position and Need for Additional Capital

We have incurred significant losses and expect to continue to incur losses for the foreseeable future.

We have never been profitable. We have generated revenues during the fiscal years ended March 31, 2023 March 31, 2024 and March 31, 2022 March 31, 2023 in the amounts of $574,245 $0 and $294,165, $574,245, respectively, primarily from our contract with the NIH, which ended in September 2022. Our revenues, from We do not currently have any research grants continue to be insufficient to cover our cost of operations. or contracts. It is possible that we may not be able to enter into future government contracts. Future profitability, if any, will require the successful commercialization of our Hemopurifier technology or any other product that we develop or from additional government contract or grant income we may obtain. We may not be able to successfully commercialize the Hemopurifier or any other products, and even if commercialization is successful, we may never be profitable. While we currently have over $9.1 million in cash and cash equivalents and have been carrying out certain expense reductions since November 2023, our planned additional expense reductions may not materialize and/or our patient recruitment may occur more rapidly than expected along with the concomitant increases in expenses; therefore there is substantial doubt that our cash on hand will carry the company for 12 months beyond the filing date of the financial statements included in this Annual Report.

We do plan to access the equity markets for additional capital, however, there can be no assurance that we will be able to access such additional capital.

We will require additional financing to sustain our operations, achieve our business objectives and satisfy our cash obligations, which may dilute the ownership of our existing stockholders.

We will require significant additional financing for our operations and for expected additional future clinical trials in the United States, India and Australia, regulatory clearances, and continued research and development activities for the Hemopurifier and other future products. In addition, as we expand our activities, our overhead costs to support personnel, laboratory materials and infrastructure will increase. We may also choose to raise additional funds in debt or equity financings if they are available to us on reasonable terms to increase our working capital and to strengthen our financial position. Any sale of additional equity or convertible debt securities could result in dilution of the equity interests of our existing stockholders. Additionally, new investors may require that we and certain of our stockholders enter into voting arrangements that give them additional voting control or representation on our Board of Directors. If required financing is unavailable to us on reasonable terms, or at all, we may be unable to support our operations, including our research and development activities, which would have a material adverse effect on our ability to commercialize our products or continue our business.

Our ability to raise additional funds may be adversely impacted by our ability to remain listed on Nasdaq, the potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States, including due to bank failures, actual or perceived changes in interest rates and economic inflation, and worldwide resulting from macroeconomic factors. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Risks Related to Our Business Operations

Delays, interruptions or the cessation of production by our third-party suppliers of important materials or delays in qualifying new materials, has and may continue to prevent or delay our ability to manufacture our Hemopurifier.

Most of the raw materials used in the process for manufacturing our Hemopurifier are available from more than one supplier. However, there are materials within the manufacturing and production process that come from single suppliers. We do not have written contracts with all of our single source suppliers, and at any time they could stop supplying our orders. FDA review of a new supplier is required if these materials become unavailable from our current suppliers. Currently, In the recent past, we are experiencing experienced an interruption in the manufacturing of our Hemopurifier as we sought to transition to a new supplier of galanthus nivalis agglutinin, or GNA, used in the manufacture of our Hemopurifier. We have not received the required FDA approval of our proposal to approve IDE supplement for a new qualified supplier of the GNA and are working with the FDA to gain approval of this supplier. Although we have completed the manufacture of 112 Hemopurifiers, which have passed resumed purchasing GNA from our quality control measures, prior supplier, it is possible that we cannot ship the cartridges for domestic use until could experience future disruptions from this supplier as we have FDA approval of our new GNA work to qualify a second supplier. FDA review of the new second supplier could take several additional months to obtain.

In addition, an uncorrected impurity, a supplier's variation in a raw material or testing, either unknown to us or incompatible with its manufacturing process, or any other problem with our materials, testing or components, would prevent or delay the release of our Hemopurifiers for use in our clinical trials. For example, in late 2020, we identified during our device quality review procedures prior to product release that one of our critical suppliers had produced a Hemopurifier component that was not produced to our specifications, although no affected Hemopurifiers were released into our inventory or to any clinical trial sites. Our current inventory of Hemopurifiers expired on September 30, 2022. Any further delay in achieving the required FDA approvals for our new such future supplier will limit our ability to meet any demand for the Hemopurifier in the United States and delay our clinical trials in the United States, which issues could have a material adverse impact on our business, results of operations and financial condition.

Difficulties in manufacturing our Hemopurifier could have an adverse effect upon our expenses, our product revenues and our ability to complete our clinical trials.

We currently outsource most of only recently received approval from the manufacturing of FDA for our Hemopurifier. IDE supplement to manufacture Hemopurifiers at our site in San Diego. The manufacturing of our Hemopurifier is difficult and complex. To support our current clinical trial needs, we comply with and intend to continue to comply with cGMP in the manufacture of our product. Our ability to adequately manufacture and supply our Hemopurifier in a timely matter is dependent on the uninterrupted and efficient operation of our facilities and those of third parties producing raw materials and supplies upon which we rely in our manufacturing. We currently are experiencing an interruption in our Hemopurifier manufacturing due to delays in obtaining necessary regulatory approval of a new manufacturer of GNA. The manufacture of our products may also be impacted by:

- availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier;
- our ability to comply with new regulatory requirements, including our ability to comply with cGMP;
- natural disasters;
- changes in forecasts of future demand for product components;
- potential facility contamination by microorganisms or viruses;
- updating of manufacturing specifications;
- product quality success rates and yields; and
- global viruses and pandemics, including the current COVID-19 pandemic. pandemics.

The current

Any future interruption in the manufacture and supply of our Hemopurifier has and may continue to could delay shipments of our Hemopurifier for use in clinical trials in the United States. States, Australia and India.

Our products are manufactured with raw materials that are sourced from specialty suppliers with limited competitors and we may therefore be unable to access the materials we need to manufacture our products.

Specifically, the Hemopurifier contains three critical components with limited supplier numbers. The base cartridge on which the Hemopurifier is constructed is sourced from Medica S.p.A and we are dependent on the continued availability of these cartridges. We currently purchase the diatomaceous earth from Janus Scientific Inc., our distributor; however, the product is manufactured by Imerys Minerals Ltd., which is the only supplier of this product. The GNA is sourced from Vector Laboratories, Inc. and also is available from other suppliers; however, Sigma Aldrich is our only back up supplier at this time and we are in the process of working with the FDA to obtain regulatory approval for this supplier. A business interruption at any of these sources, including the interruption resulting from the delay in obtaining FDA approval of our new GNA supplier, has and may continue to have a material impact on our ability to manufacture the Hemopurifier.

We face intense competition in the medical device industry.

We compete with numerous U.S. and foreign companies in the medical device industry, and many of our competitors have greater financial, personnel, operational and research and development resources than we do. We believe that because the field of exosome research is burgeoning, multiple competitors are or will be developing competing technologies to address exosomes in cancer. Progress is constant in the treatment and prevention of viral diseases, so the opportunities for the Hemopurifier may be reduced there as well. Diagnostic technology may be developed that can supplant diagnostics we are developing for viruses and cancer. Our commercial opportunities will be reduced or eliminated if our competitors develop and market products for any of the diseases we target that:

- are more effective;
- have fewer or less severe adverse side effects;
- are better tolerated;
- are more adaptable to various modes of dosing;
- are easier to administer; or
- are less expensive than the products or product candidates we are developing.

Even if we are successful in developing the Hemopurifier and obtain FDA and other regulatory approvals necessary for commercialization, our products may not compete effectively with other successful products. Researchers are continually learning more about diseases, which may lead to new technologies for treatment. Our competitors may succeed in developing and marketing products that are either more effective than those that we may develop, alone or with our collaborators, or that are marketed before any products we develop are marketed. Our competitors include fully integrated pharmaceutical companies and biotechnology companies as well as universities and public and private research institutions. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in product development and in obtaining regulatory approvals, and greater marketing capabilities than we do. If our competitors develop more effective pharmaceutical treatments for infectious disease or cancer, or bring those treatments to market before we can commercialize the Hemopurifier for such uses, we may be unable to obtain any market traction for our products, or the diseases we seek to treat may be substantially addressed by competing treatments. If we are unable to successfully compete against larger companies in the pharmaceutical industry, we may never generate significant revenue or be profitable.

We have limited experience in identifying and working with large-scale contracts with medical device manufacturers; manufacture of our devices must comply with good manufacturing practices in the United States.

To achieve the levels of production necessary to commercialize our Hemopurifier and any other future products, we will need to secure large-scale manufacturing agreements with contract manufacturers which comply with good manufacturing practice standards and other standards prescribed by various federal, state and local regulatory agencies in the United States and any other country of use. We have limited experience coordinating and overseeing the manufacture of medical device products on a large-scale. It is possible that manufacturing and control problems will arise as we attempt to commercialize our products and that manufacturing may not be completed in a timely manner or at a commercially reasonable cost. In addition, we may not be able to adequately finance the manufacture and distribution of our products on terms acceptable to us, if at all. If we cannot successfully oversee and finance the manufacture of our products if they obtain regulatory clearances, we may never generate revenue from product sales and we may never be profitable.

Our Hemopurifier technology may become obsolete.

Our Hemopurifier product may be made unmarketable prior to commercialization by us by new scientific or technological developments by others with new treatment modalities that are more efficacious and/or more economical than our products. The homeland security industry is growing rapidly with many competitors that are trying to develop products or vaccines to protect against infectious disease. Any one of our competitors could develop a more effective product which would render our technology obsolete. Further, our ability to achieve significant and sustained penetration of our key target markets will depend upon our success in developing or acquiring technologies developed by other companies, either independently, through joint ventures or through acquisitions. If we fail to develop or acquire, and manufacture and sell, products that satisfy our customers' demands, or we fail to respond effectively to new product announcements by our competitors by quickly introducing competitive products, then market acceptance of our products could be reduced and our business could be adversely affected. Our products may not remain competitive with products based on new technologies.

Our success is We are highly dependent in part on our executive officers. key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our success ability to compete in the highly competitive biotechnology and medical device industries depends upon our ability to a critical extent attract and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our management, scientific, and medical personnel. The loss of the continued services of any of our Chief Executive Officer, Charles J. Fisher, Jr., M.D., our Chief Financial Officer, James B. Frakes, our Chief Medical Officer, Steven LaRosa, M.D., our Chief Scientific Officer, Lee D. Arnold, Ph.D., executive officers or other key employees and our Chief Business Officer, Guy Cipriani. If any of these key executive officers were inability to leave us, we would be forced to expend significant time and money in the pursuit of a replacement, which would result in both a delay in the implementation of find suitable replacements could potentially harm our business, plan and the diversion prospects, financial condition or results of limited working capital. The unique knowledge and expertise of these individuals would be difficult to replace within the biotechnology field. operations.

We do not currently carry key man life insurance policies on any of our key executive officers which would assist us in recouping our costs in the event of the loss of those officers. If any of our key officers were to leave us, it could make it impossible, if not cause substantial delays and costs, to implement our long-term business objectives and growth.

Our inability to attract and retain qualified personnel could impede our ability to achieve our business objectives.

We have 15 14 full-time employees. We utilize, whenever appropriate, consultants in order to conserve cash and resources. Although we believe that these employees and consultants will be able to handle most of our additional administrative, research and development and business development in the near term, we will nevertheless be required over the longer-term to hire highly skilled managerial, scientific and administrative personnel to fully implement our business plan and growth strategies. Due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific, technical and managerial personnel. Competition for these individuals, especially in San Diego, California, where many biotechnology companies are located, is intense and we may not be able to attract, assimilate or retain additional highly qualified personnel in the future. We may not be able to engage the services of qualified personnel at competitive prices or at all, particularly given the risks of employment attributable to our limited financial resources and lack of an established track record. Also, if we are required to attract personnel from other parts of the U.S. or abroad, we may have significant difficulty doing so due to the high cost of living in the Southern California area and due to the costs incurred with transferring personnel to the area. If we cannot attract and retain qualified staff and executives, we will be unable to develop our products and achieve regulatory clearance, and our business could fail.

We plan to expand our operations, which may strain our resources; our inability to manage our growth could delay or derail implementation of our business objectives.

We will need to significantly expand our operations to implement our longer-term business plan and growth strategies. We will also be required to manage multiple relationships with various strategic partners, technology licensors, customers, manufacturers and suppliers, consultants and other third parties. This expansion and these expanded relationships will require us to significantly improve or replace our existing managerial, operational and financial systems, procedures and controls; to improve the coordination between our various corporate functions; and to manage, train, motivate and maintain a growing employee base. The time and costs to effectuate these steps may place a significant strain on our management personnel, systems and resources, particularly given the limited amount of financial resources and skilled employees that may be available at the time. We may not be able to institute, in a timely manner or at all, the improvements to our managerial, operational and financial systems, procedures and controls necessary to support our anticipated increased levels of operations and to coordinate our various corporate functions, or that we will be able to properly manage, train, motivate and retain our anticipated increased employee base. If we cannot manage our growth initiatives, including our expansion of our clinical trials in India and potentially in other countries, we will be unable to commercialize our products on a large-scale in a timely manner, if at all, and our business could fail.

We may enter new business areas, such as the organ transplant market or diagnostics. We do not have any experience in these areas. We would likely the organ transplant market and face competition from entities more familiar with these businesses this business and our efforts may not succeed.

In We are investigating whether the future, we may expand our operations Hemopurifier, when incorporated into business areas, such as the a machine perfusion organ transplant market which we currently are exploring, where we do not have any experience. These areas would be preservation circuit, can remove harmful viruses, exosomes, RNA molecules, cytokines, chemokines and other inflammatory molecules from recovered organs. This area is new to our product development and management personnel, and we may not be successful in these new areas. the organ transplant market where we do not have any experience. Even if we are successful in developing our Hemopurifier for the organ transplant market, we may not be able to compete effectively or generate significant revenues in this new area. Many companies of all sizes, including major pharmaceutical companies, specialized biotechnology companies, and traditional healthcare providers, are engaged in redesigning organ transplant care and diagnostic medicine. care. Competitors operating in these potential new business areas this area may have substantially greater financial and other resources, larger research and development staff, and more experience in these business areas. this area. It is possible that, even if we are successful in these new areas, the organ transplant field, that the market will not accept our product, or that our product will generate significant revenues for us.

As a public company with limited financial resources undertaking the launch of new medical technologies, we may have difficulty attracting and retaining executive management and directors.

The directors and management of publicly traded corporations are increasingly concerned with the extent of their personal exposure to lawsuits and stockholder claims, as well as governmental and creditor claims which may be made against them, particularly in view of recent changes in securities laws imposing additional duties, obligations and liabilities on management and directors. Due to these perceived risks, directors and management are also becoming increasingly concerned with the availability of directors' and officers' liability insurance to pay on a timely basis the costs incurred in defending such claims. While we currently carry directors' and officers' liability insurance, such insurance is expensive and could be difficult to obtain. maintain in the future. If we are unable to continue or provide directors' and officers' liability insurance at affordable rates or at all, it may become increasingly more difficult to attract and retain qualified outside directors to serve on our Board of Directors. We may lose potential independent board members and management candidates to other companies in the biotechnology field that have greater directors' and officers' liability insurance to insure them from liability or to biotechnology companies that have revenues or have received greater funding to date which can offer greater compensation packages. The fees of directors are also rising in response to their increased duties, obligations and liabilities. In addition, our products could potentially be harmful to users, and we are exposed to claims of product liability including for injury or death. We have limited insurance and may not be able to afford robust coverage even as our products are introduced into the market. As a company with limited resources and potential exposures to management, we will have a more difficult time attracting and retaining management and outside independent directors than a more established public or private company due to these enhanced duties, obligations and potential liabilities.

If we fail to comply with extensive regulations of U.S. and foreign regulatory agencies, the commercialization of our products could be delayed or prevented entirely.

Our Hemopurifier product is subject to extensive government regulations related to development, testing, manufacturing and commercialization in the United States and other countries. The determination of when and whether a product is ready for large-scale purchase and potential use will be made by the U.S. Government through consultation with a number of governmental agencies, including the FDA, the National Institutes of Health, the Centers for Disease Control and Prevention CDC and the Department of Homeland Security. Our Hemopurifier has not received required regulatory approval from the FDA, or any foreign regulatory agencies, to be commercially marketed and sold. The process of obtaining and complying with FDA and other governmental regulatory approvals and regulations in the United States and in foreign countries is costly, time consuming, uncertain and subject to unanticipated delays. Obtaining such regulatory approvals, if any, can take several years. Despite the time and expense exerted, regulatory approval is never guaranteed. We also are subject to the following risks and obligations, among others:

- the FDA may refuse to approve an application if it believes that applicable regulatory criteria are not satisfied;
- the FDA may require additional testing for safety and effectiveness;
- the FDA may interpret data from pre-clinical testing and clinical trials in different ways than we interpret them;
- if regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
- the FDA may change its approval policies and/or adopt new regulations.

Failure to comply with these or other regulatory requirements of the FDA may subject us to administrative or judicially imposed sanctions, including:

- warning letters;
- civil penalties;
- criminal penalties;
- injunctions;
- product seizure or detention;
- product recalls; and
- total or partial suspension of productions.

Delays in successfully commencing or completing our planned clinical trials could jeopardize our ability to obtain regulatory approval. approval and sustain our operations.

Our business prospects depend on our ability to complete studies, commence and complete our planned clinical trials, including our ongoing and planned studies in COVID-19 patients and solid tumors in cancer, obtain satisfactory results, obtain required regulatory approvals and successfully commercialize our Hemopurifier product candidate. Completion of our clinical trials, announcement of results of the trials and our ability to obtain regulatory approvals could be delayed for a variety of reasons, including:

- failure to obtain required approvals to commence our planned clinical trials;
- slow patient enrollment; enrollment in our planned clinical trials;
- serious adverse events related to our medical device candidates; Hemopurifier;
- unsatisfactory results of any clinical trial;
- the failure of our principal third-party investigators to perform our clinical trials on our anticipated schedules; and
- different interpretations of our pre-clinical and clinical data, which could initially lead to inconclusive results; and
- delays resulting from the coronavirus pandemic. results.

Our development costs will increase if we have material delays in any clinical trial or if we need to perform more or larger clinical trials than planned. If the delays are significant, or if any of our product candidates do not prove to be safe or effective or do not receive required regulatory approvals, our financial results and the commercial prospects for our product candidates will be harmed. Furthermore, our inability to complete our clinical trials in a timely manner could jeopardize our ability to obtain regulatory approval for our Hemopurifier or any other potential product candidates.

If we or our suppliers fail to comply with ongoing FDA or foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, if any, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party suppliers may be required to comply with the FDA's Quality System Regulation, or QSR. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements in the United States, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

In addition, the FDA assesses compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearances or premarket approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Moreover, the FDA strictly regulates the promotional claims that may be made about approved products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We outsource many of our operational and development activities, and if any party to which we have outsourced certain essential functions fails to perform its obligations under agreements with us, the development and commercialization of our lead Hemopurifier product candidate and any future product candidates that we may develop could be delayed or terminated.

We rely on third-party consultants or other vendors to manage and implement much of the day-to-day conduct of our clinical trials and the manufacturing our Hemopurifier product candidate. Accordingly, we are and will continue to be dependent on the timeliness and effectiveness of the efforts of these third parties. Our dependence on third parties includes key suppliers and third-party service providers supporting the development, manufacture and regulatory approval of our Hemopurifier, as well as support for our information technology systems and other infrastructure. While our management team oversees these vendors, failure of any of these third parties to meet their contractual, regulatory and other obligations or the development of factors that materially disrupt the performance of these third parties could have a material adverse effect on our business. For example, all of the key oversight responsibilities for the development and manufacture of our Hemopurifier are conducted by our management team, but all other activities are the responsibility of third-party vendors.

If a clinical research organization that we utilize is unable to allocate sufficient qualified personnel to our studies in a timely manner or if the work performed by it does not fully satisfy the requirements of the FDA or other regulatory agencies, we may encounter substantial delays and increased costs in completing our development efforts. Any manufacturer that we select may encounter difficulties in the manufacture of new products in commercial quantities, including problems involving product yields, product stability or shelf life, quality control, adequacy of control procedures and policies, compliance with FDA regulations and the need for further FDA approval of any new manufacturing processes and facilities. If any of these occur, the development and commercialization of our Hemopurifier product candidate could be delayed, curtailed or terminated, because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own.

If we or our contractors or service providers fail to comply with regulatory laws and regulations, we or they could be subject to regulatory actions, which could affect our ability to develop, market and sell our Hemopurifier product candidate and any other future product candidates that we may develop, if any, and may harm our reputation.

If we or our manufacturers or other third-party contractors fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to regulatory actions, which could affect our ability to successfully develop, market and sell our Hemopurifier product candidate or any future product candidates, if any, and could harm our reputation and lead to reduced or non-acceptance of our proposed product candidates by the market. Even technical recommendations or evidence by the FDA through letters, site visits, and overall recommendations to academia or biotechnology companies may make the manufacturing of a clinical product extremely labor intensive or expensive, making the product candidate no longer viable to manufacture in a cost-efficient manner. The mode of administration may make the product candidate not commercially viable. The required testing of the product candidate may make that candidate no longer commercially viable. The conduct of clinical trials may be critiqued by the FDA, or a clinical trial site's Institutional Review Board IRB or Institutional Biosafety Committee, which may delay or make impossible clinical testing of a product candidate. The Institutional Review Board IRB for a clinical trial may stop a trial or deem a product candidate unsafe to continue testing. This would have a material adverse effect on the value of the product candidate and our business prospects.

We will need to outsource and rely on third parties for the clinical development, and manufacturing, sales and marketing of our Hemopurifier or any future product candidates that we may develop, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.

We do not have the required financial and human resources to carry out on our own all the pre-clinical and clinical development for our Hemopurifier product candidate or any other or future product candidates that we may develop, and do not have the capability and resources to manufacture, market or sell our Hemopurifier product candidate or any future product candidates that we may develop. Our business model calls for the partial or full outsourcing of the clinical and other development, and manufacturing, sales and marketing of our product candidates in order to reduce our capital and infrastructure costs as a means of potentially improving our financial position. Our success will depend on the performance of these outsourced providers. If these providers fail to perform adequately, our development of product candidates may be delayed and any delay in the development of our product candidates would have a material and adverse effect on our business prospects.

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. Claims may 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 may not be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, and such insurance may not 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.

Our Hemopurifier product candidate may be used in connection with medical procedures in which it is important that those products function with precision and accuracy. If our product candidates, including our Hemopurifier, do not function as designed, or are designed improperly, we may be forced by regulatory agencies to withdraw such products from the market. In addition, if medical personnel or their patients suffer injury as a result of any failure of our products to function as designed, or our products are designed inappropriately, we may be subject to lawsuits seeking significant compensatory and punitive damages. The risk of product liability claims, product recalls and associated adverse publicity is inherent in the testing, manufacturing, marketing and sale of medical products. We have obtained general clinical trial liability insurance coverage. However, our insurance coverage may not be adequate or available. We may not be able to secure product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any product recall or lawsuit seeking significant monetary damages may have a material effect on our business and financial condition. Any liability for mandatory damages could exceed the amount of our coverage. Moreover, a product recall could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other future product candidates.

We have not received, and may never receive, approval from the FDA to market a medical device in the United States.

Before a new medical device can be marketed in the United States, it must first receive a PMA or 510(k) clearance from the FDA, unless an exemption applies. A PMA submission, which is a higher standard than a 510(k) clearance, is used to demonstrate to the FDA that a new or modified device is safe and effective. The 510(k) is used to demonstrate that a device is "substantially equivalent" to a predicate device, that is, one that has been cleared by the FDA. We expect that any product we seek regulatory approval for, including the Hemopurifier, will require a PMA. The FDA approval process involves, among other things, successfully completing clinical trials and filing for and obtaining a PMA. The PMA process requires us to prove the safety and effectiveness of our products to the FDA's satisfaction. This process, which includes preclinical studies and clinical trials, can take many years and requires the expenditure of substantial resources and may include post-marketing surveillance to establish the safety and efficacy of the product. Notwithstanding the effort and expense incurred, the process may never result in the FDA granting a PMA. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval. Delays or rejections may also be encountered based upon changes in governmental policies for medical devices during the period of product development. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our inability to demonstrate safety or effectiveness of the Hemopurifier, or any other product we develop, to the FDA's satisfaction;
- insufficient data from our preclinical studies and clinical trials, including for our Hemopurifier, to support approval;
- failure of the facilities of our third-party manufacturer or suppliers to meet applicable requirements;
- inadequate compliance with preclinical, clinical or other regulations;
- our failure to meet the FDA's statistical requirements for approval; and
- changes in the FDA's approval policies, or the adoption of new regulations that require additional data or additional clinical trials.

Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much costlier and more uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained. Any of our products considered to be a class III device, which are considered to pose the greatest risk and the approval of which is governed by the strictest guidelines, will require the submission and approval of a PMA in order for us to market it in the United States. We also may design new products in the future that could require the clearance of a 510(k).

Although we have received approval to proceed with clinical trials of the Hemopurifier in the United States under the investigational device exemption, the current approval from the FDA to proceed could be revoked, the study could be unsuccessful, or the FDA PMA approval may not be obtained or could be revoked. Even if we obtain approval, the FDA or other regulatory authorities may require expensive or burdensome post-market testing or controls. Any delay in, or failure to receive or maintain, clearance or approval for our future products could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some physicians from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

The approval requirements for medical products used to fight bioterrorism and pandemics are still evolving, and any products we develop for such uses may not meet these requirements.

We are advancing product candidates under governmental policies that regulate the development and commercialization of medical treatment countermeasures against bioterror and pandemic threats. While we intend to pursue FDA market clearance to treat infectious bioterror and pandemic threats, it is often not feasible to conduct human studies against these deadly high threat pathogens. For example, the Hemopurifier is an investigational device that has not yet received FDA approval for any indication. We continue to investigate the potential for the use of the Hemopurifier in viral diseases under an open IDE and our FDA Breakthrough Designation for "…the treatment of life-threatening glycosylated viruses that are not addressed with an approved therapy." We currently have an open FDA approved Expanded Access Protocol for the treatment of Ebola infected patients in the United States and a corresponding HealthCanada approval in Canada. Based on our studies to date, the Hemopurifier can potentially clear many viruses that are pathogenic in humans, including HCV, HIV, Monkeypox and Ebola.

For example, in June 2020, the FDA approved a supplement to our open IDE for the Hemopurifier in viral disease to allow for the testing of the Hemopurifier in patients with SARS-CoV-2/COVID-19 in a New Feasibility Study. This study was designed to enroll up to 40 subjects at up to 20 centers in the United States. Subjects had to have an established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU, and have had acute lung injury and/or severe or life threatening life-threatening disease, among other criteria. Due to lack of COVID-19 patients in the ICUs of our trial sites, we terminated this study in 2022.

As a result of the termination of our COVID-19 study due to lack of patients in the ICUs, we were unable to demonstrate the effectiveness of our treatment countermeasures through controlled human efficacy studies in this U.S. study. Additionally, a change in government policies could impair our ability to obtain regulatory approval for the Hemopurifier.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Any research and development, pre-clinical testing and clinical trial activities involving our Hemopurifier and any additional products that we may develop are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, the results of these trials may not support our product candidate claims and the FDA may not agree with our conclusions regarding the trial results. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and the later trials may not replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be on our product development efforts.

Our current and future business activities are subject to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to significant penalties.

We are currently and will in the future be subject to healthcare regulation and enforcement by the U.S. federal government and the states in which we will conduct our business if our product candidates are approved by the FDA and commercialized in the United States. In addition to the FDA's restrictions on marketing of approved products, the U.S. healthcare laws and regulations that may affect our ability to operate include: the federal fraud and abuse laws, including the federal anti-kickback and false claims laws; federal data privacy and security laws; and federal transparency laws related to payments and/or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals. Many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. These laws may adversely affect our sales, marketing and other activities with respect to any product candidate for which we receive approval to market in the United States by imposing administrative and compliance burdens on us.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, particularly any sales and marketing activities after a product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We and the third parties with whom we work are subject to stringent and changing U.S. and foreign laws, rules, regulations and standards as well as policies, contracts and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations, or such failure by the third parties with whom we work, could lead to regulatory investigations or actions, fines and penalties, a disruption of our clinical trials or commercialization of our products, private litigation, including class claims, and mass arbitration demands, harm to our reputation, or other adverse effects on our business or prospects.

In the ordinary course of business, we collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, (collectively, or collectively, "Process" or "Processing") personal information data and other Sensitive Information (as defined below), including proprietary and confidential business data, trade secrets, and intellectual property that we collect in connection with clinical trials, as necessary to operate our business, for legal and marketing purposes, and for other business-related purposes. Our data Processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, representations, certifications, standards, publications, frameworks, and contractual requirements and other obligations related to data privacy information and security and Processing (collectively, collectively, "Data Protection Obligations").

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information.

In addition, over the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal information data of consumers, business representatives, and employees who are California residents, and requires covered businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA also provides for civil penalties for noncompliance (up fines of up to $7,500 per violation) intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although there are limited exemptions for clinical trial data under the The CCPA the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the California Privacy Rights Act of 2020, or CPRA, expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, including Colorado, Connecticut, Utah and Virginia, have enacted data comprehensive U.S. state privacy laws and similar laws are being considered in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. While these states, like the CCPA, also exempt some data processing Processing in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the enactment of such third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and others could have potentially conflicting requirements that would make compliance challenging local levels, and expose us we expect more states to additional liability. pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to may govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, or collectively GDPR, Australia's Privacy Act, and India's Information Technology Act and supplementary rules impose strict requirements for processing Processing personal data. Companies that violate the For example, under GDPR, companies can face private litigation related to processing Processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, temporary or definitive restrictions on data processing and Processing or other corrective actions, and fines of up to the greater of 20 million Euros under the EU GDPR / 17.5 million pounds streamline under the UK GDPR or 4% of their worldwide annual revenue, whichever is greater. GDPR litigation risk may increase as a result of a recent decision of the EU's highest court finding that a consumer protection association may bring representative actions alleging violations of the GDPR even without a mandate to do so from any specific individuals and whether or not specific individuals' data protection rights have been violated.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or EEA, and the United Kingdom, or UK, have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework) these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators individual litigants and activist groups.

We publish privacy policies and may publish marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Data Protection Obligations, and consumers' data privacy expectations, are quickly changing, in an becoming increasingly stringent, fashion, and creating some uncertainty as to the effective future legal framework. uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Although we endeavor to comply with all applicable Data Protection Obligations, we may at times fail, (or or be perceived to have failed) failed, to do so. Moreover, despite our efforts, our personnel or third parties upon with whom we rely work may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others.

If we or third parties fail, or are perceived to have failed, to address or comply with applicable Data Protection Obligations, it could: increase our compliance and operational costs; expose us to regulatory scrutiny, actions, fines and penalties; result in reputational harm; interrupt or stop our clinical trials; result in litigation and liability; result in an inability to process personal data or to operate in certain jurisdictions; harm our business operations or financial results or otherwise result in a material harm to our business, or other material adverse impact on our business, results of operations and financial condition. Additionally, given that Data Protection Obligations impose complex and burdensome obligations and that there is substantial uncertainty over the interpretation and application of these obligations, we may be required to incur material costs, divert management attention, and change our business operations, including our clinical trials, in an effort to comply, which could materially adversely affect our business operations and financial results.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations including, as relevant, clinical trials inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

If our information technology systems, or data, or those of third parties upon which with whom we rely, work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to: regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and third parties upon which with whom we rely work may process proprietary, confidential and sensitive information, including personal data, intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other third parties, or collectively, Sensitive Information. We may use and share Sensitive Information with service providers and subprocessors and other third parties upon with whom we rely work to help us operate our business. If we our service providers, partners, or other relevant such third parties with who we work have experienced, or in the future experience, any security incident(s) that result in any data loss; deletion or destruction; unauthorized access to; loss, unauthorized acquisition, disclosure, or exposure of, Sensitive Information, or other compromise related to the security, confidentiality, integrity of our, (or their) or their, information technology, software, services, communications or data, (any, or collection, a "Security Breach"), Security Breach, it may result in a material an adverse impact on our business, results of operations and financial condition, including the diversion of funds to address the breach, and interruptions, delays, or outages in our operations and development programs. business.

Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent, and continue to increase. These threats rise, and are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which with whom we rely work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which with whom we rely may be work are subject to a variety of evolving threats, including but not limited to social-engineering attacks, (including including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), attacks, supply-chain attacks, loss of data or other information technology assets, adware, software bugs, malicious code, (such such as viruses and worms), worms, employee theft or misuse, denial-of-service attacks, (such such as credential stuffing) stuffing, and ransomware attacks. We may also be the subject of phishing attacks, viruses, malware, (including including as a result of advanced persistent threat intrusions), intrusions, server malfunction, software or hardware failures, loss of data or other computer assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, or other similar issues. threats.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of data Sensitive Information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions, (such such as acquisitions or integrations) integrations, could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-parties and their technologies to operate critical business systems to process Sensitive Information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a Security Breach or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services.

While we have implemented security measures designed to protect against Security Breaches, these measures may not be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information technology systems, including our products, hardware and/or software, including that of third parties upon which we rely. We may not, however, detect or remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patched designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a Security Breach or other interruption and disrupt our ability (and and that of third parties upon with whom we rely) work to provide our services.

We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including clinical trial activities, or information technology in an effort to protect against Security Breaches and to mitigate, detect and remediate actual and potential vulnerabilities. Applicable Data Protection Obligations (as defined above) may require us to implement specific security measures or use industry-standard or reasonable measures to protect against Security Breaches. There can be no assurances that our Our security measures, or those of third parties upon with whom we rely, will work, may not be effective in protecting against Security Breaches.

While we have implemented security measures designed to protect against Security Breaches, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities in our information technology systems (including our products), but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a Security Breach has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable Data Protection Obligations (as defined above) may require us to notify relevant stakeholders of Security Breaches, including affected individuals, customers, investors, partners, collaborators, regulators, law enforcement agencies and others, others, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosures or the failure to comply with such requirements could lead to a material an adverse impact on our business, results of operations and financial condition. If we (or or a third party upon with whom we rely) experience work experiences a Security Breach or are perceived to have experienced a Security Breach, we may experience adverse consequences. These consequences may include: government enforcement actions, (for for example, investigations, fines, penalties, audits, and inspections); inspections; additional reporting requirements and/or oversight; restrictions on processing Sensitive Information, (including including personal data); data; litigation, (including including class claims); claims; indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations, (including including availability of data); data; financial loss; and other similar harms. Security Breaches or other interruptions and attendant consequences may prevent or cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

There can be no assurances that Our contracts may not contain limitations of liability, and even where they do, any such limitations or exclusions of liability in our contracts would may not be adequate or would otherwise to protect us from liabilities or damages if we fail to comply with Data Protection Obligations related to information security or Security Breaches.

We cannot be sure that our Our insurance coverage will may not be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or other material adverse impact on our business, results of operations and financial condition arising out of our Processing operations, privacy and security practices, or Security Breaches that we may experience. In addition, such coverage may not continue to be available on commercially reasonable terms or at all or be sufficient coverage to pay future claims. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies, (including including premium increases or the imposition of large excess or deductible or co-insurance requirements), requirements, could have a material adverse impact on our business, results of operations and financial condition.

In addition to experiencing a Security Breach, third parties may gather, collect, or infer Sensitive Information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Should our products be approved for commercialization, lack of third-party coverage and reimbursement for our devices could delay or limit their adoption.

In both the U.S. and international markets, the use of medical devices is dependent in part on the availability of reimbursement from third-party payors, such as government and private insurance plans. Healthcare providers that use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services. Should our products under development be approved for commercialization by the FDA, any such products may not be considered cost-effective, reimbursement may not be available in the United States or other countries, if approved, and reimbursement may not be sufficient to allow sales of our future products, including the Hemopurifier, on a profitable basis. The coverage decisions of third-party payors will be significantly influenced by the assessment of our future products by health technology assessment bodies. These assessments are outside our control and any such evaluations may not be conducted or have a favorable outcome.

If approved for use in the United States, we expect that any products that we develop, including the Hemopurifier, will be purchased primarily by medical institutions, which will in turn bill various third-party payors for the health care services provided to patients at their facility. Payors may include the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program and works in partnership with state governments to administer Medicaid, other government programs and private insurance plans. The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive. Further, Medicare coverage is based on our ability to demonstrate that the treatment is “reasonable and necessary” for Medicare beneficiaries. Even if products utilizing our Aethlon Hemopurifier technology receive FDA and other regulatory clearance or approval, they may not be granted coverage and reimbursement by any payor, including by CMS. For some governmental programs, such as Medicaid, coverage and adequate reimbursement differ from state to state and some state Medicaid programs may not pay adequate amounts for the procedure necessary to utilize products utilizing our technology system, or any payment at all. Moreover, many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies and amounts. However, no uniform policy requirement for coverage and reimbursement for medical devices exists among third-party payors in the United States. Therefore, coverage and reimbursement can differ significantly from payor to payor. If CMS or other agencies limit coverage or decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors for any products that we develop.

Should our Hemopurifier or any of our potential future products, including the Hemopurifier, be approved for commercialization, certain health reform measures and adverse changes in reimbursement policies and procedures may impact our ability to market and sell our products.

Healthcare costs have risen significantly over the past decade, and there have been and continue to be proposals by legislators, regulators and third-party payors to decrease costs. Third-party payors are increasingly challenging the prices charged for medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services.

For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, among other things, reduced and/or limited Medicare reimbursement to certain providers. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business. The Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare’s payments to providers by two percent through fiscal year 2032These reductions may reduce providers’ revenues or profits, which could affect their ability to purchase new technologies. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. In July 2021, the Biden Administration released an executive order, “Promoting Competition in the American Economy,” which contained provisions relating to prescription drugs. On September 9, 2021, in response to this executive order, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

Legislation could be adopted in the future that limits payments for our products from governmental payors. In addition, commercial payors such as insurance companies, could adopt similar policies that limit reimbursement for medical device manufacturers' products. Therefore, it is possible that our product or the procedures or patient care performed using our product will not be reimbursed at a cost-effective level. We face similar risks relating to adverse changes in reimbursement procedures and policies in other countries where we may market our products. Reimbursement and healthcare payment systems vary significantly among international markets. Our inability to obtain international reimbursement approval, or any adverse changes in the reimbursement policies of foreign payors, could negatively affect our ability to sell our products and have a material adverse effect on our business and financial condition.

Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses loss carryforwards in a taxable year is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. income in such year. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. If we achieve profitability and an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Effective January 1, 2022, the The Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation.

Our use of hazardous materials, chemicals and viruses exposes us to potential liabilities for which we may not have adequate insurance.

Our research and development involves the controlled use of hazardous materials, chemicals and viruses. The primary hazardous materials include chemicals needed to construct the Hemopurifier cartridges and the infected plasma samples used in preclinical testing of the Hemopurifier. All other chemicals are fully inventoried and reported to the appropriate authorities, such as the fire department, which inspects the facility on a regular basis. We are subject to federal, state, local and foreign laws governing the use, manufacture, storage, handling and disposal of such materials. Although we believe that our safety procedures for the use, manufacture, storage, handling and disposal of such materials comply with the standards prescribed by federal, state, local and foreign regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We have had no incidents or problems involving hazardous chemicals or biological samples. In the event of such an accident, we could be held liable for significant damages or fines.

We currently carry a limited amount of insurance to protect us from bodily injury or property damages arising from hazardous materials. Our product liability policy has a $5,000,000 limit of liability. For our facilities, our property policy provides $25,000 in coverage for contaminant clean-up or removal and $100,000 in coverage for damages to the premises resulting from contamination. Should we violate any regulations concerning the handling or use of hazardous materials, or should any injuries or death result from our use or handling of hazardous materials, we could be the subject of substantial lawsuits by governmental agencies or individuals. We may not have adequate insurance to cover all or any of such claims, if any. If we were responsible to pay significant damages for violations or injuries, if any, we might be forced to cease operations since such payments could deplete our available resources.

Our products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, including a third-country authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. For the FDA, the authority to require a recall must be based on a finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or another third-country competent authority. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or another third-country competent authority. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report recalls. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals.

Even though we have received breakthrough device designation for the Hemopurifier for two independent indications, this designation may not expedite the development or review of the Hemopurifier and does not provide assurance ultimately of PMA submission or approval by the FDA.

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed.

Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Although we obtained breakthrough device designation for the Hemopurifier for two indications, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. For example, the time required to identify and resolve issues relating to manufacturing and controls, the acquisition of a sufficient supply of our product for clinical trial purposes or the need to conduct additional nonclinical or clinical studies may delay approval by the FDA, even if the product qualifies for breakthrough designation or access to any other expedited program. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for the product.

Our bylaws designate the Eighth Judicial District Court of Clark County, Nevada, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our bylaws require that, to the fullest extent permitted by law, and unless the Company consents in writing to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada, will, to the fullest extent permitted by law, be the sole and exclusive forum for each of the following:

- any derivative action or proceeding brought in the name or right of the Company or on its behalf,
- any action asserting a claim for breach of any fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's stockholders,
- any action arising or asserting a claim arising pursuant to any provision of NRS Chapters 78 or 92A or any provision of our articles of incorporation or bylaws, or
- any action asserting a claim governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws.

However, our bylaws provide that the exclusive forum provisions do not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Nevada law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

Risks Related to Our Intellectual Property and Related Litigation

We rely upon licenses and patent rights from third parties which are subject to termination or expiration.

We rely in part upon third-party licenses and ownership rights assigned from third parties for the development of specific uses for our Hemopurifier devices. For example, we are researching, developing and testing cancer-related applications for our devices under patents assigned from the London Health Science Center Research, Inc. Should any of our licenses be prematurely terminated for any reason, or if the patents and intellectual property assigned to us or owned by such entities that we have licensed are challenged or defeated by third parties, our research efforts could be materially and adversely affected. Our licenses and patents assigned to us may not continue in force for as long as we require for our research, development and testing of cancer treatments. It is possible that, if our licenses terminate or the underlying patents and intellectual property is challenged or defeated or the patents and intellectual property assigned to us is challenged or defeated, suitable replacements may not be obtained or developed on terms acceptable to us, if at all. There is also the related risk that we may not be able to make the required payments under any patent license or assignment agreement, in which case we may lose to ability to use one or more of the licensed or assigned patents.

We could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from selling our commercially available products and/or reduce the margins we may realize from our products.

The medical devices industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the determination is often uncertain. There may be existing patents of which we are unaware that our products under development may inadvertently infringe. The likelihood that patent infringement claims may be brought against us increases as the number of participants in the infectious market increases and as we achieve more visibility in the marketplace and introduce products to market.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. In some cases, litigation may be threatened or brought by a patent holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence. If we are found to infringe any patents, we could be required to pay substantial damages, including triple damages if an infringement is found to be willful. We also could be required to pay royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. We may not be able to obtain a license enabling us to sell our products on reasonable terms, or at all. If we fail to obtain any required licenses or make any necessary changes to our technologies or the products, we may be unable to commercialize one or more of our products or may have to withdraw products from the market, all of which would have a material adverse effect on our business, financial condition and results of operations.

If the combination of patents, trade secrets and contractual provisions upon which we rely to protect our intellectual property is inadequate, our ability to commercialize our products successfully will be harmed.

Our success depends significantly on our ability to protect our proprietary rights to the technologies incorporated in our products. We currently have five issued U.S. patents and four two pending U.S. patent applications. We also have 32 24 issued foreign patents and have applied for nine 15 additional foreign and international patents. Our issued patents begin to expire in August 2024, with the last of these patents expiring in 2036, 2031, although terminal disclaimers, patent term extension or patent term adjustment can shorten or lengthen the patent term. We rely on a combination of patent protection, trade secret laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these may not adequately protect our rights or permit us to gain or keep any competitive advantage.

The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office or foreign patent offices where our applications are pending. The U.S. Patent and Trademark Office or foreign offices may deny or require significant narrowing of claims in our pending patent applications. Patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the U.S. Patent and Trademark Office or foreign offices could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. The laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S., if at all. Some of our patents may expire before we receive FDA approval to market our products in the United States or we receive approval to market our products in a foreign country. Although we believe that certain patent applications and/or other patents issued more recently will help protect the proprietary nature of the Hemopurifier treatment technology, this protection may not be sufficient to protect us during the development of that technology.

Our competitors may successfully challenge and invalidate or render unenforceable our issued patents, including any patents that may issue in the future, which could prevent or limit our ability to market our products and could limit our ability to stop competitors from marketing products that are substantially equivalent to ours. In addition, competitors may be able to design around our patents or develop products that provide outcomes that are comparable to our products but that are not covered by our patents.

We have also entered into confidentiality and assignment of intellectual property agreements with all of our employees, consultants and advisors directly involved in the development of our technology as one of the ways we seek to protect our intellectual property and other proprietary technology. However, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

In the event a competitor infringes upon any of our patents or other intellectual property rights, enforcing our rights may be difficult, time consuming and expensive, and would divert management's attention from managing our business. We may not be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights.

We may rely on licenses for new technology, which may affect our continued operations with respect thereto.

As we develop our technology, we may need to license additional technologies to optimize the performance of our products. We may not be able to license these technologies on commercially reasonable terms or at all. In addition, we may fail to successfully integrate any licensed technology into our proposed products. Our inability to obtain any necessary licenses could delay our product development and testing until alternative technologies can be identified, licensed and integrated. The inability to obtain any necessary third-party licenses could cause us to abandon a particular development path, which could seriously harm our business, financial position and results of our operations.

New technology may lead to our competitors developing superior products which would reduce demand for our products.

Research into technologies similar to ours is proceeding at a rapid pace, and many private and public companies and research institutions are actively engaged in the development of products similar to ours. These new technologies may, if successfully developed, offer significant performance or price advantages when compared with our technologies. Our existing patents or our pending and proposed patent applications may not offer meaningful protection if a competitor develops a novel product based on a new technology.

If we are unable to protect our proprietary technology and preserve our trade secrets, we will increase our vulnerability to competitors which could materially adversely impact our ability to remain in business.

Our ability to successfully commercialize our products will depend on our ability to protect those products and our technology with domestic and foreign patents. We will also need to continue to preserve our trade secrets. The issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. The patent positions of technology companies, including us, are uncertain and involve complex legal and factual issues. Our patents may not prevent other companies from developing similar products or products which produce benefits substantially the same as our products, and other companies may be issued patents that may prevent the sale of our products or require us to pay significant licensing fees in order to market our products.

From time to time, we may need to obtain licenses to patents and other proprietary rights held by third parties in order to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented. Our pending patent applications may not result in issued patents, patent protection may not be secured for any particular technology, and our issued patents may not be valid or enforceable or provide us with meaningful protection.

If we are required to engage in expensive and lengthy litigation to enforce our intellectual property rights, such litigation could be very costly and the results of such litigation may not be satisfactory.

Although we have entered into invention assignment agreements with our employees and with certain advisors, and we routinely enter into confidentiality agreements with our contract partners, if those employees, advisors or contract partners develop inventions or processes independently that may relate to products or technology under development by us, disputes may arise about the ownership of those inventions or processes. Time-consuming and costly litigation could be necessary to enforce and determine the scope of our rights under these agreements. In addition, we may be required to commence litigation to enforce such agreements if they are violated, and it is certainly possible that we will not have adequate remedies for breaches of our confidentiality agreements as monetary damages may not be sufficient to compensate us. We may be unable to fund the costs of any such litigation to a satisfactory conclusion, which could leave us without recourse to enforce contracts that protect our intellectual property rights.

Other companies may claim that our technology infringes on their intellectual property or proprietary rights and commence legal proceedings against us which could be time-consuming and expensive and could result in our being prohibited from developing, marketing, selling or distributing our products.

Because of the complex and difficult legal and factual questions that relate to patent positions in our industry, it is possible that our products or technology could be found to infringe upon the intellectual property or proprietary rights of others. Third parties may claim that our products or technology infringe on their patents, copyrights, trademarks or other proprietary rights and demand that we cease development or marketing of those products or technology or pay license fees. We may not be able to avoid costly patent infringement litigation, which will divert the attention of management away from the development of new products and the operation of our business. We may not prevail in any such litigation. If we are found to have infringed on a third-party's intellectual property rights, we may be liable for money damages, encounter significant delays in bringing products to market or be precluded from manufacturing particular products or using particular technology.

Other parties may challenge certain of our foreign patent applications. If any such parties are successful in opposing our foreign patent applications, we may not gain the protection afforded by those patent applications in particular jurisdictions and may face additional proceedings with respect to similar patents in other jurisdictions, as well as related patents. The loss of patent protection in one jurisdiction may influence our ability to maintain patent protection for the same technology in other jurisdictions.

Risks Related to U.S. Government Contracts

We may not obtain additional U.S. Government contracts to further develop our technology.

While we have previously had U.S. government contracts, we may not be successful in obtaining additional government grants or contracts. The process of obtaining government contracts is lengthy with the uncertainty that we will be successful in obtaining announced grants or contracts for therapeutics as a medical device technology. Accordingly, although we have obtained government contracts in the past, we may not be awarded any additional U.S. Government grants or contracts utilizing our Hemopurifier platform technology.

U.S. Government agencies have special contracting requirements, including a right to audit us, which create additional risks; a negative audit would be detrimental to us.

Our business plan to utilize the Aethlon Hemopurifier technology may seek to involve contracts with the U.S. Government. Many government contracts, typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which would subject us to additional risks should we obtain contracts with the U.S. Government in the future. These risks include the ability of the U.S. Government to unilaterally:

- suspend or prevent us for a period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products; and
- change certain terms and conditions in our contracts.

As a former and potential future U.S. Government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and would be subject to periodic audits and reviews. As part of any such audit or review, the U.S. Government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. Government may adjust our contract-related costs and fees, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we would possibly be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. Government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. Although we have not had any government audits and reviews to date, future audits and reviews could cause adverse effects. In addition, under U.S. Government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our research and development costs, and some marketing expenses, would possibly not be reimbursable or allowed under such contracts. Further, as a former and potential future U.S. Government contractor, we would be subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities.

As a potential future U.S. Government contractor, we would be subject to a number of procurement rules and regulations.

Government contractors must comply with specific procurement regulations and other requirements. These requirements, although customary in government contracts, would impact our performance and compliance costs. In addition, current U.S. Government budgetary constraints could lead to changes in the procurement environment, including the Department of Defense's initiative focused on efficiencies, affordability and cost growth and other changes to its procurement practices. If and to the extent such changes occur, they could affect whether and, if so, how we pursue certain opportunities and the terms under which we are able to do so.

In addition, failure to comply with these regulations and requirements could result in reductions of the value of contracts, contract modifications or termination, and the assessment of penalties and fines, which could negatively impact our results of operations and financial condition. Our failure to comply with these regulations and requirements could also lead to suspension or debarment, for cause, from government contracting or subcontracting for a period of time. Among the causes for debarment are violations of various statutes, including those related to procurement integrity, export control, government security regulations, employment practices, protection of the environment, accuracy of records and the recording of costs, and foreign corruption. The termination of any government contract we may obtain as a result of any of these acts could have a negative impact on our results of operations and financial condition and could have a negative impact on our reputation and ability to procure other government contracts in the future.

Risks Relating to Our Common Stock and Our Corporate Governance

If we are unable to regain compliance with the listing requirements of the Nasdaq Capital Market, our common stock may be delisted from the Nasdaq Capital Market, which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.

Our common stock is listed on the Nasdaq Capital Market and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly held shares, market value of listed shares, minimum bid price per share (subject to a 180-day grace period, as discussed below), and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from the Nasdaq Capital Market.

On October 25, 2022 June 27, 2024, we received a notice, letter, or Notice, from The Nasdaq Stock Market, or Nasdaq, that we were not in compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2), or the Minimum Bid Price Requirement. The Notice indicated that, consistent with Nasdaq Listing Rule 5810(c)(3)(A), we had have 180 calendar days to regain compliance with the Minimum Bid Price Requirement by having the closing bid price of our common stock meet or exceed $1.00 per share for at least ten consecutive business days. We subsequently requested an extension of time to regain compliance with the Nasdaq Listing Rule 5550(a)(2) and submitted to Nasdaq a plan to regain compliance. On April 25, 2023, Nasdaq informed us that the request for extension was granted. As a result of the extension, we have until October 23, 2023 to provide evidence that we have regained compliance with Nasdaq Listing Rule 5550(a)(2), by trading at or above $1.00 per share for ten consecutive trading dates prior to that date.

There can be no assurance, however, that we will be able to regain compliance with the Minimum Bid Price Requirement. Even if we do regain compliance, we may not be able to maintain compliance with the continued listing requirements for the Nasdaq Capital Market or our common stock could be delisted in the future. In addition, we may be unable to meet other applicable listing requirements of the Nasdaq Capital Market, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the Minimum Bid Price Requirement.

Delisting from the Nasdaq Capital Market may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

Historically we have not paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never paid cash dividends on our common stock. We intend to retain our future earnings, if any, to fund operational and capital expenditure needs of our business, and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our common stockholders in the foreseeable future.

Our stock price is speculative, and there is a risk of litigation.

The trading price of our common stock has in the past and may in the future be subject to wide fluctuations in response to factors such as the following:

- failure to raise additional funds when needed;
- announcements regarding our ongoing development of the Hemopurifier;
- results regarding the progress of our clinical trials with the Hemopurifier;
- results reported from our clinical trials with the Hemopurifier;
- failure to meet the continued listing requirements of and maintain our listing on Nasdaq;
- results of operations or revenue in any quarter failing to meet the expectations, published or otherwise, of the investment community;
- reduced investor confidence in equity markets;
- speculation in the press or analyst community;
- wide fluctuations in stock prices, particularly with respect to the stock prices for other medical device companies;
- announcements of technological innovations by us or our competitors;
- new products or the acquisition of significant customers by us or our competitors;

- changes in interest rates;
- changes in investors' beliefs as to the appropriate price-earnings ratios for us and our competitors;
- changes in recommendations or financial estimates by securities analysts who track our common stock or the stock of other medical device companies;
- changes in management;
- sales of common stock by directors and executive officers;

- rumors or dissemination of false or misleading information, particularly through Internet chat rooms, instant messaging, and other rapid-dissemination methods;
- conditions and trends in the medical device industry generally;
- the announcement of acquisitions or other significant transactions by us or our competitors;
- adoption of new accounting standards affecting our industry;
- changes in the structure of healthcare payment systems;
- general market conditions;
- domestic or international terrorism and other factors; and
- the other factors described in this section.

Fluctuations in the price of our common stock may expose us to the risk of securities class action lawsuits. Although no such lawsuits are currently pending against us and we are not aware that any such lawsuit is threatened to be filed in the future, future lawsuits are possible as a result of fluctuations in the price of our common stock. Defending against any such suits could result in substantial cost and divert management's attention and resources. In addition, any settlement or adverse determination of such lawsuits could subject us to significant liability.

If at any time our common stock is subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.

If at any time our common stock is not listed on a national securities exchange or we have net tangible assets of $2,000,000 or less, or we have an average revenue of less than $6,000,000 for the last three years, and our common stock has a market price per share of less than $5.00, transactions in our common stock will be subject to the SEC's "penny stock" rules. Currently, our common stock is subject to the SEC's "penny stock" rules promulgated under the Exchange Act and as a result, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person’s account for transactions in penny stocks;
- furnish the investor a disclosure document describing the risks of investing in penny stocks;
- disclose to the investor the current market quotation, if any, for the penny stock;
- disclose to the investor the amount of compensation the firm and its broker will receive for the trade; and
- The broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

Our common stock has had an unpredictable trading volume which means you may not be able to sell our shares at or near trading prices or at all.

Trading in our common shares historically has been volatile and often has been thin, meaning that the number of persons interested in purchasing our common shares at or near trading prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. A broader or more active public trading market for our common shares may not develop or be sustained, and current trading levels may decrease.

The market price for our common stock is volatile; you may not be able to sell our common stock at or above the price you have paid for it, which may result in losses to you.

The market for our common stock is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than a seasoned issuer for the indefinite future. During the 52-week period ended March 31, 2023 March 31, 2024, the high and low closing sale prices for a share of our common stock were $1.99 $6.10 and $0.25, $1.42, respectively. The volatility in our share price is attributable to a number of factors. First, as noted above, trading in our common stock often has been thin. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of our common shares are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without adverse impact on its share price. Secondly, we are a speculative investment due to our limited operating history, limited amount of cash and revenue, lack of profit to date, and the uncertainty of future market acceptance for our potential products. As a consequence of this enhanced risk, more risk-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer.

The following factors also may add to the volatility in the price of our common stock: actual or anticipated variations in our quarterly or annual operating results; announcements regarding our clinical trials and the development and manufacture of our Hemopurifier; acceptance of our proprietary technology as a viable method of augmenting the immune response of clearing viruses and toxins from human blood; government regulations, announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments and additions or departures of our key personnel. Many of these factors are beyond our control and may decrease the market price of our common shares regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common shares will sustain their current market prices, or as to what effect the sale of shares or the availability of common shares for sale at any time will have on the prevailing market price.

Our issuance of additional shares of common stock or convertible securities could be dilutive.

We are entitled under our articles of incorporation to issue up to 60,000,000 shares of common stock. As of March 31, 2023 March 31, 2024, we have reserved for issuance 2,045,006 124,028 of those shares of common stock for outstanding restricted stock units, stock options and warrants, excluding an aggregate of 348,837 131,576 issuances of restricted stock units to our independent directors under our 2020 Equity Incentive Plan made subsequent to March 31, 2023 March 31, 2024. As of March 31, 2023 March 31, 2024, we had issued and outstanding 22,992,466 2,629,725 shares of common stock. As a result, as of March 31, 2023 March 31, 2024 we had 34,962,528 57,246,247 shares of common stock available for issuance to new investors or for use to satisfy indebtedness or pay service providers.

On May 17, 2024, we closed a public offering pursuant to which we sold an aggregate of: (i) 2,450,000 shares of our common stock and accompanying Class A warrants to purchase up to 2,450,000 shares of common stock and Class B warrants to purchase up to 2,450,000 shares of common stock, at a combined public offering price of $0.58 per share and accompanying warrants; and (ii) in lieu of common stock, pre-funded warrants to purchase 5,650,000 shares of common stock and accompanying Class A warrants to purchase up to 5,650,000 shares of common stock and Class B warrants to purchase up to 5,650,000 shares of common stock, at a combined public offering price of $0.579 per pre-funded warrant and accompanying warrants, which is equal to the public offering price per share of common stock, and accompanying warrants less the $0.001 per share exercise price of each such pre-funded warrant.

On March 24, 2022, we entered into an At the Market Offering Agreement, or the 2022 ATM Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, which established an at-the-market equity program pursuant to which we may offer and sell shares of our common stock from time to time as set forth in the 2022 ATM Agreement. Through March 31, 2023 During the fiscal year ended March 31, 2024, we sold an aggregate of 7,480,836 296,056 shares under the 2022 ATM Agreement for net proceeds of $8,927,211. $1,322,383. As of March 31, 2024, $5,302,617 of shares of common stock remained available for sale under the 2022 ATM Agreement.

Our Board of Directors may generally issue shares of common stock, restricted stock units or stock options or warrants to purchase those shares, without further approval by our stockholders, based upon such factors as our Board of Directors may deem relevant at that time. It is likely that we will be required to issue a large amount of additional securities to raise capital to further our development. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our stock plans.

Our officers and directors are entitled to indemnification from us for liabilities under our articles of incorporation, which could be costly to us and may discourage the exercise of stockholder rights.

Our articles of incorporation provide that we possess and may exercise all powers of indemnification of our officers, directors, employees, agents and other persons and our bylaws also require us to indemnify our officers and directors as permitted under the provisions of the Nevada Revised Statutes, or NRS. We may also have contractual indemnification obligations under our agreements with our directors, officers and employees. The foregoing indemnification obligations could result in our company incurring substantial expenditures to cover the cost of settlement or damage awards against directors and officers. These provisions and resultant costs may also discourage our company from bringing a lawsuit against directors, officers and employees for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our stockholders against our directors, officers and employees even though such actions, if successful, might otherwise benefit our company and stockholders.

Our bylaws and Nevada law may discourage, delay or prevent a change of control of our company or changes in our management, would have the result of depressing the trading price of our common stock.

Certain anti-takeover provisions of Nevada law could have the effect of delaying or preventing a third-party from acquiring us, even if the acquisition arguably could benefit our stockholders.

Nevada's "combinations with interested stockholders" statutes (NRS 78.411 through 78.444, inclusive) prohibit specified types of business "combinations" between certain Nevada corporations and any person deemed to be an "interested stockholder" for two years after such person first becomes an "interested stockholder" unless the corporation's board of directors approves the combination (or the transaction by which such person becomes an "interested stockholder") in advance, or unless the combination is approved by the board of directors and sixty percent of the corporation's voting power not beneficially owned by the interested stockholder, its affiliates and associates. Further, in the absence of prior approval certain restrictions may apply even after such two year period. However, these statutes do not apply to any combination of a corporation and an interested stockholder after the expiration of four years after the person first became an interested stockholder. For purposes of these statutes, an "interested stockholder" is any person who is (1) the beneficial owner, directly or indirectly, of ten percent or more of the voting power of the outstanding voting shares of the corporation, or (2) an affiliate or associate of the corporation and at any time within the two previous years was the beneficial owner, directly or indirectly, of ten percent or more of the voting power of the then outstanding shares of the corporation. The definition of the term "combination" is sufficiently broad to cover most significant transactions between a corporation and an "interested stockholder." A Nevada corporation may elect in its articles of incorporation not to be governed by these particular laws, but if such election is not made in the corporation's original articles of incorporation, the amendment (1) must be approved by the affirmative vote of the holders of stock representing a majority of the outstanding voting power of the corporation not beneficially owned by interested stockholders or their affiliates and associates, and (2) is not effective until 18 months after the vote approving the amendment and does not apply to any combination with a person who first became an interested stockholder on or before the effective date of the amendment. We did not make such an election in our original articles of incorporation and have not amended our articles of incorporation to so elect.

Nevada's "acquisition of controlling interest" statutes (NRS 78.378 through 78.3793, inclusive) contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These "control share" laws provide generally that any person that acquires a "controlling interest" in certain Nevada corporations may be denied voting rights, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights. These laws would apply to us if we were to have 200 or more stockholders of record (at least 100 of whom have addresses in Nevada appearing on our stock ledger) and do business in the State of Nevada directly or through an affiliated corporation, unless our articles of incorporation or bylaws in effect on the tenth day after the acquisition of a controlling interest provide otherwise. These laws provide that a person acquires a "controlling interest" whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the NRS, would enable that person to exercise (1) one fifth or more, but less than one third, (2) one third or more, but less than a majority or (3) a majority or more, of all of the voting power of the corporation in the election of directors. Once an acquirer crosses one of these thresholds, shares which it acquired in the transaction taking it over the threshold and within the 90 days immediately preceding the date when the acquiring person acquired or offered to acquire a controlling interest become "control shares" to which the voting restrictions described above apply. These laws may have a chilling effect on certain transactions if our articles of incorporation or bylaws are not amended to provide that these provisions do not apply to us or to an acquisition of a controlling interest, or if our disinterested stockholders do not confer voting rights in the control shares.

Various provisions of our bylaws may delay, defer or prevent a tender offer or takeover attempt of us that a stockholder might consider in his or her best interest. Our bylaws may be adopted, amended or repealed by the affirmative vote of the holders of at least a majority of our outstanding shares of capital stock entitled to vote for the election of directors, and except as provided by Nevada law, our Board of Directors shall have the power to adopt, amend or repeal the bylaws by a vote of not less than a majority of our directors. The interests of these stockholders and directors may not be consistent with your interests, and they may make changes to the bylaws that are not in line with your concerns.

Nevada law also provides that directors may resist a change or potential change in control if the directors determine that the change is opposed to, or not in the best interests of, the corporation. The existence of the foregoing provisions and other potential anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

We incur substantial costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, insurance, accounting and other expenses, including costs associated with public company reporting. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development and commercialization activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. These laws and regulations could make it more difficult and costly for us to obtain director and officer liability insurance for our directors and officers, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and qualified members of our Board of Directors, particularly to serve on our audit and compensation committees. In addition, if we are unable to continue to meet the legal, regulatory and other requirements related to being a public company, we may not be able to maintain the quotation of our common stock on the Nasdaq Capital Market or on any other senior market to which we may apply for listing, which would likely have a material adverse effect on the trading price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, information related to our clinical trials, and information of our employees, or Information Systems and Data.

The Company's Chief Financial Officer, or CFO, with assistance from our third-party cybersecurity vendors, is responsible for identifying, assessing, and managing our cybersecurity threats and risks. Together, they identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, automated tools, evaluating our and our industry's risk profile, conducting real-time monitoring of certain systems, and implementing escalation protocols with our third-party cybersecurity vendors.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response plan; incident detection and response tools; encryption of certain sensitive data and certain data on mobile systems; certain access controls enforcing the principle of need-to-know encryption of certain sensitive data and certain data on mobile systems; physical security measures; asset management, tracking and disposal; monitoring of certain systems; and employee training.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, cybersecurity risk is addressed through our quality management system and processes and overseen by our audit committee of the board of directors. We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including, for example, professional services firms, including legal counsel and certain cybersecurity service providers.

We use third-party service providers to perform a variety of functions throughout our business, such as hosting companies and contract research organizations. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. The program includes conducting a risk assessment for certain vendors.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*If our information technology systems, or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to: regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.*"

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including the Interim Chief Executive Officer, or CEO, and CFO.

The CFO is responsible for hiring appropriate personnel (including selecting third-party cybersecurity vendors), helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. The CFO is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including CFO and CEO. The CFO and CEO work with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response plan includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from the CFO concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

ITEM 2. PROPERTIES

Office, Lab and Manufacturing Space Leases

In December 2020, we entered into an agreement to lease approximately 2,823 square feet of office space and 1,807 square feet of laboratory space located at 11555 Sorrento Valley Road, Suite 203, San Diego, California 92121 and 11575 Sorrento Valley Road, Suite 200, San Diego, California 92121, respectively. The agreement carries a term of 63 months and we took possession of the office space effective October 1, 2021. We took possession of the laboratory space effective January 1, 2022. In October 2021, we entered into another lease for approximately 2,655 square feet of space to house our manufacturing operations located at 11588 Sorrento Valley Road, San Diego, California 92121. The term is for 55 months and we took possession of the manufacturing space in August 2022. The current monthly base rent under the office and laboratory component of the lease is $13,772. $14,158. The current monthly base rent under the manufacturing component of the lease is $12,080.

During the fiscal year ended March 31, 2023, we recorded a $625,471 right-of-use lease asset and associated lease liability related to the manufacturing space component of the lease based on the present value of lease payments over the expected lease term of 55 months, discounted using our estimated incremental borrowing rate of 4.25%. $12,452

The office, lab and manufacturing leases are coterminous with a remaining term of 48 36 months. The weighted average discount rate is 4.25%.

As of our March 31, 2023 March 31, 2024 balance sheet, we have a right-of-use lease asset of $1,151,909. $883,054.

The following table presents a maturity analysis of expected undiscounted cash flows for operating leases on an annual basis for the next four three fiscal years. All of our leases conterminously expire during the fiscal year ending March 31, 2027.

Fiscal Year Ended March 31,		
2024	$ 314,493	
2025	323,812	323,812
2026	333,462	333,462
2027	343,351	343,352
Total minimum lease payments	1,315,118	1,000,626
Less amount representing imputed interest	(106,090)	(60,310)
Present value of minimum lease payments	$ 1,209,028	$ 940,316

Mobile Clean Room

In addition, we rented a mobile clean room on a short term, month-to-month basis, where we housed our manufacturing operations until our permanent manufacturing space was completed. The mobile clean room was located on leased land near our office and lab and we paid $2,000 per month for the right to locate it there. We paid approximately $168,171 in total rent expense to lease the mobile clean room located on this space during the fiscal year ended March 31, 2023. The arrangement was terminated in September 2022 and the mobile clean room was returned to the vendor that leased it to us.

Overall, our rent expense, which is included in general and administrative expenses, approximated $519,000 and $401,000 for the fiscal years ended March 31, 2023 and 2022, respectively.

ITEM 3. LEGAL PROCEEDINGS

We may be involved from time to time in various claims, lawsuits, and/or disputes with third parties or breach of contract actions incidental to the normal course of our business operations. We are currently not involved in any litigation or any pending legal proceedings.

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

Our common stock is traded on the Nasdaq Capital Market under the trading symbol "AEMD." On July 7, 2015, The Nasdaq Stock Market LLC approved our application for listing our common stock on the Nasdaq Capital Market under the symbol "AEMD," and we commenced trading on the Nasdaq Capital Market on July 13, 2015. Previously, our common stock was quoted on the OTCQB Marketplace under the trading symbol "AEMD."

Holders of Record

There were approximately 68 62 record holders of our common stock at June 26, 2023 June 25, 2024. The number of registered stockholders includes any beneficial owners of common shares held in street name.

Dividend Policy

We have not paid any dividends on our common stock to date and do not anticipate that we will pay dividends in the foreseeable future. Any payment of cash dividends on our common stock in the future will be dependent upon the amount of funds legally available, our earnings, if any, our financial condition, our anticipated capital requirements and other factors that the Board of Directors may think are relevant. However, we currently intend for the foreseeable future to follow a policy of retaining all of our earnings, if any, to finance the development and expansion of our business and, therefore, do not expect to pay any dividends on our common stock in the foreseeable future.

Recent Sales of Unregistered Securities

The Company did not have any sales of unregistered securities for the period covered by this Annual Report.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

The following discussion and analysis should be read in conjunction with the consolidated Financial Statements and Notes thereto appearing elsewhere in this Annual Report.

We are a medical therapeutic company focused on developing products to treat cancer and life-threatening infectious diseases. The Aethlon the Hemopurifier, is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. infections and for use in organ transplantation. In cancer, human studies, 164 sessions with 38 patients, the Hemopurifier is designed was safely utilized and demonstrated the potential to deplete remove life-threatening viruses. In pre-clinical studies, the presence of circulating tumor-derived Hemopurifier has demonstrated the potential to remove harmful exosomes that and exosomal particles from biological fluids, utilizing its proprietary lectin-based technology. This action has potential applications in cancer, where exosomes and exosomal particles may promote immune suppression seed the spread of and metastasis, and inhibit the benefit of leading cancer therapies. in life-threatening infectious diseases. The FDA has designated the Hemopurifier as a "Breakthrough Device" for two independent indications:

- the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes or exosomal particles have been shown to participate in the development or severity of the disease; and
- the treatment of life-threatening viruses that are not addressed with approved therapies.

Oncology

We believe the Hemopurifier can may be a substantial advance advancement in the treatment of patients with advanced and metastatic cancer through the clearance of its design to bind to and remove harmful exosomes and exosomal particles that promote the growth and spread of tumors through multiple mechanisms. tumors. In October 2022, we formed a wholly-owned subsidiary in Australia to initially conduct oncology-related clinical research, then seek regulatory approval and commercialize our Hemopurifier in Australia. We are currently working with our new contract research organization, or CRO, on preparations to conduct a clinical trial in Australia in patients with solid tumors, including head and neck cancer, and gastrointestinal cancers and other cancers.

On October 4, 2019, the FDA approved our Investigational Device Exemption, or IDE, application to initiate an Early Feasibility Study, or EFS, of the Hemopurifier in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda). The primary endpoint for the EFS, designed to enroll 10 to 12 subjects at a single center, is safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. This clinical trial, initially conducted at the UPMC Hillman Cancer Center in Pittsburgh, PA, or UPMC, treated two patients. Due to lack of further patient enrollment, we and UPMC terminated this trial.

In January 2023, we entered into an agreement with North American Science Associates, LLC, or NAMSA, a world leading MedTech medical technology CRO offering global end-to-end development services, to oversee our planned clinical trials investigating the Hemopurifier for oncology indications. Pursuant to the agreement, NAMSA will agreed to manage our planned clinical trials of the Hemopurifier for patients in the United States and Australia with various types of cancer tumors.

We anticipate recently completed an *in vitro* binding study of relevant oncology targets, to provide pre-clinical evidence to support our trial design and translational endpoints. Our study indicated positive results from this study, providing evidence that the initial our Hemopurifier removes extracellular vesicles, or EVs, from plasma. This translational study provides pre-clinical evidence to support our planned phase 1 safety, feasibility and dose-finding clinical trials will begin of our Hemopurifier in Australia. patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment, such as Keytruda® or Opdivo®. In addition to an interested initial trial site in India, we had three interested sites in Australia that were awaiting our completion of this *in vitro* binding study. We added the data from this study to our Clinical Investigator Brochure and submitted that brochure to the Ethics Committee of Royal Adelaide Hospital in Australia and in June 2024, we received approval for our proposed phase 1 oncology trial from the Ethics Committee from Royal Adelaide Hospital. We are currently in the process of applying to the Ethics Committees of the two additional interested clinical trial sites in Australia and the site in India.

Life-Threatening Viral Infections

We also believe that the Hemopurifier can be part of the broad-spectrum treatment of life-threatening highly glycosylated, or carbohydrate coated, viruses that are not addressed with an already approved treatment. In small-scale or early feasibility human studies, the Hemopurifier has been used in the past to treat individuals infected with human immunodeficiency virus, or HIV, hepatitis-C and Ebola.

Additionally, *in vitro*, the Hemopurifier has been demonstrated to capture Zika virus, Lassa virus, MERS-CoV, cytomegalovirus, Epstein-Barr virus, Herpes simplex virus, Chikungunya virus, Dengue virus, West Nile virus, smallpox-related viruses, H1N1 swine flu virus, H5N1 bird flu virus, Monkeypox virus and the reconstructed Spanish flu virus of 1918. In several cases, these studies were conducted in collaboration with leading government or non-government research institutes.

We believe the Hemopurifier can be part of the treatment of severe SARS-CoV-2 viremia/COVID-19, or COVID-19, cases. COVID viremia is detected in approximately 34% of patients and is associated with severity, requirement for intensive care unit, or ICU, stay, development of multi-organ failure and poor outcomes. EVs and exosomal miRNAs may play a role in the spread of infection as well as ongoing inflammation, development of coagulopathy and lung injury. Our proprietary *Galanthus nivalis* agglutinin, or GNA, affinity resin has been shown to bind multiple clinically relevant SARS-CoV-2 variants. Furthermore, studies have demonstrated *in vitro* removal of seven SARS-CoV2 variants (104 PFU/mL) in phosphate buffered saline passed over a column of GNA affinity resin (1g) three times, with capture efficiencies between 53% and 89%.

On June 17, 2020, the FDA approved a supplement to our open Investigational Device Exemption, or IDE, for the Hemopurifier in viral disease to allow for the testing of the Hemopurifier in patients with SARS-CoV-2/COVID-19, or COVID-19, in a New Feasibility Study. new feasibility study. That study was designed to enroll up to 40 subjects at up to 20 centers in the United States. Subjects had were to have an established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU and have acute lung injury and/or severe or life-threatening disease, among other criteria. Endpoints for this study, in addition to safety, included reduction in circulating virus, as well as clinical outcomes (NCT # 04595903). In January 2021, the Hemopurifier was used to treat a viremic patient, under our emergency use approval, with a predicted risk of mortality of 80% and the Hemopurifier was able to reduce the patient's SARS-CoV-2 plasma viral load by 58.4%. In June 2022, the first patient in this study was enrolled and completed the Hemopurifier treatment phase of the protocol. Due to the lack of COVID-19 patients in the ICUs of our trial sites, we terminated this study in 2022. However, our IDE for this indication remains open, as we have an active COVID-19 trial in India and wish to preserve the option of enrolling patients if the situation with COVID-19 changes.

Under Single Patient Emergency Use regulations, the Company Aethlon has treated two patients with COVID-19 with the Hemopurifier, in addition to the COVID-19 patient treated with our Hemopurifier in our COVID-19 clinical trial discussed above.

We currently are experiencing previously reported a disruption in our Hemopurifier supply, as our then existing supply of Hemopurifiers expired on September 30, 2022, and, also as previously disclosed, we are dependent on FDA approval of qualified suppliers to manufacture our Hemopurifier. We recently completed final testing in order to begin manufacturing Hemopurifiers at our new manufacturing facility in San Diego, California for use in planned U.S. clinical trials, using GNA from our current supplier.

In April 2024, we received a notice of approval from the FDA for our IDE supplement to add our San Diego manufacturing facility and we now are able to manufacture Hemopurifiers at this site. We also have sufficient Hemopurifiers on hand for use in our planned Australia and India oncology trials. Our intended transition to a new supplier for galanthus nivalis agglutinin, or GNA, a component of our Hemopurifier, is continues to be delayed as we work with the FDA for approval of our supplement to our IDE, which is required to make this manufacturing supplier change.

In October 2022, we launched a wholly owned subsidiary in Australia, formed We are working with the FDA to conduct clinical research, seek regulatory approval and commercialize qualify this second supplier of our Hemopurifier in that country. The subsidiary will initially focus on oncology trials in Australia. GNA.

We also obtained ethics review board, or ERB, approval from and entered into a clinical trial agreement with Medanta Medicity Hospital, a multi-specialty hospital in Delhi NCR, India, for a COVID-19 clinical trial at that location. We now have two sites in India for this trial with the Medanta Medicity Hospital and Maulana Azad Medical College, or MAMC. One patient has completed participation been treated to date; however, we have been informed by our CRO that a new COVID-19 subvariant was detected in India recently. Our COVID-19 trial in India remains open in the Indian event that there are COVID-19 study. The relevant authorities admissions to the ICUs at our sites in India have accepted the use of the Hemopurifiers made with the GNA from our new supplier. India.

In May 2023, we also received ERB approval from the Maulana Azad Medical College, or MAMC, for a second site for our clinical trial in India to treat severe COVID-19. MAMC was established in 1958 and is located in New Delhi, India. MMAC MAMC is affiliated with the University of Delhi and is operated by the Delhi government.

We also recently announced that we also have begun investigating the use of our Hemopurifier in the organ transplant setting. Our objective is to confirm that the Hemopurifier, in our translational studies, when incorporated into a machine perfusion organ preservation circuit, can remove harmful viruses and exosomes from harvested organs. We have previously demonstrated the removal of multiple viruses and exosomes from buffer solutions, in vitro, utilizing a scaled-down version of our Hemopurifier. This process potentially may reduce complications following transplantation of the harvested organ, which can include viral infection, delayed graft function and rejection. We believe this new approach could be additive to existing technologies that currently are in place to increase the number of viable organs for transplant.

Previously we were the majority owner of ESI a company formed to focus on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases, and thus consolidated ESI in our consolidated financial statements. For more than four years, the primary activities of ESI were limited to the payment of patent maintenance fees and applications. In September 2022, the Board of Directors of ESI and we, as the majority stockholder of ESI, approved the dissolution of ESI.

Organ Transplantation

Additionally, based on preclinical data with acellular kidney perfusates, we believe that the Hemopurifier has potential applications in organ transplantation. We are investigating whether the Hemopurifier, when incorporated into a machine perfusion organ preservation circuit, can remove harmful viruses, exosomes, RNA molecules, cytokines, chemokines and other inflammatory molecules from recovered organs. We initially are focused on recovered kidneys from deceased donors. We have previously demonstrated the removal of multiple viruses and exosomes and exosomal particles from buffer solutions, *in vitro*, utilizing a scaled-down version of our Hemopurifier and believe this process could reduce transplantation complications by improving graft function, reducing graft rejection, maintaining or improving organ viability prior to transplantation, and potentially reducing the number of kidneys rejected for transplant.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we plan to market and sell the Hemopurifier. Some of our patents may expire before FDA approval or approval in a foreign country, if any, is obtained. However, we believe that certain patent applications and/or other patents issued to us more recently will help protect the proprietary nature of the our Hemopurifier treatment technology.

In addition to the foregoing, we are monitoring closely the impact of inflation, recent bank failures and the war between Russia and Ukraine and the military conflicts in Ukraine Israel and the surrounding areas, as well as related political and economic responses and counter-responses by various global factors on our business. Given the level of uncertainty regarding the duration and impact of these events on capital markets and the U.S. economy, we are unable to assess the impact on our timelines and future access to capital. The full extent to which inflation, recent bank failures and the war in Ukraine ongoing military conflicts will impact our business, results of operations, financial condition, clinical trials and preclinical research will depend on future developments, as well as the economic impact on national and international markets that are highly uncertain.

Our executive offices are located at 11555 Sorrento Valley Road, Suite 203, San Diego, California 92121. Our telephone number is (619) 941-0360. Our website address is www.aethlonmedical.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report.

Our common stock is listed on the Nasdaq Capital Market under the symbol “AEMD.”

Fiscal Years Ended March 31, 2023 March 31, 2024 and 2022 2023

Results of Operations

Government Contract Revenues

We For the fiscal year ended March 31, 2024, we did not have any active revenue-generating government contracts and, consequently, did not record any government contract revenue for that period. For the fiscal year ended March 31, 2023, we recorded government contract revenue in the fiscal years ended March 31, 2023 and 2022. This revenue resulted of $574,245 resulting from work performed under our government contracts contract Phase 2 Melanoma Cancer with the NIH and our subaward with the University of Pittsburgh as follows:

	Fiscal Year Ended 3/31/23	Fiscal Year Ended 3/31/22	Change in Dollars
Phase 2 Melanoma Cancer Contract	$ 574,245	$ 229,698	$ 344,547
Subaward with University of Pittsburgh	–	64,467	(64,467)
Total Government Contract and Grant Revenue	$ 574,245	$ 294,165	$ 280,080

NIH.

We have recognized revenue under the following contracts/grants:

Phase 2 Melanoma Cancer Contract

On September 12, 2019, the NCI awarded to us the Award Contract. The Award Contract amount was $1,860,561 and, as amended, ran for the period from September 16, 2019 through September 15, 2022.

The work performed pursuant to this Award Contract was focused on melanoma exosomes. This work followed from our completion of a Phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018, as described below. Following on the Phase I work, the deliverables in the Phase II program involved the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

The Award Contract ended on September 15, 2022 and we We presented the required final report to the NCI. As the NCI completed its close out review of the contract, we recognized as revenue the $574,245 previously recorded as deferred revenue on our December 31, 2022 balance sheet.

statement of operations for the fiscal year ended March 31, 2023.

Subaward with University of Pittsburgh

In December 2020, we entered into a cost reimbursable subaward arrangement with the University of Pittsburgh in connection with an NIH contract entitled "Depleting Exosomes to Improve Responses to Immune Therapy in HNNCC." Our share of the award was $256,750. We did not record revenue related to this subaward in the fiscal year ended March 31, 2023. We recorded $64,467 of revenue related to this subaward in the fiscal year ended March 31, 2022.

In October 2022, we agreed with the University of Pittsburgh to terminate the subaward arrangement, effective as of November 10, 2022, since it related to our clinical trial in head and neck cancer in which the University of Pittsburgh was unable to recruit patients. There are no provisions in the subaward arrangement requiring repayment of cash received for work completed through November 10, 2022.

Operating Costs and Expenses

Consolidated operating expenses were $12,636,568 for the fiscal year ended March 31, 2024, compared to $12,472,883 for the fiscal year ended March 31, 2023, compared to $10,715,050 for the fiscal year ended March 31, 2022, an increase of $1,757,833. $163,685. The $1,757,833 $163,685 increase in the fiscal year ended March 31, 2023 March 31, 2024 was due to increases an increase in payroll and related expenses of $762,899 partially offset by a decrease of $578,112 in general and administrative expense expenses and a decrease of $1,026,081 $21,102 in professional fees.

The $762,899 increase in the fiscal year ended March 31, 2024 in our payroll and professional fees related expenses was primarily due to an increase in separation expenses of $914,002, which were $861,994 for a former executive and an increase of $126,571 associated with an increase in average headcount, partially offset by a decrease in payroll and related expenses stock-based compensation of $182,250. $225,666.

The $1,026,081 increase $578,112 decrease in the fiscal year ended March 31, 2023 March 31, 2024 in our general and administrative expenses was primarily driven by the following: a decrease of $819,327 in clinical trial expenses related to the closed U.S. COVID-19 clinical trial, a decrease of $279,504 in subcontract expense was due related to contracts and grants with the NIH, a $98,755 decrease in rent expense associated with a mobile clean room leased in the prior year, a decrease of $29,849 in travel related expenses associated with a former remote employee and a decrease of $22,053 expenses related to various other general office operating expenses. These decreases were partially offset by an increase of $404,918 in manufacturing and research and development supplies of $411,211 related to the manufacture manufacturing of the our Hemopurifier device and various research and development activities. Other increases included $146,962 $118,165 in subcontract depreciation expense and amortization expense related to revenue recognized from contracts and grants with the NIH, $154,608 associated with the close out of the US COVID-19 clinical trial, $103,602 associated with our Australian subsidiary and launch of our oncology clinical trial in Australia, $117,772 in rent expense related to the addition of the manufacturing suite in fiscal year 2023 and a full year of rent for our office and laboratory space, $117,207 in depreciation and amortization expense associated with leasehold improvements to our manufacturing space, and $93,510 $69,894 increase in insurance expenses to include medical, D&O and medical insurance. We also had liability, an increase in of $82,421 primarily related to our utility expense of $31,924, largely as the result of our increased space under lease. These increases were offset by decreases in manufacturing facility, encompassing equipment maintenance, utilities, and outside services of $65,377, laboratory fees of $61,258 and decreases in office supplies and equipment of $32,154. services.

The $914,002 increase decrease in professional fees of $21,102 in the fiscal year ended March 31, 2023 in our professional fees March 31, 2024 was primarily due to increases a decrease in outside scientific, product research and regulatory services of $290,762 $302,390, a decrease of $60,229 in recruiting fees and a $32,631 decrease in legal expenses, $334,828 in contract labor associated with product development and scientific analytical services, $176,443 in regulatory consulting, $39,999 in investor relations, $73,066 in recruiting expense and $16,250 in director fees, which fees. These decreases were partially offset by a decrease increases in investor relations of $151,475, accounting fees of $16,601. $137,026, board of director fees of $33,750 and outside operational and administration expenses of $53,964.

As a result of the above factors, our net loss before noncontrolling interests increased to $12,208,174 for the fiscal year ended March 31, 2024, from $12,029,786 for the fiscal year ended March 31, 2023, from $10,420,885 for the fiscal year ended March 31, 2022.

Liquidity and Capital Resources

As of March 31, 2023 March 31, 2024, we had a cash balance of $5,441,978 and working capital of $4,395,889. This compares to a cash balance of $14,532,943 and working capital of $13,585,477. This compares $13,585,478 at March 31, 2023.

On May 17, 2024, we closed a public offering pursuant to which we sold an aggregate of: (i) 2,450,000 shares of our common stock and accompanying Class A warrants to purchase up to 2,450,000 shares of common stock and Class B warrants to purchase up to 2,450,000 shares of common stock, at a cash balance combined public offering price of $17,072,419 $0.58 per share and working capital accompanying warrants; and (ii) in lieu of $16,332,958 common stock, pre-funded warrants to purchase 5,650,000 shares of common stock and accompanying Class A warrants to purchase up to 5,650,000 shares of common stock and Class B warrants to purchase up to 5,650,000 shares of common stock, at March 31, 2022. We expect our existing cash as a combined public offering price of March 31, 2023 $0.579 per pre-funded warrant and accompanying warrants, which is equal to be sufficient to fund the Company's operations for at least twelve months public offering price per share of common stock, and accompanying warrants less the $0.001 per share exercise price of each such pre-funded warrant. The gross proceeds from the issuance offering, before deducting the placement agent's fees and other offering expenses, were approximately $4.7 million. In June 2024, holders of Class A and Class B warrants exercised 295,000 shares and 2,875,000 shares, respectively, for total proceeds of $1,838,600.

While we currently have over $9.1 million in cash and cash equivalents and have been carrying out certain expense reductions since November 2023, our planned expense reductions may not materialize and/or our patient recruitment may occur more rapidly than expected along with the concomitant increases in expenses, there is substantial doubt that our cash on hand will carry the company for 12 months beyond the filing date of the financial statements included in this Annual Report.

The primary sources of our cash from financing activities during

During the fiscal years ended March 31, 2023 March 31, 2024 and 2022 were sales of our common stock, as follows:

Financings During the fiscal year ended March 31, 2023:

During the fiscal year ended March 31, 2023, 2023, we raised capital only through our At The Market Offering Agreement, or the 2022 ATM Agreement, with H.C. Wainwright & Co., LLC, or Wainwright.

2022 At The Market Offering Agreement with H.C. Wainwright & Co., LLC

On March 24, 2022, we entered into the 2022 ATM Agreement with Wainwright, which established an at-the-market equity program pursuant to which we may offer and sell shares of our common stock from time to time as set forth in the 2022 ATM Agreement.

The offering was registered under the Securities Act of 1933, as amended, or the Securities Act, pursuant to our shelf registration statement on Form S-3 (Registration Statement No. 333-259909), as previously filed with the SEC and declared effective on October 21, 2021. We filed a prospectus supplement, dated March 24, 2022, with the SEC that provides for the sale of shares of our common stock, or the 2022 ATM Shares, having an aggregate offering price of up to $15,000,000, or which was subsequently and most recently updated pursuant to our prospectus supplement, dated September 29, 2022, filed with the SEC that provides for the sale of 2022 ATM Shares having an aggregate offering price of up to $6,625,000. As of March 31, 2024, $5,302,617 of 2022 ATM Shares remained available for sale under the 2022 ATM Shares. Agreement.

Under the 2022 ATM Agreement, Wainwright may sell the 2022 ATM Shares by any method permitted by law and deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act, including sales made directly on the Nasdaq Capital Market, or on any other existing trading market for the 2022 ATM Shares. In addition, under the 2022 ATM Agreement, Wainwright may sell the 2022 ATM Shares in privately negotiated transactions with our consent and in block transactions. Under certain circumstances, we may instruct Wainwright not to sell the 2022 ATM Shares if the sales cannot be effected at or above the price designated by us from time to time.

We are not obligated to make any further sales of the 2022 ATM Shares under the 2022 ATM Agreement. The offering of the 2022 ATM Shares pursuant to the 2022 ATM Agreement will terminate upon the termination of the 2022 ATM Agreement by Wainwright or us, as permitted therein.

The 2022 ATM Agreement contains customary representations, warranties and agreements by us, and customary indemnification and contribution rights and obligations of the parties. We agreed to pay Wainwright a placement fee of up to 3.0% of the aggregate gross proceeds from each sale of the 2022 ATM Shares. We also agreed to reimburse Wainwright for certain specified expenses in connection with entering into the 2022 ATM Agreement.

Financings During the Fiscal Year Ended March 31, 2024:

In the fiscal year ended March 31, 2024, we raised aggregate net proceeds of $1,322,383, net of $34,118 in commissions to Wainwright and $8,202 in other offering expense, through the sale of 296,056 shares of our common stock at an average price of $4.47 per share under the 2022 ATM Agreement.

Financings During the Fiscal Year Ended March 31, 2023:

During the fiscal year ended March 31, 2023, we raised aggregate net proceeds of $8,927,211, net of $229,610 in commissions to Wainwright and $27,153 in other offering expense, through the sale of 7,480,836 748,084 shares of our common stock at an average price of $1.19 $11.93 per share under the 2022 ATM Agreement.

Financings During the fiscal year ended March 31, 2022:

During the fiscal year ended March 31, 2022, we raised capital through our 2021 ATM Agreement (as defined below) with Wainwright and in a registered direct financing through Maxim Group LLC.

2021 ATM Agreement

On March 22, 2021, we entered into an At the Market Offering Agreement, or the 2021 ATM Agreement, with Wainwright, as sales agent, pursuant to which we could offer and sell shares of our common stock, from time to time as set forth in the 2021 ATM Agreement.

The offering was registered under the Securities Act pursuant to our shelf registration statement on Form S-3 (Registration Statement No. 333-237269), as previously filed with the SEC and declared effective on March 30, 2020. We filed a prospectus supplement, dated March 22, 2021, with the SEC in connection with the offer and sale of the shares of common stock, pursuant to which we could offer and sell shares of common stock having an aggregate offering price of up to $5,080,000 from time to time.

Subject to the terms and conditions set forth in the 2021 ATM Agreement, Wainwright agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares under the 2021 ATM Agreement from time to time, based upon our instructions. We provided Wainwright with customary indemnification rights under the 2021 ATM Agreement, and Wainwright was entitled to a commission at a fixed rate equal to up to three percent of the gross proceeds per share sold. In addition, we agreed to reimburse Wainwright for certain specified expenses in connection with entering into the 2021 ATM Agreement. The 2021 ATM Agreement provided that it would terminate upon the written termination by either party as permitted thereunder.

Sales of the shares, under the 2021 ATM Agreement are made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act, including sales made by means of ordinary brokers' transactions, including on the Nasdaq Capital Market, at market prices or as otherwise agreed with Wainwright. The 2021 ATM Agreement provided that we have no obligation under the 2021 ATM Agreement to sell any of the shares, and, at any time, we could suspend offers under the 2021 ATM Agreement or terminate the agreement.

In the fiscal year ended March 31, 2022, we raised aggregate net proceeds under the 2021 ATM Agreement described above of $4,947,785, net of $126,922 in commissions to Wainwright and $2,154 in other offering expense, through the sale of 626,000 shares of our common stock at an average price of $7.90 per share of net proceeds. No further sales may be made under the 2021 ATM Agreement.

Registered Direct Financing

In the fiscal year ended March 31, 2022, we sold an aggregate of 1,380,555 shares of our common stock at a purchase price per share of $9.00, for aggregate net proceeds to us of $11,659,044, after deducting fees payable to Maxim Group LLC, the placement agent, and other offering expenses. These shares were sold through a securities purchase agreement with certain institutional investors, The shares were issued pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the SEC on March 19, 2020, and was declared effective on March 30, 2020 (File No. 333-237269) and a prospectus supplement thereunder.

Material Cash Requirements

As noted above in the results of operations, our clinical trial expense for the preparation for our planned oncology trial in Australia was $103,602 in the fiscal year ended March 31, 2023. We expect our clinical trial expenses to continue for the planned oncology trials in Australia and India to increase for the foreseeable future. Those increases in clinical trial expenses include the cost of manufacturing additional Hemopurifiers for the planned clinical trials. Hemopurifiers.

In addition, we have entered into leases for our new headquarters, laboratory and manufacturing facilities. As noted above in the results of operations, our rent expense increased by $117,772 in the fiscal year ended March 31, 2023. We expect our rent expense payments to continue to increase for the foreseeable future.

Future capital requirements will depend upon many factors, including progress with pre-clinical testing and clinical trials, the number and breadth of our clinical programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, as well as our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We expect to continue to incur increasing negative cash flows and net losses for the foreseeable future. We will continue to need to raise additional capital either through equity and/or debt financing for the foreseeable future.

As a result of the COVID-19 pandemic and actions taken to slow its spread, global events, political changes, bank failures, actual or perceived changes in interest rates and economic inflation, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in inflation and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. Any of these actions could materially harm our business, results of operations and future prospects.

While we currently have over $9.1 million in cash and cash equivalents and have been carrying out certain expense reductions since November 2023, our planned additional expense reductions may not materialize and/or our patient recruitment may occur more rapidly than expected along with the concomitant increases in expenses; therefore there is substantial doubt that our cash on hand will carry the company for 12 months beyond the filing date of the financial statements included in this Annual Report.

We do plan to access the equity markets for additional capital, however, there can be no assurance that we will be able to access such additional capital.

Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States, including due to bank failures, actual or perceived changes in interest rates and economic inflation, and worldwide resulting from macroeconomic factors. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and we may never be profitable or generate positive cash flow from operating activities.

Cash Flows

Cash flows from operating, investing and financing activities, as reflected in the accompanying Consolidated Statements of Cash Flows, are summarized as follows (in thousands):

	For the year ended		For the year ended	
	March 31, 2023	March 31, 2022	March 31, 2024	March 31, 2023
Cash (used in) provided by:				
Operating activities	$ (10,505)	$ (9,767)	$ (10,130)	$ (10,505)
Investing activities	(943)	(349)	(251)	(943)
Financing activities	8,915	17,368	1,288	8,915
Net (decrease) increase in cash	$ (2,533)	$ 7,252		
Effect of exchange rate on cash			2	(6)
Net decrease in cash			$ (9,091)	$ (2,539)

Net Cash Used in Operating Activities

We used cash in our operating activities due to our losses from operations. Net cash used in operating activities was approximately $10,505,000 $10,130,000 in fiscal 2023, 2024, compared to net cash used in operating activities of approximately $9,767,000 in fiscal 2022, an increase of approximately $738,000. The primary factors in this $738,000 increase in cash used in operations $10,505,000 in fiscal 2023, a decrease of approximately $375,000. The decrease in cash flows was primarily driven by a $1,613,695 positive change in our working capital items of $413,000 mainly from the increase in our accounts payable and accrued expenses offset by an increase in net loss. loss of approximately $38,000 before non-cash items.

Net Cash Used in Investing Activities

During the fiscal years ended March 31, 2023 March 31, 2024 and 2022, 2023, we purchased approximately $943,000 $251,000 and $349,000 $943,000 of equipment, respectively.

Net Cash from Financing Activities

Net cash generated from financing activities decreased from approximately $17,368,000 in the fiscal year ended March 31, 2022 to approximately $8,915,000 in the fiscal year ended March 31, 2023 to approximately $1,288,000 in the fiscal year ended March 31, 2024.

In the fiscal year ended March 31, 2023 March 31, 2024, we raised approximately $8,927,000 $1,322,383 from the issuance of common stock, which was partially offset by the use of approximately $35,000 to pay for the tax withholding on the issuance of restricted stock units, or RSUs. During the fiscal year ended March 31, 2023, we raised $8,927,211 from the issuance of common stock, which was partially offset by the use of approximately $12,000 to pay for the tax withholding on the issuance of restricted stock units, or RSUs. In the fiscal year ended March 31, 2022, we raised approximately $17,456,000 from the issuance of common stock, which was partially offset by the use of approximately $88,000 to pay for the tax withholding on the issuance of RSUs.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires us to make a number of 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. Such These estimates and assumptions affect the reported amounts of expenses during the reporting period. On an ongoing basis, we evaluate estimates and assumptions based upon historical experience and various other factors and circumstances. We believe our estimates and assumptions are reasonable in the circumstances; however, actual results may differ from these estimates under different future conditions.

We believe that the estimates and assumptions that are most important to the portrayal of our financial condition and results of operations, in that they require the most difficult, subjective or complex judgments, form the basis for the accounting policies deemed to be most critical to us. These critical

There were no accounting estimates relate in the year ended March 31, 2024 with a high degree of uncertainty or amounts that are with a high likelihood to revenue recognition, stock purchase warrants issued with notes payable, beneficial conversion feature change from period to period that would materially impact the presentation of convertible notes payable, impairment of intangible assets and long lived assets, stock compensation, deferred tax asset valuation allowance, and contingencies.

Revenue Recognition

Our revenues consist entirely of amounts earned under contracts and grants with the NIH. During the fiscal years ended March 31, 2023 and 2022, we recognized revenues totaling $574,245 and $294,165, respectively, under such contracts. We have concluded that these agreements are not within the scope of ASC Topic, 606, Revenue from Contracts with Customers, or Topic 606, as the NIH grants and contracts do not meet the definition of a “customer” as defined by Topic 606. Prior to the effective date of ASC Topic 606, which our financial statements for the Company was April 1, 2018, we accounted for our grant/contract revenues under the Milestone Method as prescribed by the legacy guidance of ASC 605-28, Revenue Recognition – Milestone Method, or the Milestone Method. In the absence of other applicable guidance under US GAAP, effective April 1, 2018, we elected to continue to use the Milestone Method by analogy to recognize revenue under these grants/contracts.

Common Stock Warrants

In the past, we have granted warrants to purchase our common stock in connection with financing transactions. When such warrants are classified as equity, we measure the relative estimated fair value of such warrants which represents a discount from the face amount of the notes payable. Such discounts are amortized to interest expense over the term of the notes. We analyze such warrants for classification as either equity or derivative liabilities and value them based on binomial lattice models. year ended March 31, 2024.

Share-based Compensation

We account for share-based compensation awards using the fair-value method and record such expense based on the grant date fair value in the consolidated financial statements over the requisite service period.

Derivative Instruments

We evaluate free-standing derivative instruments (or embedded derivatives) to properly classify such instruments within equity or as liabilities in our financial statements. Our policy is to settle instruments indexed to our common shares on a first-in-first-out basis.

The classification of a derivative instrument is reassessed at each reporting date. If the classification changes as a result of events during a reporting period, the instrument is reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified.

Instruments classified as derivative liabilities are remeasured each reporting period (or upon reclassification) and the change in fair value is recorded on our consolidated statement of operations in other expense (income). We had no derivative instruments at March 31, 2023 or March 31, 2022.

Income Taxes

Deferred tax assets are recognized for the future tax consequences attributable to the difference between the consolidated financial statements and their respective tax basis. Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts reported for income tax purposes, and (b) tax credit carryforwards. We record a valuation allowance for deferred tax assets when, based on our best estimate of taxable income (if any) in the foreseeable future, it is more likely than not that some portion of the deferred tax assets may not be realized.

Convertible Notes Payable

There were no convertible notes outstanding as of March 31, 2023 or 2022.

RSU Grants to Non-Employee Directors

The Company maintains the Amended and Restated Non-Employee Director Compensation Policy, or the Director Compensation Policy, which provides for cash and equity compensation for persons serving as non-employee directors of the Company. Under this policy, each new director receives either stock options or a grant of RSUs upon appointment/election, as well as either an annual grant of stock options or of RSUs at the beginning of each fiscal year. The (i) stock options are subject to vesting and (ii) RSUs are subject to vesting and represent the right to be issued on a future date shares of our common stock upon vesting.

The Compensation Committee of theOn April 16, 2024, our Board of Directors of the Company, or Compensation Committee, approved, effective as of April 1, 2022, pursuant to the terms of the Company's Amended and Restated Non-Employee Director Compensation Policy, or the Director Compensation Policy, the grant of the annual RSUs under the Director Compensation Policy to each of the two four non-employee directors of the Company then serving on the Board of Directors of the Company, or Board, and the grant of an RSU for the then newly appointed director. The RSU grants were made subject to stockholder approval of an increase of 1,800,000 shares of common stock authorized for issuance under the Company's 2020 Equity Incentive Plan, or the 2020 Plan, at the Company's 2022 annual meeting of stockholders. The increase was approved at the Company's 2022 annual meeting of stockholders held in September 2022. Directors. The Director Compensation Policy provides for a grant of stock options or $50,000 worth of RSUs at the beginning of each fiscal year for current non-employee directors then serving on the Board of Directors, and for a grant of stock options or $75,000 worth of RSUs for a newly elected non-employee director, with each RSU priced at the average for the closing prices for the five days preceding and including the date of grant, or $1.46 $1.52 per share as of April 1, 2022. The two then-current for the RSUs granted in April 2024. As a result, in April 2024 the four eligible directors were each was granted a contingent an RSU in the amount of 34,247 32,894 shares under the Company's 2020 Equity Incentive Plan, and the then newly appointed director received a contingent RSU grant for 51,370 shares under or the 2020 Plan. The RSUs were are subject to vesting in three four equal installments, 50% on September 30, 2022, and with 25% of the restricted stock units vesting on each of December 31, 2022 June 30, 2024, September 30, 2024, December 31, 2024, and March 31, 2023 March 31, 2025, subject in each case to the recipient's continued service with director's Continuous Service (as defined in the Company on each 2020 Plan), through such dates. Vesting will terminate upon the director's termination of Continuous Service prior to any vesting date.

There were no vested RSUs outstanding as of March 31, 2023 March 31, 2024.

Recent Events

Sales Under 2022 ATM Agreement

Subsequent to March 31, 2023 On May 17, 2024, we raised net proceeds of $1,086,119, net of $27,999 in commissions closed a public offering pursuant to Wainwright and $5,846 in other offering expense, through the sale of 1,778,901 which we sold an aggregate of: (i) 2,450,000 shares of our common stock and accompanying Class A warrants to purchase up to 2,450,000 shares of common stock and Class B warrants to purchase up to 2,450,000 shares of common stock, at an average a combined public offering price of $0.61 $0.58 per share under and accompanying warrants; and (ii) in lieu of common stock, pre-funded warrants to purchase 5,650,000 shares of common stock and accompanying Class A warrants to purchase up to 5,650,000 shares of common stock and Class B warrants to purchase up to 5,650,000 shares of common stock, at a combined public offering price of $0.579 per pre-funded warrant and accompanying warrants, which is equal to the 2022 ATM Agreement. public offering price per share of common stock, and accompanying warrants less the $0.001 per share exercise price of each such pre-funded warrant.

The Class A and Class B warrants each have an exercise price of $0.58 per share, are immediately exercisable, and, in the case of Class A warrants, will expire on May 17, 2029, and in the case of Class B warrants, will expire on May 19, 2025. The exercise price of the Class A and Class B warrants is also subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in such warrants. Maxim Group LLC acted as the exclusive placement agent for the offering.

The gross proceeds from the offering, before deducting the placement agent's fees and other offering expenses, were approximately $4.7 million. The Company intends to use the net proceeds from this offering for general corporate purposes, which may include clinical trial expenses, research and development expenses, capital expenditures and working capital.

In June 2024, holders of Class A and Class B warrants exercised 295,000 shares and 2,875,000 shares, respectively, for total proceeds of $1,838,600.

RSU Grants

In April 2023, the Compensation Committee 2024, our Board of Directors approved, pursuant to the terms of the Director Compensation Policy, the grant of the annual RSUs under the Director Compensation Policy to each of the three four non-employee directors of the Company then serving on the Board. Board of Directors. The Director Compensation Policy provides for a grant of stock options or $50,000 worth of RSUs at the beginning of each fiscal year for current non-employee directors then serving on the Board of Directors, and for a grant of stock options or $75,000 worth of RSUs for a newly elected non-employee director, with each RSU priced at the average for the closing prices for the five days preceding and including the date of grant, or $0.43 $1.52 per share for the April 2023 2024 RSU grants. As a result, in April 2023 2024 the three four eligible directors were each was granted an RSU in the amount of 116,279 32,894 shares under the 2020 Plan. The RSUs are subject to vesting in four equal installments, with 25% of the restricted stock units vesting on each of June 30, 2023 June 30, 2024, September 30, 2023 September 30, 2024, December 31, 2023 December 31, 2024, and March 31, 2024 March 31, 2025, subject in each case to the director's Continuous Service (as defined in the 2020 Plan), through such dates. Vesting will terminate upon the director's termination of Continuous Service prior to any vesting date.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable to a "smaller reporting company" as defined under Item 10(f)(1) of Regulation S-K of the Securities Act.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed, in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Interim Chief Executive Officer and Chief Financial Officer (who are is our principal executive officer and principal financial officer, respectively) officer), to allow timely decisions regarding required disclosures.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation as of the end of the period covered by this Annual Report under the supervision and with the participation of our management, including our Interim Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures.

Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report, our disclosure controls and procedures were effective.

(a) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed 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.

Under the supervision and with the participation of our management, including our Interim Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of March 31, 2023 March 31, 2024. According to the guidelines established by Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, one or more material weaknesses renders a company's internal control over financial reporting ineffective. Based on this evaluation, we have concluded that our internal control over financial reporting was not effective as of March 31, 2023. March 31, 2024 due to the material weaknesses described below.

Description of Material Weaknesses

Based on such evaluation, management identified a material weakness in the segregation of duties within our financial systems. Specifically, user access controls were not sufficiently maintained to properly restrict both user and privileged access to financial applications within our accounting software system to initiate, record and approve entries. Also noted that check stock was secured in an authorized signatory's office.

It is difficult to design and maintain appropriate segregation of duties in the initiation, recording, and approval of transactions within financial systems with a limited number of personnel. This, coupled with management having not designed and maintained user access controls that adequately restrict user and privileged access to financial applications, and the absence of sufficient other mitigating controls, created a segregation of duties weakness which could potentially have resulted in a material misstatement. Management has identified remediation actions that may require the addition of personnel to the finance and accounting function or a change in accounting software, which will allow the Company to design the control environment in a manner that provides effective segregation of duties. Management has identified certain actions beyond staff changes or accounting software changes. As of May 2024, the accounting software was updated, and distinct user roles were created. Transactions are recorded by personnel who are independent of those who initiate them and are approved by separate personnel who are independent of those who record them. Additionally, check stock was relocated in November 2023.

During 2017 through 2020, the Company incorrectly recorded accrued commission liability of approximately $404,000. The Company reversed accrued commission liability of approximately $404,000 during the year ended March 31, 2024 related to this error in accounting under U.S. GAAP. The Company originally failed to correctly apply appropriate accounting principles in recording the transaction, and the error was not detected and corrected in a timely manner, resulting in an adjustment to the financial statements.

Management has discussed with counsel appropriate measures to record such potential commission liabilities in the future and will implement a quarterly review of all accruals. The reversal of the accrued commission liability into equity as of March 31, 2024 corrected the impact of the error. The Company is in the process of implementing quarterly review controls over review and assessment of accruals. This plan, with oversight from our Audit Committee, is in the process of implementation in response to the identified material weakness.

Limitation on Effectiveness of Controls

In designing and evaluating our disclosure controls and procedures, management recognized that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. No evaluation of internal control can provide absolute assurance that all internal control issues and instances of fraud, if any, within a company are detected. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

(b) Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the last fiscal quarter ended March 31, 2023 March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None. On June 27, 2024, we received a letter, or Notice, from The Nasdaq Stock Market, or Nasdaq, advising us that for 31 consecutive trading days preceding the date of the Notice, the bid price of our common stock had closed below the $1.00 per share minimum required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or the Minimum Bid Price Requirement. The Notice has no effect on the listing of our common stock at this time, and our common stock continues to trade on The Nasdaq Capital Market under the symbol "AEMD."

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days to regain compliance with the Minimum Bid Requirement, or the Grace Period, subject to a potential 180 calendar day extension, as described below. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of ten consecutive business days within the Grace Period.

If we do not achieve compliance with the Minimum Bid Requirement by December 24, 2024, the end of the Grace Period, we may be eligible for an additional 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for the market value of our publicly held shares and all other Nasdaq initial listing standards, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period. However, if it appears to Nasdaq staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, Nasdaq could provide notice that our common stock will be subject to delisting. In the event we receive notice that our common stock is being delisted, we would be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report and incorporated by reference to our definitive proxy statement for our 2023 2024 Annual Meeting of Stockholders, or the Proxy Statement, to be filed pursuant to Regulation 14A of the Exchange Act. If our Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report, the omitted information will be included in an amendment to this Annual Report filed not later than the end of such 120-day period.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Except as set forth below, the information required by this item will be contained in the sections titled "Information About our Board of Directors and Executive Officers," "Information About our Board of Directors and Executive Officers – Code of Ethics," "Information About our Board of Directors and Executive Officers – Information Regarding Committees of the Board of Directors – Nominating and Corporate Governance Committee," "Information About our Board of Directors and Executive Officers – Information Regarding Committees of the Board of Directors – Audit Committee and Audit Committee Financial Expert," "Information About our Board of Directors and Executive Officers – Information Regarding Committees of the Board of Directors – Compensation Committee" and "Executive and Director Compensation" in our Proxy Statement and is incorporated herein by reference.

We maintain a Code of Business Conduct and Ethics that applies to all our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics is posted on our website at www.aethlonmedical.com on the "Governance" page of the section titled "Investors." If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K. Information contained in, or that can be accessed through, our website is not incorporated by reference herein, and you should not consider information on our website to be part of this Annual Report.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in the sections titled "Executive and Director Compensation" and "Information About our Board of Directors and Executive Officers – Information Regarding Committees of the Board of Directors – Compensation Committee" in our Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be contained in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Executive and Director Compensation – Narrative Disclosure to Executive Summary – Equity-Based Incentive Awards" in our Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in the sections titled "Information About our Board of Directors and Executive Officers – Board of Directors" and "Certain Relationships and Related Transactions" in our Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be contained in the section titled "Ratification of Appointment of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report:

(a)(1) Financial Statements.
The response to this portion of Item 15 is set forth under Part II, Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits required by Item 601 of Regulation S-K.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	SEC File No.	Exhibit No.	Date	
3.1	Articles of Incorporation, as amended.	8-K	001-37487	3.1	September 19, 2022	
3.2	Amended and Restated Bylaws of the Company.	8-K	001-37487	3.1	September 12, 2019	
4.1	Form of Common Stock Certificate.	S-1	333-201334	4.1	December 31, 2014	
4.2	Form of Warrant to Purchase Common Stock.	S-1/A	333-234712	4.14	December 11, 2019	
4.3	Form of Underwriter Warrant.	S-1/A	333-234712	4.15	December 11, 2019	
4.4	Form of Common Stock Purchase Warrant.	8-K	001-37487	4.1	January 17, 2020	
4.5	Description of Aethlon Medical, Inc.'s Securities.	10-K	001-37487	4.16	June 25, 2020	
10.1++	Aethlon Medical, Inc. Amended and Restated Non-Employee Director Compensation Policy, as Modified on February 10, 2022.	10-Q	001-37487	10.2	February 14, 2022	
10.2++	Employment Agreement, by and between Aethlon Medical, Inc. and James Frakes, dated December 12, 2018.	10-Q	001-37487	10.3	February 11, 2019	
10.3++	Form of Indemnification Agreement for Officers and Directors.	10-Q	001-37487	10.4	February 11, 2019	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	SEC File No.	Exhibit No.	Date	
3.1	Articles of Incorporation, as amended.	8-K	001-37487	3.1	September 19, 2022	
3.2	Amended and Restated Bylaws of the Company.	8-K	001-37487	3.1	September 12, 2019	
4.1	Form of Common Stock Certificate.	S-1	333-201334	4.1	December 31, 2014	
4.2	Form of Warrant to Purchase Common Stock.	S-1/A	333-234712	4.14	December 11, 2019	
4.3	Form of Underwriter Warrant.	S-1/A	333-234712	4.15	December 11, 2019	
4.4	Form of Common Stock Purchase Warrant.	8-K	001-37487	4.1	January 17, 2020	
4.5	Form of Class A Warrant to Purchase Common Stock, issued on May 17, 2024.	8-K	001-37487	4.1	May 17, 2024	
4.6	Form of Class B Warrant to Purchase Common Stock, issued on May 17, 2024.	8-K	001-37487	4.2	May 17, 2024	
4.7	Form of Pre-Funded Warrant to Purchase Common Stock, issued on May 17, 2024.	8-K	001-37487	4.3	May 17, 2024	
4.8	Form of Placement Agent Warrant to Purchase Common Stock, issued on May 17, 2024.	8-K	001-37487	4.4	May 17, 2024	
4.9	Description of Aethlon Medical, Inc.'s Securities.	10-K	001-37487	4.16	June 25, 2020	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	SEC File No.	Exhibit No.	Date	
10.1++	Aethlon Medical, Inc. Amended and Restated Non-Employee Director Compensation Policy, as Modified on February 10, 2022.	10-Q	001-37487	10.2	February 14, 2022	
10.2++	Employment Agreement, by and between Aethlon Medical, Inc. and James Frakes, dated December 12, 2018.	10-Q	001-37487	10.3	February 11, 2019	
10.3++	Amendment No. 1 to Executive Employment Agreement, effective as of November 7, 2023, by and between the Company and James B. Frakes.	8-K	001-37487	10.1	December 22, 2023	
10.4++	Form of Indemnification Agreement for Officers and Directors.	10-Q	001-37487	10.4	February 11, 2019	
10.5++	Form of Option Grant Agreement for Officers and Directors.	10-Q	001-37487	10.5	February 11, 2019	
10.6++	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for Directors.	10-Q	001-37487	10.6	February 11, 2019	
10.7++	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for Executives.	10-Q	001-37487	10.7	February 11, 2019	
10.8	Assignment Agreement, by and between Aethlon Medical, Inc. and London Health Sciences Center Research Inc., dated November 7, 2006.	S-1	001-37487	10.27	November 15, 2019	
10.9++	Aethlon Medical, Inc. 2020 Equity Incentive Plan, Form of Restricted Stock Grant, Form of Option Grant and Agreement.	8-K	001-37487	99.1	September 19, 2022	
10.10++	Employment Agreement between the Company and Dr. Fisher, dated October 30, 2020.	8-K	001-37487	10.2	November 3, 2020	
10.11++	Separation Agreement between the Company and Dr. Fisher, effective as of November 27, 2023.	8-K	001-37487	10.1	November 27, 2023	
10.12	Lease, by and between the Company and San Diego Inspire 1, LLC. and San Diego Inspire 2, LLC, effective December 7, 2020.	10-Q	001-37487	10.3	February 10, 2021	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	SEC File No.	Exhibit No.	Date	
10.13++	Executive Employment Agreement between the Company and Guy Cipriani, dated January 1, 2021.	10-Q	001-37487	10.5	February 10, 2021	
10.14++	Amendment No. 1 to Executive Employment Agreement, effective as of November 7, 2023, by and between the Company and Guy F. Cipriani.	8-K	001-37487	10.2	December 22, 2023	
10.15++	Executive Employment Agreement between the Company and Steven P. LaRosa, MD, dated January 4, 2021.	10-Q	001-37487	10.6	February 10, 2021	
10.16++	Executive Employment Agreement, by and between Aethlon Medical, Inc. and Lee D. Arnold, Ph.D., dated February 1, 2023.	10-Q	001-37487	10.1	February 13, 2023	
10.17	Lease between Aethlon Medical, Inc. and San Diego Inspire 5, LLC, effective October 27, 2021.	10-Q	001-37487	10.1	November 9, 2021	
10.18	At the Market Offering Agreement, dated March 24, 2022, by and between Aethlon Medical, Inc. and H.C. Wainwright & Co., LLC.	8-K	001-37487	1.1	March 24, 2022	
10.19++	Amendment No. 1 to Executive Employment Agreement, by and between Aethlon Medical, Inc. and Lee D. Arnold, Ph.D., dated May 1, 2023.	10-K	001-37487	10.18	June 28, 2023	
21.1	List of Subsidiaries.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (see signature page)					X
31.1	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.					X
32.1*	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.					X

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	SEC File No.	Exhibit No.	Date	
10.4++	Form of Option Grant Agreement for Officers and Directors.	10-Q	001-37487	10.5	February 11, 2019	
10.5++	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for Directors.	10-Q	001-37487	10.6	February 11, 2019	
10.6++	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for Executives.	10-Q	001-37487	10.7	February 11, 2019	
10.7	SBIR Phase II Award Contract, by and among Aethlon Medical, Inc., the National Institutes of Health and the National Cancer Institute, dated September 12, 2019.	10-Q	001-37487	10.2	November 1, 2019	
10.8	Amendment to SBIR Phase II Award Contract, by and among Aethlon Medical, Inc., the National Institutes of Health and the National Cancer Institute, dated October 28, 2020.	10-K	001-37487	10.8	June 28, 2022	
10.9	Assignment Agreement, by and between Aethlon Medical, Inc. and London Health Sciences Center Research Inc., dated November 7, 2006.	S-1	001-37487	10.27	November 15, 2019	
10.10++	Aethlon Medical, Inc. 2020 Equity Incentive Plan, Form of Restricted Stock Grant, Form of Option Grant and Agreement.	8-K	001-37487	99.1	September 19, 2022	
10.11++	Employment Agreement between the Company and Dr. Fisher, dated October 30, 2020.	8-K	001-37487	10.2	November 3, 2020	
10.12	Lease, by and between the Company and San Diego Inspire 1, LLC. and San Diego Inspire 2, LLC, effective December 7, 2020.	10-Q	001-37487	10.3	February 10, 2021	
10.13++	Executive Employment Agreement between the Company and Guy Cipriani, dated January 1, 2021.	10-Q	001-37487	10.5	February 10, 2021	
10.14++	Executive Employment Agreement between the Company and Steven P. LaRosa, MD, dated January 4, 2021.	10-Q	001-37487	10.6	February 10, 2021	
10.15++	Executive Employment Agreement, by and between Aethlon Medical, Inc. and Lee D. Arnold, Ph.D., dated February 1, 2023.	10-Q	001-37487	10.1	February 13, 2023	
10.16	Lease between Aethlon Medical, Inc. and San Diego Inspire 5, LLC, effective October 27, 2021.	10-Q	001-37487	10.1	November 9, 2021	
10.17	At the Market Offering Agreement, dated March 24, 2022, by and between Aethlon Medical, Inc. and H.C. Wainwright & Co., LLC.	8-K	001-37487	1.1	March 24, 2022	

Exhibit Number	Exhibit Description	Form	Incorporated by Reference			Filed Herewith
	97.1	Incentive Compensation Recoupment Policy.	SEC File No.	Exhibit No.	Date	
10.18++	Amendment No. 1 to Executive Employment Agreement, by and between Aethlon Medical, Inc. and Lee D. Arnold, Ph.D., dated May 1, 2023.					X
21.1	List of Subsidiaries.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (see signature page)					X
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.					X
32.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.					X
		X				
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)					X
		X				
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
		X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
		X				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
		X				

101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
				X		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X	
			X			
104	Cover Page Interactive Data File (formatted in IXBRL, and included in exhibit 101)				X	
						X

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++ Indicates management contract or compensatory plan.

* The information in Exhibit 32.1 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Annual Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 28 27th day of June, 2023. 2024.

By: /s/ CHARLES J. FISHER JAMES B. FRAKES
Charles J. Fisher, Jr., M.D.
JAMES B. FRAKES
INTERIM CHIEF EXECUTIVE OFFICER CHIEF FINANCIAL OFFICER.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James B. Frakes and Charles J. Fisher, Jr., M.D., his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact attorney-in-fact and agents, and each of them, agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact attorney-in-fact and agents, or any of them, or their agent or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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/ CHARLES J. FISHER JAMES B. FRAKES Charles J. Fisher, Jr., M.D. James B. Frakes	Interim Chief Executive Officer and Chief Financial Officer, Principal Executive Officer, Principal Financial and Accounting Officer and Director	June 28, 2023 27, 2024
/s/ JAMES B. FRAKES James B. Frakes	Chief Financial Officer and Principal Financial and Accounting Officer	June 28, 2023
/s/ EDWARD G. BROENNIMAN Edward G. Broenniman	Chairman and Director	June 28, 2023 27, 2024
/s/ CHETAN S. SHAH Chetan S. Shah, M.D.	Director	June 28, 2023 27, 2024
/s/ ANGELA ROSSETTI Angela Rossetti	Director	June 28, 2023 27, 2024
/s/ GUY CIPRIANI NICOLAS GIKAKIS Nicolas Gikakis Guy Cipriani	Senior Vice President, Chief Business Officer and Director	June 28, 2023 27, 2024

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Aethlon Medical, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aethlon Medical, Inc. and its subsidiary (the Company) as of March 31, 2023 March 31, 2024 and 2022, 2023, the related consolidated statements of operations and comprehensive loss, equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2023 March 31, 2024 and 2022, 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has recurring losses from operations, an accumulated deficit, expects to incur losses for the foreseeable future and requires additional working capital. These are the reasons that raise substantial doubt about the Company's 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 contain any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 Company'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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2001.

San Diego, California
June 28, 2023
27, 2024

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	March 31,		March 31,	
	2023	2022	2024	2023
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	$ 14,532,943	$ 17,072,419	$ 5,441,978	$ 14,532,943
Accounts receivable	–	127,965		
Deferred offering costs			277,827	–
Prepaid expenses and other current assets	557,623	956,623	505,983	557,623
TOTAL CURRENT ASSETS	15,090,566	18,157,007	6,225,788	15,090,566
Property and equipment, net	1,144,004	441,238	1,015,229	1,144,004
Right-of-use lease asset	1,151,909	696,698		
Right-of-use lease asset, net			883,054	1,151,909
Patents, net	1,650	2,200	1,100	1,650
Restricted cash	87,506	87,506	87,506	87,506
Deposits	33,305	33,305	33,305	33,305
TOTAL ASSETS	$ 17,508,940	$ 19,417,954	$ 8,245,982	$ 17,508,940
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES				
Accounts payable	$ 432,890	$ 499,962	$ 777,862	$ 432,889
Due to related parties	214,221	155,742	546,434	214,221
Deferred revenue	–	344,547		
Lease liability, current portion	269,386	126,905	290,565	269,386
Other current liabilities	588,592	696,893	215,038	588,592
TOTAL CURRENT LIABILITIES	1,505,089	1,824,049	1,829,899	1,505,088
Lease liability, less current portion	939,642	602,505	649,751	939,642
TOTAL LIABILITIES	2,444,731	2,426,554	2,479,650	2,444,730
COMMITMENTS AND CONTINGENCIES (Note 9)				
COMMITMENTS AND CONTINGENCIES (Note 8)				
STOCKHOLDERS' EQUITY				
Common stock, $0.001 par value, 60,000,000 and 30,000,000 shares authorized at March 31, 2023 and 2022, respectively; 22,992,466 and 15,419,163 shares issued and outstanding at March 31, 2023 and 2022, respectively	22,994	15,421		
Common stock, $0.001 par value, 60,000,000 shares authorized at March 31, 2024 and 2023; 2,629,725 and 2,299,259 shares issued and outstanding at March 31, 2024 and 2023, respectively			2,629	2,299
Additional paid-in capital	157,405,911	147,446,868	160,337,371	157,426,606
Accumulated other comprehensive loss	(6,141)	–	(6,940)	(6,141)
Accumulated deficit	(142,358,555)	(130,329,181)	(154,566,728)	(142,358,554)
TOTAL AETHLON MEDICAL, INC. STOCKHOLDERS' EQUITY BEFORE NONCONTROLLING INTERESTS	15,064,209	17,133,108	5,766,332	15,064,210

NONCONTROLLING INTERESTS	–	(141,708)		
TOTAL STOCKHOLDERS' EQUITY	15,064,209	16,991,400	5,766,332	15,064,210
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,508,940	$ 19,417,954	$ 8,245,982	$ 17,508,940

See accompanying notes to the consolidated financial statements.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years Ended March 31,		Years Ended March 31,	
	2023	2022	2024	2023
REVENUES:				
Government contract and grant revenue	$ 574,245	$ 294,165	$ –	$ 574,245
Total revenues	574,245	294,165	–	574,245
OPERATING COSTS AND EXPENSES				
Professional fees	3,548,028	2,634,026	3,526,926	3,548,028
Payroll and related expenses	4,443,552	4,625,802	5,206,451	4,443,552
General and administrative	4,481,303	3,455,222	3,903,191	4,481,303
Total operating expenses	12,472,883	10,715,050	12,636,568	12,472,883
OPERATING LOSS	(11,898,638)	(10,420,885)	(12,636,568)	(11,898,638)
OTHER EXPENSE (INCOME)				
Loss on dissolution of subsidiary	142,121	–	–	142,121
Interest income	(10,973)	–		
Interest income and other			(428,394)	(10,973)
Other expense (income)	131,148	–	(428,394)	131,148
NET LOSS BEFORE NONCONTROLLING INTERESTS	(12,029,786)	(10,420,885)		
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS			(12,208,174)	(12,029,786)
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	–	(4,794)		
Basic and diluted net loss per share attributable to common stockholders			$ (4.86)	$ (5.86)
Weighted average number of common shares outstanding - basic and diluted			2,512,774	2,053,744
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	(12,029,786)	(10,416,091)	(12,208,174)	(12,029,786)
OTHER COMPREHENSIVE LOSS	(6,141)	–	(799)	(6,141)
COMPREHENSIVE LOSS	$ (12,035,927)	$ (10,416,091)	$ (12,208,973)	$ (12,035,927)
Basic and diluted net loss per share attributable to common stockholders	$ (0.59)	$ (0.71)		
Weighted average number of common shares outstanding - basic and diluted	20,537,434	14,756,967		

See accompanying notes to the consolidated financial statements.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF EQUITY
FOR THE YEARS ENDED MARCH 31, 2023 2024 AND 2022 2023

`	ATTRIBUTABLE TO AETHLON MEDICAL, INC.							
	COMMON STOCK		ADDITIONAL PAID IN	ACCUMULATED	ACCUMULATED COMPREHENSIVE	NON-CONTROLLING	TOTAL	
	SHARES	AMOUNT	CAPITAL	DEFICIT	LOSS	INTERESTS	EQUITY	ATTRIBUTABLE TO AETHLON MEDICAL, INC.
BALANCE - MARCH 31, 2021	12,150,597	$ 12,152	$ 129,331,542	$ (119,913,090)	$ –	$ (136,914)	$ 9,293,690	
Issuances of common stock for cash under at the market program	626,000	626	4,947,159	–	–	–	4,947,785	
Issuances of common stock for cash in registered direct financing	1,380,555	1,381	11,657,663	–	–	–	11,659,044	
Issuances of common stock for cash under warrant exercises	531,167	531	820,407	–	–	–	820,938	
Issuances of common stock for cash under stock option exercises	11,562	11	28,314	–	–	–	28,325	
Issuances of common stock under cashless warrant exercises	675,554	676	(676)	–	–	–	–	
Issuance of common shares upon vesting of restricted stock units and net stock option exercise	43,728	44	(88,162)	–	–	–	(88,118)	
Stock-based compensation expense	–	–	750,621	–	–	–	750,621	
Net loss	–	–	–	(10,416,091)	–	(4,794)	(10,420,885)	
BALANCE - MARCH 31, 2022	15,419,163	$ 15,421	$ 147,446,868	$ (130,329,181)	$ –	$ (141,708)	$ 16,991,400	

	COMMON STOCK		ADDITIONAL PAID IN	ACCUMULATED	ACCUMUL COMPREH
	SHARES	AMOUNT	CAPITAL	DEFICIT	LOS
	1,541,926	$ 1,542	$ 147,460,747	$ (130,329,181)	$

Issuances of common stock for cash under at the market program	7,480,836	7,481	8,919,730	–	–	–	8,927,211	748,084	748	8,926,463	–	
Issuance of common shares upon vesting of restricted stock units	92,467	92	(12,585)	–	–	–	(12,493)					
Issuance of common shares upon vesting of restricted stock units and net stock option exercise								9,249	9	(12,502)	–	
Loss on dissolution of subsidiary	–	–	–	–	–	142,121	142,121	–	–	–	–	
Stock-based compensation expense	–	–	1,051,898	–	–	–	1,051,898	–	–	1,051,898	–	
Net loss	–	–	–	(12,029,373)	–	(413)	(12,029,786)	–	–	–	(12,029,373)	
Other comprehensive loss	–	–	–	–	(6,141)	–	(6,141)	–	–	–	–	
BALANCE - MARCH 31, 2023	22,992,466	$ 22,994	$ 157,405,911	$ (142,358,554)	$ (6,141)	$ –	$ 15,064,209	2,299,259	$ 2,299	$ 157,426,606	$ (142,358,554)	$
Issuances of common stock for cash under at the market program								296,056	296	1,322,087	–	
Rounding for reverse split								32	–	–	–	
Issuance of common shares upon vesting of restricted stock units								34,378	34	(34,812)	–	
Reversal of accrued commission liability (see Note 6)								–	–	404,120	–	

Stock-based compensation expense	–	–	1,219,370	–	
Net loss	–	–	–	(12,208,174)	
Other comprehensive loss	–	–	–	–	
BALANCE - MARCH 31, 2024	2,629,725	$ 2,629	$ 160,337,371	$ (154,566,728)	$

See accompanying notes to the consolidated financial statements.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED MARCH 31, 2023 2024 AND 2022 2023

	Years Ended March 31,		Years Ended March 31,	
	2023	2022	2024	2023
Cash flows from operating activities:				
Net loss	$ (12,029,786)	$ (10,420,885)	$ (12,208,174)	$ (12,029,786)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	240,892	123,685	359,057	240,892
Stock based compensation	1,051,898	750,621		
Loss of dissolution of subsidiary	142,121	–		
Accretion of right-of-use lease asset	24,408	30,532		
Stock-based compensation			1,219,370	1,051,898
Loss on disposal of property, plant and equipment			21,135	–
Loss on dissolution of Subsidiary			–	142,121
Non-cash lease expense			143	24,408
Changes in operating assets and liabilities:				
Accounts receivable	127,965	21,117	–	127,965
Prepaid expenses and other current assets	398,169	(636,688)	(10,232)	398,169
Accounts payable and other current liabilities	(174,727)	97,541	156,678	(174,727)
Deferred revenue	(344,547)	229,698	–	(344,547)
Due to related parties	58,479	37,222	332,213	58,479
Net cash used in operating activities	(10,505,128)	(9,767,157)	(10,129,810)	(10,505,128)
Cash flows from investing activities:				
Purchases of property and equipment	(943,109)	(349,193)	(250,867)	(943,109)
Net cash used in investing activities	(943,109)	(349,193)	(250,867)	(943,109)
Cash flows from financing activities:				
Tax withholding payments or tax equivalent payments for net share settlement of restricted stock units	(12,493)	(88,118)	(34,778)	(12,493)
Net proceeds from the issuance of common stock and exercise of warrants	8,927,211	17,456,092		
Net proceeds from the issuance of common stock			1,322,383	8,927,211
Net cash provided by financing activities	8,914,718	17,367,974	1,287,605	8,914,718
Effect of Exchange Rate on Changes on Cash	(5,957)	–	2,107	(5,957)
Net (decrease) increase in cash and restricted cash	(2,533,519)	7,251,624		
Net decrease in cash and restricted cash			(9,090,965)	(2,539,476)
Cash and restricted cash at beginning of year	17,159,925	9,908,301	14,620,449	17,159,925
Cash and restricted cash at end of year	$ 14,620,449	$ 17,159,925	$ 5,529,484	$ 14,620,449
Supplemental information of non-cash investing and financing activities:				
Issuances of common stock under cashless warrant exercises	$ –	$ 676		
Initial recognition of right-of-use lease asset and lease liability	$ 625,471	$ 744,430	$ –	$ 625,471
Issuance of shares under vested restricted stock units, net stock option exercises and unvested share issuance for services	$ 92	$ 44	$ 35	$ 92
Reversal of accrued commission liability (see Note 6)			$ 404,120	$ –
Deferred offering costs not yet paid			$ 219,117	$ –

Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets:				
Cash and cash equivalents	$ 14,532,943	$ 17,072,419	$ 5,441,978	$ 14,532,943
Restricted cash	87,506	87,506	87,506	87,506
Cash and restricted cash	$ 14,620,449	$ 17,159,925	$ 5,529,484	$ 14,620,449

See accompanying notes to the consolidated financial statements.

1. ORGANIZATION, LIQUIDITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION

Aethlon Medical, Inc., or Aethlon, the Company, we or us, is a medical therapeutic company focused on developing products to treat cancer and life-threatening infectious diseases. The Aethlon the Hemopurifier, is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. infections and for use in organ transplantation. In cancer, human studies, 164 sessions with 38 patients, the Hemopurifier is designed was safely utilized and demonstrated the potential to deplete remove life-threatening viruses. In pre-clinical studies, the presence of circulating tumor-derived Hemopurifier has demonstrated the potential to remove harmful exosomes that and exosomal particles from biological fluids, utilizing its proprietary lectin-based technology. This action has potential applications in cancer, where exosomes and exosomal particles may promote immune suppression seed the spread of and metastasis, and inhibit the benefit of leading cancer therapies. in life-threatening infectious diseases. The U.S. Food and Drug Administration, or FDA, has designated the Hemopurifier as a "Breakthrough Device" for two independent indications:

- the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease; and
- the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease; and
-
- the treatment of life-threatening viruses that are not addressed with approved therapies.

Oncology

We believe the Hemopurifier can may be a substantial advance advancement in the treatment of patients with advanced and metastatic cancer through the clearance of its design to bind to and remove harmful exosomes and exosomal particles that promote the growth and spread of tumors through multiple mechanisms. tumors. In October 2022, we formed a wholly-owned subsidiary in Australia to initially conduct oncology-related clinical research, then seek regulatory approval and commercialize our Hemopurifier in Australia. We are currently working with our new contract research organization, or CRO, on preparations to conduct a clinical trial in Australia in patients with solid tumors, including head and neck cancer, and gastrointestinal cancers and other cancers.
On October 4, 2019, the FDA approved our Investigational Device Exemption, or IDE, application to initiate an Early Feasibility Study, or EFS, of the Hemopurifier in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda). The primary endpoint for the EFS, designed to enroll 10 to 12 subjects at a single center, is safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. This clinical trial, initially conducted at the UPMC Hillman Cancer Center in Pittsburgh, PA, or UPMC, treated two patients. Due to lack of further patient enrollment, we and UPMC terminated this trial.

In January 2023, we entered into an agreement with North American Science Associates, LLC, or NAMSA, a world leading MedTech medical technology CRO offering global end-to-end development services, to oversee our planned clinical trials investigating the Hemopurifier for oncology indications. Pursuant to the agreement, NAMSA will agreed to manage our planned clinical trials of the Hemopurifier for patients in the United States and Australia with various types of cancer tumors.
We anticipate recently completed an *in vitro* binding study of relevant oncology targets, to provide pre-clinical evidence to support our trial design and translational endpoints. Our study indicated positive results from this study, providing evidence that the initial our Hemopurifier removes extracellular vesicles, or EVs, from plasma. This translational study provides pre-clinical evidence to support our planned phase 1 safety, feasibility and dose-finding clinical trials will begin of our Hemopurifier in Australia. patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment, such as Keytruda® or Opdivo®. In addition to an interested initial trial site in India, we had three interested sites in Australia that were awaiting our completion of this *in vitro* binding study. We added the data from this study to our Clinical Investigator Brochure and submitted that brochure to the Ethics Committee of Royal Adelaide Hospital in Australia and in June 2024, we received approval for our proposed phase 1 oncology trial from the Ethics Committee from Royal Adelaide Hospital. We are currently in the process of applying to the Ethics Committees of the two additional interested clinical trial sites in Australia and the site in India.

Life-Threatening Viral Infections

We also believe that the Hemopurifier can be part of the broad-spectrum treatment of life-threatening highly glycosylated, or carbohydrate coated, viruses that are not addressed with an already approved treatment. In small-scale or early feasibility human studies, the Hemopurifier has been used in the past to treat individuals infected with human immunodeficiency virus, or HIV, hepatitis-C and Ebola.

Additionally, in vitro, the Hemopurifier has been demonstrated to capture Zika virus, Lassa virus, MERS-CoV, cytomegalovirus, Epstein-Barr virus, Herpes simplex virus, Chikungunya virus, Dengue virus, West Nile virus, smallpox-related viruses, H1N1 swine flu virus, H5N1 bird flu virus, Monkeypox virus and the reconstructed Spanish flu virus of 1918. In several cases, these studies were conducted in collaboration with leading government or non-government research institutes.

We believe the Hemopurifier can be part of the treatment of severe SARS-CoV-2 viremia/COVID-19, or COVID-19, cases. COVID viremia is detected in approximately 34% of patients and is associated with severity, requirement for intensive care unit, or ICU, stay, development of multi-organ failure and poor outcomes. EVs and exosomal miRNAs may play a role in the spread of infection as well as ongoing inflammation, development of coagulopathy and lung injury. Our proprietary *Galanthus nivalis* agglutinin, or GNA, affinity resin has been shown to bind multiple clinically relevant SARS-CoV-2 variants. Furthermore, studies have demonstrated *in vitro* removal of seven SARS-CoV2 variants (104 PFU/mL) in phosphate buffered saline passed over a column of GNA affinity resin (1g) three times, with capture efficiencies between 53% and 89%.
On June 17, 2020, the FDA approved a supplement to our open Investigational Device Exemption, or IDE, for the Hemopurifier in viral disease to allow for the testing of the Hemopurifier in patients with SARS-CoV-2/COVID-19, or COVID-19, in a New Feasibility Study. new feasibility study. That study was designed to enroll up to 40 subjects at up to 20 centers in the United States. Subjects had were to have an established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU, and have acute lung injury and/or severe or life-threatening disease, among other criteria. Endpoints for this study, in addition to safety, included reduction in circulating virus as well as clinical outcomes (NCT # 04595903). In January 2021, the Hemopurifier was used to treat a viremic patient, under our emergency use approval, with a predicted risk of mortality of 80% and the Hemopurifier was able to reduce the patient's SARS-CoV-2 plasma viral load by 58.4%. In June 2022, the first patient in this study was enrolled and completed the Hemopurifier treatment phase of the protocol. Due to the lack of COVID-19 patients in the ICUs of our trial sites, we terminated this study in 2022. However, our IDE for this indication remains open, as we have an active COVID-19 trial in India and wish to preserve the option of enrolling patients if the situation with COVID-19 changes.

Under Single Patient Emergency Use regulations, the Company Aethlon has treated two patients with COVID-19 with the Hemopurifier, in addition to the COVID-19 patient treated with our Hemopurifier in our COVID-19 clinical trial discussed above. above.

We currently are experiencing previously reported a disruption in our Hemopurifier supply, as our then existing supply of Hemopurifiers expired on September 30, 2022 and, also as previously disclosed, we are dependent on FDA approval of qualified suppliers to manufacture our Hemopurifier. We recently completed final testing in order to begin manufacturing Hemopurifiers at our new manufacturing facility in San Diego, California for use in planned U.S. clinical trials, using GNA from our current supplier. In April 2024, we received a notice of approval from the FDA for our IDE supplement to add our San Diego manufacturing facility and we now are able to manufacture Hemopurifiers at this site. We also have sufficient Hemopurifiers on hand for use in our planned Australia and India oncology trials. Our intended transition to a new supplier for galanthus nivalis agglutinin, or GNA, a component of our Hemopurifier, is continues to be delayed as we work with the FDA for approval of our supplement to our IDE, which is required to make this manufacturing supplier change.
In October 2022, we launched a wholly owned subsidiary in Australia, formed We are working with the FDA to conduct clinical research, seek regulatory approval and commercialize qualify this second supplier of our Hemopurifier in that country. The subsidiary will initially focus on oncology trials in Australia. There were only insignificant expenses in that subsidiary in the three months ended December 31, 2022. GNA.

We also obtained Ethics Review Board, ethics review board, or ERB, approval from and entered into a clinical trial agreement with Medanta Medicity Hospital, a multi-specialty hospital in Delhi NCR, India, for a COVID-19 clinical trial at that location. One patient has completed participation in the Indian COVID-19 study. The relevant authorities in India have accepted the use of the Hemopurifiers made with the GNA from our new supplier.

In May 2023, we also received ERB approval from the Maulana Azad Medical College, or MAMC, for a second site for our clinical trial in India to treat severe COVID-19. MAMC was established in 1958 and is located in New Delhi, India. MMAC MAMC is affiliated with the University of Delhi and is operated by the Delhi government.

We also recently announced now have two sites in India for this trial with the Medanta Medicity Hospital and Maulana Azad Medical College, or MAMC. One patient has been treated to date; however, we have been informed by our CRO that we also have begun investigating the use of our Hemopurifier a new COVID-19 subvariant was detected in India recently. Our COVID-19 trial in India remains open in the organ transplant setting. Our objective is event that there are COVID-19 admissions to confirm the ICUs at our sites in India.

Organ Transplantation

Additionally, based on preclinical data with acellular kidney perfusates, we believe that the Hemopurifier has potential applications in our translational studies, organ transplantation. We are investigating whether the Hemopurifier, when incorporated into a machine perfusion organ preservation circuit, can remove harmful viruses, exosomes, RNA molecules, cytokines, chemokines and exosomes other inflammatory molecules from harvested recovered organs. We initially are focused on recovered kidneys from deceased donors. We have previously demonstrated the removal of multiple viruses and exosomes and exosomal particles from buffer solutions, *in vitro*, utilizing a scaled-down version of our Hemopurifier. This Hemopurifier and believe this process potentially may could reduce transplantation complications following transplantation of the harvested organ, which can include viral infection, delayed by improving graft function, reducing graft rejection, maintaining or improving organ viability prior to transplantation, and rejection. We believe this new approach could be additive to existing technologies that currently are in place to increase potentially reducing the number of viable organs kidneys rejected for transplant.

Previously, we were the majority owner of Exosome Sciences, Inc., or ESI, a company formed to focus on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases, and thus consolidated ESI in our consolidated financial statements. For more than four years, the primary activities of ESI were limited to the payment of patent maintenance fees and applications. In September 2022, the Board of Directors of ESI and we, as the majority stockholder of ESI, approved the dissolution of ESI.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we plan to market and sell the Hemopurifier. Some of our patents may expire before FDA approval or approval in a foreign country, if any, is obtained. However, we believe that certain patent applications and/or other patents issued to us more recently will help protect the proprietary nature of the our Hemopurifier treatment technology.

In addition to the foregoing, we are monitoring closely the impact of inflation, recent bank failures and the war between Russia and Ukraine and the military conflicts in Ukraine Israel and the surrounding areas, as well as related political and economic responses and counter-responses by various global factors on our business. Given the level of uncertainty regarding the duration and impact of these events on capital markets and the U.S. economy, we are unable to assess the impact on our timelines and future access to capital. The full extent to which inflation, recent bank failures and the war in Ukraine ongoing military conflicts will impact our business, results of operations, financial condition, clinical trials and preclinical research will depend on future developments, as well as the economic impact on national and international markets that are highly uncertain.

Our executive offices are located at 11555 Sorrento Valley Road, Suite 203, San Diego, California 92121. Our telephone number is (619) 941-0360. Our website address is www.aethlonmedical.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.
.
Our common stock is listed on the Nasdaq Capital Market under the symbol “AEMD.”

LIQUIDITY AND GOING CONCERN

Management expects existing cash The Company has incurred losses since inception in devoting substantially all of its efforts toward research and development and has an accumulated deficit of $154,566,728 as of March 31, 2023 March 31, 2024. During the year ended March 31, 2024, the Company generated a net loss of approximately $12,208,000 and funds raised subsequent the Company expects that it will continue to generate operating losses for the foreseeable future. While the Company currently has over $9.1 million in cash and cash equivalents and have been carrying out certain expense reductions since November 2023; our planned additional expense reductions may not materialize and/or our patient recruitment may occur more rapidly than expected along with the concomitant increases in expenses, therefore there is substantial doubt that our cash on hand will carry the company for 12 months beyond the filing date of the financial statements included in this Annual Report.

The Company's ability to execute its current operating plan depends on its ability to reduce expenses and obtain additional funding via the sale of equity, or other sources of capital. The Company plans to continue actively pursuing financing alternatives, however, there can be sufficient to fund no assurance that it will obtain the necessary funding, raising substantial doubt about the Company's operations for at least twelve months ability to continue as a going concern within one year of the date these financial statements are issued. The accompanying financial statements do not include any adjustments that might result from the issuance date outcome of these consolidated financial statements. this uncertainty.

PRINCIPLES OF CONSOLIDATION

The accompanying consolidated financial statements include the accounts of Aethlon Medical, Inc. and its wholly owned subsidiary, Aethlon Medical Australia Pty Ltd, as well as its previously majority-owned subsidiary, ESI, which dissolved in September 2022. Operations in our Australian subsidiary is recorded in their functional currency. The results of operations for our Australian subsidiary are translated from functional currency into U.S. dollars using the current exchange rate on the date the expense was recognized. Assets and liabilities are translated using the period end exchange rates. The U.S dollar effects that arise from translating the net assets of are recorded in other comprehensive income (loss). All significant inter-company transactions and balances have been eliminated in consolidation. The consolidated financial statements contain all normal recurring accruals and adjustments that, in the opinion of management, are necessary to present fairly the consolidated financial statements as of and for the fiscal years ended March 31, 2023 March 31, 2024 and 2022, 2023, and the consolidated statement of cash flows for the fiscal years ended March 31, 2023 March 31, 2024 and 2022. Estimates were made relating to useful lives of fixed assets, impairment of assets, share-based compensation expense and accruals for clinical trial and research and development expenses. 2023.

RISKS AND UNCERTAINTIES

We operate in an industry that is subject to intense competition, government regulation and rapid technological change. Our operations are subject to significant risk and uncertainties including financial, operational, technological, regulatory, and including the potential risk of business failure.

USE OF ESTIMATES

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, which requires us to make a number of 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. Such estimates and assumptions affect the reported amounts of expenses during the reporting period. On an ongoing basis, we evaluate estimates and assumptions based upon historical experience and various other factors and circumstances. We believe our estimates and assumptions are reasonable in the circumstances; however, actual results may differ from these estimates under different future conditions.
We believe that the estimates and assumptions that are most important to the portrayal of our financial condition and results of operations, in that they require the most difficult, subjective or complex judgments, form the basis for the accounting policies deemed to be most critical to us. These critical accounting estimates relate to revenue recognition, stock purchase warrants issued with notes payable, beneficial conversion feature of convertible notes payable, impairment of intangible assets and long lived assets, stock compensation, deferred tax asset valuation allowance, and contingencies.

CASH AND CASH EQUIVALENTS

Accounting standards define “cash and cash equivalents” as any short-term, highly liquid investment that is both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates. For the purpose of financial statement presentation, we consider all highly liquid investment instruments with original maturities of three months or less when purchased, or any investment redeemable without penalty or loss of interest to be cash equivalents. Cash is carried at cost, which approximates fair value, and cash equivalents are carried at fair value.

As of

For the fiscal years ended March 31, 2024 and March 31, 2023, our cash and cash equivalents were comprised of the following instruments:

Cash in US bank checking account	$ 575,766
Cash equivalents held in US Treasury bills	13,910,973
Cash in Australian bank checking account	46,204
Total cash and cash equivalents	$ 14,532,943

As of March 31, 2022, we had no assets that were classified as cash equivalents.

	For the year ended	
	March 31, 2024	March 31, 2023
Cash in US bank checking account	$ 697,908	$ 575,766
Cash equivalents held in US Treasury bills	4,736,469	13,910,973
Cash in Australian bank checking account	7,601	46,204
Total cash and cash equivalents	$ 5,441,978	$ 14,532,943

CONCENTRATIONS OF CREDIT RISKS

Cash is maintained at one US financial institution in a checking account. Accounts at this institution are secured by the Federal Deposit Insurance Corporation up to $250,000. Our March 31, 2023 March 31, 2024 cash balances were approximately $574,572 568,000 over such insured amount. We do not believe that the Company is exposed to any significant risk with respect to its cash in that checking account.

At March 31, 2023 March 31, 2024, we maintained cash equivalents of approximately $13.9 4.7 million in US Treasury bills with maturities of less than three months. We do not believe that the Company is exposed to any significant risk with respect to its cash equivalents since they represent US government risk.

Cash is maintained at one Australian financial institution in checking accounts. Accounts at this institution are secured by the Financial Claims Scheme for up to Australian $250,000. $250,000. Our March 31, 2023 March 31, 2024 Australian cash balance was below that threshold.

We did not have any revenue in fiscal year ended March 31, 2024. All of our revenue in the fiscal years year ended March 31, 2023 and 2022 related to our government contracts. We did not have any accounts receivable at March 31, 2023 March 31, 2024.

RESTRICTED CASH

To comply with the terms of our laboratory, office, and manufacturing space leases, we caused our bank to issue two standby letters of credit, or the L/Cs, in the amount of $87,506 in favor of the landlord. The L/Cs are in lieu of a security deposit. In order to support the L/Cs, we agreed to have our bank withdraw $87,506 from our operating accounts and to place that amount in restricted certificates of deposit. We have classified that amount as restricted cash, a long-term asset, on our balance sheet.

PROPERTY AND EQUIPMENT

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from two to five years. Repairs and maintenance are charged to expense as incurred while improvements are capitalized. Upon the sale or retirement of property and equipment, the accounts are relieved of the cost and the related accumulated depreciation with any gain or loss included in the consolidated statements of operations.

INCOME TAXES

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the difference between the consolidated financial statements and their respective tax basis. Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts reported for income tax purposes, and (b) tax credit carryforwards. We record a valuation allowance for deferred tax assets when, based on our best estimate of taxable income (if any) in the foreseeable future, it is more likely than not that some portion of the deferred tax assets may not be realized. Management has provided a full valuation allowance against the Company's net deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are more-likely-than-not to be sustained by the applicable tax authority. Tax positions deemed to not meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There were no uncertain tax positions that require accrual to or disclosure in the consolidated financial statements as of March 31, 2024 and 2023.

LONG-LIVED ASSETS

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. If the cost basis of a long-lived asset is greater than the projected future undiscounted net cash flows from such asset, an impairment loss is recognized. We believe no impairment charges were necessary during the fiscal years ended March 31, 2023 March 31, 2024 and 2022. 2023.

LOSS PER SHARE

Basic loss per share is computed by dividing net income loss available to common stockholders by the weighted average number of common shares outstanding during the period of computation. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if potential common shares had been issued, if such additional common shares were dilutive. Since we had net losses for all periods presented, basic and diluted loss per share are the same, and additional potential common shares have been excluded as their effect would be antidilutive.

As of March 31, 2023 March 31, 2024 and 2022, 2023, a total of 2,045,006 124,028 and 2,243,838 204,501 potential common shares, consisting of shares underlying outstanding stock options, restricted stock units, or RSUs, and warrants were excluded as their inclusion would be antidilutive.

DEFERRED FINANCING OFFERING COSTS

Costs related Specific incremental costs directly attributable to an actual offering of securities may be deferred and charged against the issuance of debt are capitalized as a deduction to our convertible notes based on the accounting standard on imputation of interest, and amortized to interest expense over the life gross proceeds of the related debt using the effective interest method. There was offering. As of March 31, 2024, approximately $no278,000 amortization related to our deferred financing of costs in the fiscal years ended March 31, 2023 and 2022. have been deferred.

REVENUE RECOGNITION

We did not recognize revenue in fiscal year ended March 31, 2024. Our revenues consist in the fiscal year ended March 31, 2023 consisted entirely of amounts earned under contracts and grants with the National Institutes of Health, or NIH. During the fiscal years year ended March 31, 2023 and 2022, , we recognized revenues totaling $574,245 and $294,165, respectively, under such contracts. We have concluded that these agreements are not within the scope of ASC Topic, 606, Revenue from Contracts with Customers, or Topic 606, as the NIH grants and contracts do not meet the definition of a “customer” as defined by Topic 606. Prior to the effective date of ASC Topic 606, which for the Company was April 1, 2018, we accounted for our grant/contract revenues under the Milestone Method as prescribed by the legacy guidance of ASC 605-28, Revenue Recognition – Milestone Method, or Milestone Method. In the absence of other applicable guidance under US GAAP, effective April 1, 2018, we elected to continue to use the Milestone Method by analogy to recognize revenue under these grants/contracts.

We identify the deliverables included within these agreements and evaluate which deliverables represent separate units of accounting based on if certain criteria are met, including whether the delivered element has standalone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

A milestone is an event having all of the following characteristics:

(1) There is substantive uncertainty at the date the arrangement is entered into that the event will be achieved. A vendor's assessment that it expects to achieve a milestone does not necessarily mean that there is not substantive uncertainty associated with achieving the milestone.

(2) The event can only be achieved based in whole or in part on either: (a) the vendor's performance; or (b) a specific outcome resulting from the vendor's performance.

(3) If achieved, the event would result in additional payments being due to the vendor.

A milestone does not include events for which the occurrence is either: (a) contingent solely upon the passage of time; or (b) the result of a counterparty's performance.

The policy for recognizing deliverable consideration contingent upon achievement of a milestone must be applied consistently to similar deliverables.

The assessment of whether a milestone is substantive is performed at the inception of the arrangement. The consideration earned from the achievement of a milestone must meet all of the following for the milestone to be considered substantive:

(1) The consideration is commensurate with either: (a) the vendor's performance to achieve the milestone; or (b) the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone;

(2) The consideration relates solely to past performance; and

(3) The consideration is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

A milestone is not considered substantive if any portion of the associated milestone consideration relates to the remaining deliverables in the unit of accounting (i.e., it does not relate solely to past performance). To recognize the milestone consideration in its entirety as revenue in the period in which the milestone is achieved, the milestone must be substantive in its entirety. Milestone consideration cannot be bifurcated into substantive and nonsubstantive components. In addition, if a portion of the consideration earned from achieving a milestone may be refunded or adjusted based on future performance, the related milestone is not considered substantive.

We have recognized revenue under the following contracts/grants: contract/grant:

Phase 2 Melanoma Cancer Contract

On September 12, 2019, the National Cancer Institute, or NCI, part of the NIH, awarded to us an a SBIR Phase II Award Contract, for NIH/NCI Topic 359, entitled “A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring”, or the Award Contract. The Award Contract amount was $1,860,561$1,860,561 and, as amended, ran for the period from September 16, 2019 through September 15, 2022.

The work performed pursuant to this Award Contract was focused on melanoma exosomes. This work followed from our completion of a Phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018, as described below. Following on the Phase I work, the deliverables in the Phase II program involved the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

The Award Contract ended on September 15, 2022 and we presented the required final report to the NCI. As the NCI completed its close out review of the contract, we recognized as revenue the $574,245 previously recorded as deferred revenue on our December 31, 2022 balance sheet.

Subaward with University of Pittsburgh

In December 2020, we entered into a cost reimbursable subaward arrangement with the University of Pittsburgh in connection with an NIH contract entitled "Depleting Exosomes to Improve Responses to Immune Therapy in HNNCC." Our share of the award was $256,750. We did not record revenue related to this subaward in the fiscal year ended March 31, 2023. We recorded $64,467 of revenue related to this subaward in the fiscal year ended March 31, 2022.

In October 2022, we agreed with the University of Pittsburgh to terminate the subaward arrangement, effective as of November 10, 2022, since it related to our clinical trial in head and neck cancer in which the University of Pittsburgh was unable to recruit patients. There are no provisions in the subaward arrangement requiring repayment of cash received for work completed through November 10, 2022.

STOCK-BASED COMPENSATION

Employee stock options and rights to purchase shares under stock participation plans are accounted for under the fair value method. Accordingly, share-based compensation is measured when all granting activities have been completed, generally the grant date, based on the fair value of the award. The exercise price of options is generally equal to the market price of the Company's common stock (defined as the closing price as quoted on the Nasdaq Capital Market or OTCBB on the date of grant). Compensation cost recognized by the Company includes (a) compensation cost for all equity incentive awards granted prior to April 1, 2006, but not yet vested, based on the grant-date fair value estimated in accordance with the original provisions of the then current accounting standards, and (b) compensation cost for all equity incentive awards granted subsequent to March 31, 2006, based on the grant-date fair value estimated in accordance with the provisions of subsequent accounting standards. We use a Binomial Lattice option pricing model for estimating fair value of options granted (see Note 4).

The following table summarizes share-based compensation expenses relating to shares and options granted and the effect on loss per common share during the years ended March 31, 2023 March 31, 2024 and 2022: 2023:

	Fiscal Years Ended	
	March 31, 2023	March 31, 2022
Vesting of Stock Options and Restricted Stock Units	$ 1,051,898	$ 750,621
Total Stock-Based Compensation Expense	$ 1,051,898	$ 750,621
Weighted average number of common shares outstanding – basic and diluted	20,537,434	14,756,967
Basic and diluted loss per common share	$ (0.59)	$ (0.71)

	Fiscal Years Ended	
	March 31, 2024	March 31, 2023
Vesting of Stock Options and Restricted Stock Units	$ 1,219,370	$ 1,051,898
Total Stock-Based Compensation Expense	$ 1,219,370	$ 1,051,898
Weighted average number of common shares outstanding – basic and diluted	2,512,774	2,053,744
Basic and diluted loss per common share	$ (0.49)	$ (0.51)

We record share-based compensation expenses for awards of stock options and RSUs under ASC 718, Share-based compensation, or ASC 718. For awards to non-employees for periods prior to the adoption of ASU 2018-07, Compensation-Stock Compensation: Improvements to Non-employee Share-Based Payment Accounting, on April 1, 2019, the Company had applied ASC 505-50, Equity – Equity-based payments to non-employees, or ASC 505-50. ASC 718 establishes guidance for the recognition of expenses arising from the issuance of share-based compensation awards at their fair value at the grant date.

We recognize share-based compensation expense related to stock options and stock appreciation rights granted to employees, directors and consultants based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting share-based compensation expense, for stock options that only have service vesting requirements or performance-based vesting requirements without market conditions using the binomial lattice option-pricing model. The grant date fair value of the share-based awards with service vesting requirements is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed. For performance-based awards with market conditions, we determine the fair value of awards as of the grant date using a Monte Carlo simulation model.

We review share-based compensation on a quarterly basis for changes to the estimate of expected award forfeitures based on actual forfeiture experience. The effect of adjusting the forfeiture rate for all expense amortization after March 31, 2007 is recognized in the period the forfeiture estimate is changed. The effect of forfeiture adjustments for the fiscal year ended March 31, 2023 March 31, 2024 was insignificant.

PATENTS

Patents include both foreign and domestic patents. We capitalize the cost of patents, some of which were acquired, and amortize such costs over the shorter of the remaining legal life or their estimated economic life, upon issuance of the patent. The unamortized costs of patents are subject to our review for impairment under our long-lived asset policy above.

STOCK PURCHASE WARRANTS

In the past we issued warrants for the purchase of shares of our common stock in connection with the issuance of common stock for cash. Warrants issued in connection with common stock for cash, if classified as equity, are considered issued in connection with equity transactions and the warrant fair value is recorded to additional paid-in-capital.

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development costs are expensed as incurred. We incurred approximately $2,745,000 2,520,000 and $2,341,000 2,745,000 of research and development expenses for the years ended March 31, 2023 March 31, 2024 and 2022, 2023, respectively, which are included in various operating expenses in the accompanying consolidated statements of operations.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our consolidated financial statements.

SIGNIFICANT RECENT ACCOUNTING PRONOUNCEMENTS

In December 2023, the FASB issued Accounting Standards Update 2023-09, Improvements to Income Tax Disclosures (“ASU 2023-09”), which requires enhanced annual disclosures for specific categories in the rate reconciliation and income taxes paid disaggregated by federal, state and foreign taxes. ASU 2023-09 is effective for public business entities for annual periods beginning after December 15, 2024. The Company is evaluating if the adoption of this new standard will have a material effect on our disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments-Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The adoption of ASU No. 2016-13 for smaller reporting companies that did not previously early adopt was January 1, 2023. The Company maintained US Treasury bills with maturities of less than three months and expects zero credit losses from these securities. As a result, the Company did not record an allowance for expected credit losses.

SIGNIFICANT RECENT ACCOUNTING PRONOUNCEMENTS

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting, or ASU No. 2018-07. ASU No. 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU No. 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018. Entities must apply the guidance retrospectively with a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. The adoption of ASU No. 2018-07 on April 1, 2019 did not have a material impact on the Company's consolidated financial position, results of operations and related disclosures.

On April 1, 2019, the Company adopted ASC Topic 842, "Leases," utilizing the alternative transition method allowed for under this guidance. As a result, the Company recorded lease liabilities and right-of-use lease assets on its balance sheet.

Topic 842 also allows lessees and lessors to elect certain practical expedients. The Company elected the following practical expedients:

- Transitional practical expedients, which must be elected as a package and applied consistently to all of the Company's leases:
  - The Company need not reassess whether any expired or existing contracts are or contain leases.
  - The Company need not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with the previous guidance will be classified as operating leases, and all existing leases that were classified as capital leases in accordance with the previous guidance will be classified as finance leases).
  - The Company need not reassess initial direct costs for any existing leases.
- Hindsight practical expedient. The Company elected the hindsight practical expedient in determining the lease term (that is, when considering lessee options to extend or terminate the lease and to purchase the underlying asset) and in assessing impairment of the Company's right-of-use assets.

2. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consist of the following:

	March 31, 2023	March 31, 2022	March 31, 2024	March 31, 2023
Furniture and office equipment, at cost	$ 989,987	$ 813,412	$ 1,112,648	$ 989,987
Leasehold improvements	888,224	121,690	893,131	888,224
Accumulated depreciation	(734,207)	(493,864)	(990,550)	(734,207)
Furniture and office equipment, net	$ 1,144,004	$ 441,238		
Fixed Assets, net			$ 1,015,229	$ 1,144,004

Depreciation expense for the fiscal years ended March 31, 2023 March 31, 2024 and 2022 2023 was $240,342 358,507 and $68,931 240,342, respectively.

3. PATENTS, NET

Patents, net consist of the following:

	March 31, 2023	March 31, 2022	March 31, 2024	March 31, 2023
Issued patents	$ 157,442	$ 157,442	$ 157,442	$ 157,442
Accumulated amortization	(155,792)	(155,242)	(156,342)	(155,792)
Issued patents, net of accumulated amortization	1,650	2,200	1,100	1,650
Patents pending	–	–		
Patents, net	$ 1,650	$ 2,200	$ 1,100	$ 1,650

Amortization expense for our capitalized issued patents for each of the fiscal years ended March 31, 2023 March 31, 2024 and 2022 2023 was $550 and $54,754, respectively. . As only one capitalized patent remains to be amortized, future amortization expense on patents is estimated to be approximately $550 per year based on the estimated life of the patent. The weighted average remaining life of our remaining capitalized patent is approximately 3 2.0 years.

4. EQUITY TRANSACTIONS

REVERSE STOCK SPLIT

On October 4, 2023, we effected a 1-for-10 reverse stock split of our then outstanding shares of common stock. Accordingly, each 10 shares of outstanding common stock then held by our stockholders were combined into one share of common stock. Any fractional shares resulting from the reverse split were rounded up to the next whole share. Authorized common stock remained at 60,000,000 shares following the stock split. The accompanying consolidated financial statements and accompanying notes have been retroactively revised to reflect such reverse stock split as if it had occurred on April 1, 2022. All shares and per share amounts have been revised accordingly.

ISSUANCES OF COMMON STOCK AND WARRANTS

Equity Transactions in the Fiscal Year Ended March 31, 2023 March 31, 2024.

2022 At The Market Offering Agreement with H.C. Wainwright & Co., LLC

On March 24, 2022, we entered into an At The Market Offering Agreement, or the 2022 ATM Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, which established an at-the-market equity program pursuant to which we may offer and sell shares of our common stock from time to time as set forth in the 2022 ATM Agreement.

The offering was registered under the Securities Act of 1933, as amended, or the Securities Act, pursuant to our shelf registration statement on Form S-3 (Registration Statement No. 333-259909), as previously filed with the Securities and Exchange Commission, or SEC, and declared effective on October 21, 2021. We filed a prospectus supplement, dated March 24, 2022, with the SEC that provides for the sale of shares of our common stock, or the 2022 ATM Shares, having an aggregate offering price of up to $15,000,000, or $15,000,000, which was subsequently and most recently updated pursuant to our prospectus supplement, dated September 29, 2022, filed with the SEC that provides for the sale of 2022 ATM Shares having an aggregate offering price of up to $6,625,000. As of March 31, 2024, $5,302,617 of 2022 ATM Shares remained available for sale under the 2022 ATM Shares. Agreement.

Under the 2022 ATM Agreement, Wainwright may sell the 2022 ATM Shares by any method permitted by law and deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act, including sales made directly on the Nasdaq Capital Market, or on any other existing trading market for the 2022 ATM Shares. In addition, under the 2022 ATM Agreement, Wainwright may sell the 2022 ATM Shares in privately negotiated transactions with our consent and in block transactions. Under certain circumstances, we may instruct Wainwright not to sell the 2022 ATM Shares if the sales cannot be effected at or above the price designated by us from time to time.

We are not obligated to make any further sales of the 2022 ATM Shares under the 2022 ATM Agreement. The offering of the 2022 ATM Shares pursuant to the 2022 ATM Agreement will terminate upon the termination of the 2022 ATM Agreement by Wainwright or us, as permitted therein.

The 2022 ATM Agreement contains customary representations, warranties and agreements by us, and customary indemnification and contribution rights and obligations of the parties. We agreed to pay Wainwright a placement fee of up to 3.0% of the aggregate gross proceeds from each sale of the 2022 ATM Shares. We also agreed to reimburse Wainwright for certain specified expenses in connection with entering into the 2022 ATM Agreement.

In the fiscal year ended March 31, 2024, we raised aggregate net proceeds of $1,322,383 net of $34,118 in commissions to Wainwright and $8,202 in other offering expense, through the sale of 296,056 shares of our common stock at an average price of $4.47 per share under the 2022 ATM Agreement.

RSU Grants to Non-Employee Directors

In April 2023, the Compensation Committee of the Board, or Compensation Committee, approved, pursuant to the terms of the Company's Amended and Restated Non-Employee Director Compensation Policy, or the Director Compensation Policy, the grant of the annual RSUs under the Director Compensation Policy to each of the three non-employee directors of the Company then serving on the Board of Directors of the Company, or Board. The Director Compensation Policy provides for a grant of stock options or $50,000 worth of RSUs at the beginning of each fiscal year for current non-employee directors then serving on the Board, and for a grant of stock options or $75,000 worth of RSUs for a newly elected non-employee director, with each RSU priced at the average for the closing prices for the five days preceding and including the date of grant, or $4.30 per share for the April 2023 RSU grants. As a result, in April 2023 the three eligible directors were each granted an RSU in the amount of 11,628 shares under the 2020 Plan. The RSUs are subject to vesting in four equal installments, with 25% of the restricted stock units vesting on each of June 30, 2023, September 30, 2023, December 31, 2023, and March 31, 2024, subject in each case to the director's Continuous Service (as defined in the 2020 Plan), through such dates. Vesting will terminate upon the director's termination of Continuous Service prior to any vesting date.

Unvested RSUs covering 4,885 shares of common stock were outstanding as of March 31, 2024.

Equity Transactions in the Fiscal Year Ended March 31, 2023.

During the fiscal year ended March 31, 2023, we raised net proceeds of $8,927,211, net of $229,610 in commissions to Wainwright and $27,153 in other offering expense, through the sale of 7,480,836 748,084 shares of our common stock at an average price of $1.19 $11.90 per share under the 2022 ATM Agreement.

RSU Grants to Non-Employee Directors

The Compensation Committee of the Board of Directors of the Company, or Compensation Committee, approved, effective as of April 1, 2022, pursuant to the terms of the Company's Amended and Restated Non-Employee Director Compensation Policy, or the Director Compensation Policy, the grant of the annual RSUs to each of the two non-employee directors of the Company then serving on the Board, of Directors of the Company, or Board, and the grant of an RSU for the then newly appointed non-employee director. The RSU grants were made subject to stockholder approval of an increase of 1,800,000 shares of common stock authorized for issuance under the Company's 2020 Equity Incentive Plan, or the 2020 Plan, at the Company's 2022 annual meeting Annual Meeting of stockholders. Stockholders. The increase was approved at the Company's 2022 annual meeting Annual Meeting of stockholders Stockholders held in September 2022. The Director Compensation Policy provides for a grant of stock options or $50,000 worth of RSUs at the beginning of each fiscal year for current non-employee directors then serving on the Board and for a grant of stock options or $75,000 worth of RSUs for a newly elected non-employee director, with each RSU priced at the average for the closing prices for the five days preceding and including the date of grant, or $1.46 $14.60 per share as of April 1, 2022. The two then-current eligible directors each was granted a contingent RSU in the amount of 34,247 3,425 shares under the 2020 Plan and the then newly appointed director received a contingent RSU grant for 51,370 5,137 shares under the 2020 Plan. The RSUs were subject to vesting in three installments, 50% on September 30, 2022, and 25% on each of December 31, 2022, and March 31, 2023, subject to the recipient's continued service with the Company on each such vesting date.

Equity Transactions in the Fiscal Year Ended March 31, 2022.

2021 At The Market Offering Agreement with H.C. Wainwright & Co., LLC

On March 22, 2021, we entered into an At the Market Offering Agreement, or the 2021 ATM Agreement, with Wainwright, as sales agent, pursuant to which we could offer and sell shares of our common stock, from time to time as set forth in the 2021 ATM Agreement.

The offering was registered under the Securities Act pursuant to our shelf registration statement on Form S-3 (Registration Statement No. 333-237269), as previously filed with the SEC and declared effective on March 30, 2020. We filed a prospectus supplement with the SEC, dated March 22, 2021, in connection with the offer and sale of the shares of common stock, pursuant to which we could offer and sell shares of common stock having an aggregate offering price of up to $5,080,000 from time to time.

Subject to the terms and conditions set forth in the 2021 ATM Agreement, Wainwright agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares under the 2021 ATM Agreement from time to time, based upon our instructions. We provided Wainwright with customary indemnification rights under the 2021 ATM Agreement, and Wainwright was entitled to a commission at a fixed rate equal to up to three percent of the gross proceeds per share sold. In addition, we agreed to reimburse Wainwright for certain specified expenses in connection with entering into the 2021 ATM Agreement. The 2021 ATM Agreement provided that it would terminate upon the written termination by either party as permitted thereunder.

Sales of the shares, under the 2021 ATM Agreement are made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act, including sales made by means of ordinary brokers' transactions, including on the Nasdaq Capital Market, at market prices or as otherwise agreed with Wainwright. The 2021 ATM Agreement provided that we have no obligation under the 2021 ATM Agreement to sell any of the shares, and, at any time, we could suspend offers under the 2021 ATM Agreement or terminate the agreement.

In the fiscal year ended March 31, 2022, we raised aggregate net proceeds under the 2021 ATM Agreement described above of $4,947,785, net of $126,922 in commissions to Wainwright and $2,154 in other offering expense, through the sale of 626,000 shares of our common stock at an average price of $7.90 per share of net proceeds. No further sales can be made under the 2021 ATM Agreement.

Registered Direct Financing

In the fiscal year ended March 31, 2022, we sold an aggregate of 1,380,555 shares of our common stock at a purchase price per share of $9.00, for aggregate net proceeds to us of $11,659,044, after deducting fees payable to Maxim Group LLC, the placement agent, and other offering expenses. These shares were sold through a securities purchase agreement with certain institutional investors. The shares were issued pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the SEC on March 19, 2020, and was declared effective on March 30, 2020 (File No. 333-237269) and a prospectus supplement thereunder.

Warrant Exercises

In the fiscal year ended March 31, 2022, pursuant to the exercise of outstanding warrants to purchase 531,167 shares of our common stock, we received proceeds in the amount of $820,938 from institutional investors.

Also in the fiscal year ended March 31, 2022, pursuant to the exercise of 874,664 outstanding warrants on a cashless basis, we issued 675,554 shares of our common stock. The difference of 199,110 shares of common stock issuable pursuant to the warrants were cancelled.

Stock Option Exercises

In the fiscal year ended March 31, 2022, former employees paid us an aggregate of $28,325 for the exercise of outstanding options to purchase 11,562 shares of our common stock.

RSU Grants to Non-Employee Directors

The Company maintains the Director Compensation Policy which provides for cash and equity compensation for persons serving as non-employee directors of the Company. Under this policy, each new director receives either stock options or a grant of RSUs upon appointment/election, as well as either an annual grant of stock options or of RSUs at the beginning of each fiscal year. The (i) stock options are subject to vesting and (ii) RSUs are subject to vesting and represent the right to be issued on a future date shares of our common stock upon vesting.

On April 1, 2021, pursuant to the Director Compensation Policy, the Compensation Committee granted RSUs under the 2020 Plan to each non-employee director of the Company. The Director Compensation Policy provides for a grant of stock options or $50,000 worth of RSUs at the beginning of each fiscal year, with the RSUs priced at the average for the closing prices for the five days preceding and including the date of grant, or $2.06 per share as of April 1, 2021. Each eligible director was granted an RSU in the amount of 24,295 shares under the 2020 Plan. The RSUs were subject to vesting in four equal quarterly installments on June 30, September 30, December 31, 2021, and March 31, 2022, subject to the recipient’s continued service with the Company on each such vesting date.

In June 2021, 18,221 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All three non-employee directors elected to return 40% of their vested RSUs in exchange for cash, in order to pay their withholding taxes on the share issuances, resulting in 7,289 of the vested RSUs being cancelled in exchange for $35,786 in aggregate cash proceeds to those independent directors.

In September 2021, 18,221 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All three non-employee directors elected to return 40% of their vested RSUs in exchange for cash, in order to pay their withholding taxes on the share issuances, resulting in 7,289 of the vested RSUs being cancelled in exchange for $28,134 in aggregate cash proceeds to those independent directors.

In December 2021, 18,221 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All three non-employee directors elected to return 40% of their vested RSUs in exchange for cash, in order to pay their withholding taxes on the share issuances, resulting in 7,289 of the vested RSUs being cancelled in exchange for $13,557 in aggregate cash proceeds to those independent directors.
In March 2022, 18,221 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All three non-employee directors elected to return 40% of their vested RSUs in exchange for cash, in order to pay their withholding taxes on the share issuances, resulting in 7,289 of the vested RSUs being cancelled in exchange for $10,641 in aggregate cash proceeds to those independent directors.

There were no vested RSUs outstanding as of March 31, 2022 March 31, 2023.

WARRANTS:

We did not issue any warrants during the fiscal years ended March 31, 2023 March 31, 2024 and 2022. 2023.

A summary of the aggregate warrant activity for the years ended March 31, 2023 March 31, 2024 and 2022 2023 is presented below:

	Fiscal Year Ended March 31,				Fiscal Year Ended March 31,			
	2023		2022		2024		2023	
	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Outstanding, beginning of year	576,738	$ 11.21	1,991,973	$ 5.23	32,676	$ 20.09	57,678	$ 112.11
Granted	–	$ N/A	–	$ N/A	–	$ N/A	–	$ N/A
Exercised	–	$ N/A	(1,206,721)	$ 2.21	–	$ N/A	–	$ N/A
Cancelled/Forfeited	(249,985)	$ 23.24	(208,514)	$ 6.11	–	$ N/A	(25,002)	$ 232.38
Outstanding, end of year	326,753	$ 2.01	576,738	$ 11.21	32,676	$ 20.09	32,676	$ 20.09
Exercisable, end of year	326,753	$ 2.01	576,738	$ 11.21	32,676	$ 20.09	32,676	$ 20.09
Weighted average estimated fair value of warrants granted		$ N/A		$ N/A		$ N/A		$ N/A

The detail of the warrants outstanding and exercisable as of March 31, 2024 is as follows:

Range of Exercise Prices	Warrants Outstanding			Warrants Exercisable	
	Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Exercise Price
$18.75 or Below	20,217	.71	$ 15.66	20,217	$ 15.66
$25.00 - $27.50	12,459	.81	$ 27.28	12,459	$ 27.28
	32,676			32,676	

The detail of the warrants outstanding and exercisable as of March 31, 2023 is as follows:

Range of Exercise Prices	Warrants Outstanding			Warrants Exercisable	
	Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Exercise Price
$1.88 or Below	202,167	1.75	$ 1.57	202,167	$ 1.57
$2.50 - $2.75	124,586	1.83	$ 2.73	124,586	$ 2.73
	326,753			326,753	

Range of Exercise Prices	Warrants Outstanding: Number Outstanding	Warrants Outstanding: Weighted Average Remaining Life (Years)	Warrants Outstanding: Weighted Average Exercise Price	Warrants Exercisable: Number Outstanding	Warrants Exercisable: Weighted Average Exercise Price
$18.75 or Below	20,217	1.71	$ 15.66	20,217	$ 15.66
$25.00 - $27.50	12,459	1.81	$ 27.28	12,459	$ 27.28
	32,676			32,676	

STOCK-BASED COMPENSATION:

2020 EQUITY INCENTIVE PLAN

In September 2020, our stockholders approved the adoption of the 2020 Plan, to provide incentives to attract, retain and motivate employees, directors and consultants, whose present and potential contributions are important to our success, by offering them an opportunity to participate in our future performance through awards of options, the right to purchase common stock, stock bonuses and stock appreciation rights and other awards. We initially authorized a total of 1,842,556 168,182 common shares for issuance under the 2020 Plan pursuant to stock option grants, RSUs or other forms of stock-based compensation.

In September 2022, our stockholders approved an increase in the number of shares of common stock authorized for issuance under the 2020 Plan by 1,800,000 180,000 shares. As of March 31, 2023 March 31, 2024, there were 1,667,479 200,948 shares available under the 2020 Plan.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The Company maintains the Director Compensation Policy which provides for cash and equity compensation for persons serving as non-employee directors of the Company. Under this policy, each new non-employee director receives either stock options or a grant of RSUs upon appointment/election, as well as either an annual grant of stock options or of RSUs at the beginning of each fiscal year. The (i) stock options are subject to vesting and (ii) RSUs are subject to vesting and represent the right to be issued on a future date shares of our common stock upon vesting.

Please see above under the heading "Equity Transactions in the Fiscal Year Ended March 31, 2023 March 31, 2024—RSU Grants to Non-Employee Directors" for disclosure regarding equity awards under the Director Compensation Policy during the fiscal year ended March 31, 2023 March 31, 2024.

STOCK OPTION ACTIVITY

During the fiscal year ended March 31, 2023 March 31, 2024, we issued did not issue stock option grants to two executives for the purchase of an aggregate of 266,888 shares of our common stock under our 2020 Plan. grants. The weighted-average exercise prices for the shares subject to the options is $0.95 per share, which exercise prices were based on assumptions used in estimating the fair market value of stock options in the common stock on the applicable grant dates. fiscal year ended March 31, 2023 included volatility ranging from 136.1% to 140%, a 0% dividend rate, and risk-free rates between 1.49% and 2.14%. The shares subject to the options are subject to vesting over four years, commencing on the grant dates, or Vesting Commencement Dates, with twenty-five percent (25%) of the shares subject to the option vesting on the first anniversary of the Vesting Commencement Date and the remaining shares vesting in equal monthly installments over the following thirty-six (36) months. weighted average expected volatility was 138.07%

Options outstanding that were vested as of March 31, 2023 March 31, 2024 and options that are expected to vest subsequent to March 31, 2023 March 31, 2024 are as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Vested	755,531	$ 2.45	7.74	57,813	$ 19.41	6.96
Expected to vest	962,722	$ 2.07	8.45	28,653	$ 15.01	7.78
Total	1,718,253			86,466		

The following is a summary of the stock options outstanding at March 31, 2024 and 2023 and the changes during the years then ended:

	Fiscal Year Ended March 31,			
	2024		2023	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding, beginning of year	171,825	$ 22.4	166,595	$ 23.1
Granted	–	$ –	12,222	$ 9.50
Cancelled/Forfeited	(85,359)	$ 26.89	(6,992)	$ 17.70
Outstanding, end of year	86,466	$ 17.95	171,825	$ 22.4
Exercisable, end of year	57,813	$ 19.41	75,554	$ 24.5
Weighted average estimated fair value of options granted		$ N/A		$ N/A

There were no stock option grants during the fiscal year ended March 31, 2024. There were 12,222 stock options granted during the fiscal year ended March 31, 2023. The weighted average grant date fair value of stock options granted during the fiscal year ended March 31, 2023 was $61,146. There were 54,428 RSUs granted during the fiscal year ended March 31, 2024. The weighted average grant date fair value of RSUs granted during the fiscal year ended March 31, 2024 was $58,333. There were no stock option exercises during the fiscal years ended March 31, 2024 and 2023.

The following is a summary of the table below summarizes nonvested stock options outstanding at March 31, 2023 as of March 31, 2024 and 2022 and the changes during the years then ended: year ended March 31, 2024.

	Fiscal Year Ended March 31,			
	2023		2022	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding, beginning of year	1,665,948	$ 2.31	844,089	$ 3.07
Granted	122,220	$ .95	941,188	$ 2.48
Exercised	–	$ –	(11,562)	$ 2.45
Cancelled/Forfeited	(69,915)	$ 1.77	(107,767)	$ 9.66
Outstanding, end of year	1,718,253	$ 2.24	1,665,948	$ 2.31
Exercisable, end of year	755,531	$ 2.45	267,221	$ 2.51
Weighted average estimated fair value of options granted		$ .92		$ 2.41

	Shares	Weighted Average Grant Date Fair Value
Nonvested stock options at April 1, 2023	96,273	$ 19.99
Vested	(21,934)	$ 1.59
Forfeited	(45,686)	$ 2.55
Nonvested stock options at March 31, 2024	28,653	

The detail of the options outstanding and exercisable as of March 31, 2023 March 31, 2024 is as follows:

	Options Outstanding			Options Exercisable	
Exercise Prices	Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Exercise Price
$0.69 - $1.68	1,207,034	8.28 years	$ 1.35	505,246	$ 1.36
$2.45 - $5.17	508,654	8.05 years	$ 3.91	247,720	$ 3.77
$57.00 - $142.50	2,565	.85 years	$ 91.09	2,565	$ 91.09
	1,718,253			755,531	

	Options Outstanding			Options Exercisable	
Exercise Prices	Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Exercise Price
$6.90 - $16.80	62,204	7.48 years	$ 13.24	38,589	$ 13.48
$25.20	24,178	6.76 years	$ 25.20	19,140	$ 25.20
$1,425.00	84	.18 years	$ 1,425.00	84	$ 1,425.00
	86,466			57,813	

We recorded stock-based compensation expense related to RSU issuances and to options granted totaling $1,051,898 1,219,370 and $750,621 1,051,898 for the fiscal years ended March 31, 2023 March 31, 2024 and 2022, 2023, respectively. These expenses were recorded as stock compensation included in payroll and related expenses in the accompanying consolidated statement of operations for the years ended March 31, 2023 March 31, 2024 and 2022. 2023.

The table below summarizes restricted stock units as of March 31, 2024 and changes during the year ended March 31, 2024.

	F-21 Shares
Nonvested RSUs at April 1, 2023	–
Granted	54,428
Vested	(34,378)
Tax withholding payments or tax equivalent payments for net share settlement of restricted stock units	(15,165)
Nonvested RSUs at March 31, 2024	4,885

Our total stock-based compensation for fiscal years ended March 31, 2023 March 31, 2024 and 2022 2023 included the following:

	Fiscal Year Ended		Fiscal Year Ended	
	March 31, 2023	March 31, 2022	March 31, 2024	March 31, 2023
Vesting of restricted stock units	$ 175,000	$ 150,000	$ 206,250	$ 175,000
Vesting of restricted shares issued for services	–	16,500		
Vesting of stock options	876,898	584,121	1,013,120	876,898
Total Stock-Based Compensation	$ 1,051,898	$ 750,621	$ 1,219,370	$ 1,051,898

We review share-based compensation on a quarterly basis for changes to the estimate of expected award forfeitures based on actual forfeiture experience. The cumulative effect of adjusting the forfeiture rate for all expense amortization is recognized in the period the forfeiture estimate is changed. The effect of forfeiture adjustments for the fiscal year ended March 31, 2023 March 31, 2024 was insignificant.

On March 31, 2023 March 31, 2024, our outstanding stock options had no intrinsic value since the closing price on that date of $0.38 1.68 per share was below the weighted average exercise price of our outstanding stock options.

At March 31, 2023 March 31, 2024, there was approximately $1,877,000 400,002 of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted average period of 2.3 1.57 years.

5. RELATED PARTY TRANSACTIONS

DUE TO RELATED PARTIES

Historically, certain For the fiscal year ended March 31, 2024 we accrued unpaid fees of $68,250 owed to our officers and other non-employee directors.
As a result of entering into a Separation Agreement effective November 27, 2023 with our former Chief Executive Officer, or CEO, Charles J. Fisher, M.D., or the Separation Agreement, we paid out accrued vacation of $53,076 to Dr. Fisher in the fiscal year ended March 31, 2024. That accrued vacation was previously recorded in the due to related parties have advanced us funds, agreed account. In addition, pursuant to defer the terms of Dr. Fisher's Executive Employment Agreement, we accrued $435,378 for cash severance payments payable monthly and COBRA payments to be paid monthly over a 12-month period that began on December 1, 2023.
Additionally, $393,139 of stock-based compensation and/or paid expenses on our behalf to cover working capital deficiencies. There were no such related party transactions was recorded during the fiscal year ended March 31, 2023, except that we had accrued unpaid Board fees March 31, 2024 for the acceleration of $57,000 owed to our outside directors as vesting for 50% of March 31, 2023. then outstanding options held by Dr. Fisher at the time of his separation from the Company.

DueAmounts due to related parties were comprised of the following items:

	March 31, 2023	March 31, 2022	March 31, 2024	March 31, 2023
Accrued Board fees	$ 57,000	$ 55,750	$ 68,250	$ 57,000
Accrued vacation	157,221	99,992		
Accrued vacation to all employees			167,973	157,221
Accrued separation expenses for former executive			310,211	–
Total due to related parties	$ 214,221	$ 155,742	$ 546,434	$ 214,221

6. OTHER CURRENT LIABILITIES

Other current liabilities were comprised of the following items:

	March 31, 2023	March 31, 2022	March 31, 2024	March 31, 2023
Accrued professional fees	$ 588,592	$ 696,893	$ 215,038	$ 184,472
Accrued commission liability			–	404,120
Total other current liabilities	$ 588,592	$ 696,893	$ 215,038	$ 588,592

During 2017 through 2020, the Company incorrectly recorded accrued commission liability of approximately $404,000. The Company reversed accrued commission liability of approximately $404,000 during the year ended March 31, 2024.

7. INCOME TAXES

For the years ended March 31, 2023 March 31, 2024 and 2022, 2023, we had no income tax expense due to our net operating losses and 100% deferred tax asset valuation allowance.

At March 31, 2023 March 31, 2024 and 2022, 2023, we had net deferred tax assets as detailed below. These deferred tax assets are primarily composed of capitalized research and development costs and tax net operating loss carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a 100% valuation allowance has been established to offset the net deferred tax assets.

Significant components of our net deferred tax assets at March 31, 2023 March 31, 2024 and 2022 2023 are shown below:

	YEAR ENDED MARCH 31,		YEAR ENDED MARCH 31,	
	2023	2022	2024	2023
Deferred tax assets:				
Research and development credit carryforwards	$ 3,442,000	$ 3,442,000	$ 3,442,000	$ 3,442,000
Capitalized research and development costs	519,000	–	646,000	519,000
Net operating loss carryforwards[1]	24,158,000	22,039,000	26,927,000	24,158,000
Stock compensation	1,903,000	1,609,000	2,244,000	1,903,000
Total deferred tax assets	30,022,000	27,090,000	33,259,000	30,022,000
Total deferred tax liabilities	–	–	–	–
Net deferred tax assets	30,022,000	27,090,000	33,259,000	30,022,000
Valuation allowance for deferred tax assets	(30,022,000)	(27,090,000)	(33,259,000)	(30,022,000)
Net deferred tax assets	$ –	$ –	$ –	$ –

(1) Pursuant to Internal Revenue Code Section 382, use of our tax net operating loss carryforwards may be limited. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. If and when the Company utilizes the NOL carryforwards in a future period, it will perform an analysis to determine the effect, if any, of these loss limitation rules on the NOL carryforward balances.

At March 31, 2023 March 31, 2024, we had tax net operating loss carryforwards for federal and state purposes approximating $88 98 million and $80 91 million, respectively, portions of which began to expire in the year 2021. The indefinite position is approximately $36 million. Research and Development credits begin to expire in 2025.

The provision for income taxes on earnings subject to income taxes differs from the statutory federal rate for the years ended March 31, 2023 March 31, 2024 and 2022 2023 due to the following:

	2023	2022	2024	2023
Income taxes (benefit) at federal statutory rate of 21.00%	$ (2,526,000)	$ (2,188,000)	$ (2,564,000)	$ (2,526,000)
Tax effect on non-deductible expenses and credits	2,000	1,000	2,000	2,000
True up items	57,000	(5,000)	(29,000)	57,000
Expiration of net operating loss carryforwards [1]	353,000	593,000	204,000	353,000
Change in valuation allowance	2,114,000	1,599,000	2,387,000	2,114,000
Income Tax Expense (Benefit)	$ –	$ –	$ –	$ –

(1) Pursuant to Internal Revenue Code Section 382, use of our tax net operating loss carryforwards may be limited.

ASC 740, “Income Taxes”, clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements, and prescribes recognition thresholds and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under ASC 740, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, ASC 740 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. During the years ended March 31, 2023 March 31, 2024 and 2022, 2023, we did not recognize any interest or penalties relating to tax matters.

At and for the years ended March 31, 2023 March 31, 2024 and 2022, 2023, management does not believe the Company has any uncertain tax positions. Accordingly, there are no unrecognized tax benefits at March 31, 2023 March 31, 2024 or March 31, 2022 March 31, 2023.

Our tax returns remain open for examination by the applicable authorities, generally 3 years for federal and 4 years for state. We are currently not under examination by any taxing authorities.

8. COMMITMENTS AND CONTINGENCIES

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

We have had the following material changes to our contractual obligations and commitments outside the ordinary course of business during the fiscal year ended March 31, 2023 March 31, 2024:

LEASE COMMITMENTS

Office, Lab and Manufacturing Space Leases

In December 2020, we entered into an agreement to lease approximately 2,823 square feet of office space and 1,807 square feet of laboratory space located at 11555 Sorrento Valley Road, Suite 203, San Diego, California 92121 and 11575 Sorrento Valley Road, Suite 200, San Diego, California 92121, respectively. The agreement carries a term of 63 months and we took possession of the office space effective October 1, 2021. We took possession of the laboratory space effective January 1, 2022. In October 2021, we entered into another lease for approximately 2,655 square feet of space to house our manufacturing operations located at 11588 Sorrento Valley Road, San Diego, California 92121. The term is for 55 months and we took possession of the manufacturing space in August 2022. The current monthly base rent under the office and laboratory component of the lease is $13,772 14,158. The current monthly base rent under the manufacturing component of the lease is $12,080 12,452.

During the fiscal year ended March 31, 2023, we recorded a $625,471 right-of-use lease asset and associated lease liability related to the manufacturing space component of the lease based on the present value of lease payments over the expected lease term of 55 months, discounted using our estimated incremental borrowing rate of 4.25%.

The office, lab and manufacturing leases are coterminous with a remaining term of 48 36 months. The weighted average discount rate is 4.25%.

As of our March 31, 2023 March 31, 2024 balance sheet, we have a right-of-use lease asset of $1,151,909 883,054.

The following table presents a maturity analysis of expected undiscounted cash flows for operating leases on an annual basis for the next four three fiscal years. All of our leases conterminously expire during the fiscal year ending March 31, 2027.

Fiscal Years Ended March 31,		
2024	$ 314,493	
2025	323,812	$ 323,812
2026	333,462	333,462
2027	343,351	343,352
Total minimum lease payments	1,315,118	1,000,626
Less amount representing imputed interest	(106,090)	(60,310)
Present value of minimum lease payments	$ 1,209,028	$ 940,316

Mobile Clean Room

In addition, we rented a mobile clean room on a short term, month-to-month basis, where we housed our manufacturing operations until our permanent manufacturing space was completed. The mobile clean room was located on leased land near our office and lab and we paid $2,000$2,000 per month for the right to locate it there. We paid approximately $168,171 in total rent expense to lease the mobile clean room located on this space during the fiscal year ended March 31, 2023. The arrangement was terminated in September 2022 and the mobile clean room was returned to the vendor that leased it to us.

Overall, our rent expense, which is included in general and administrative expenses, approximated $519,000 420,353and $401,000 519,000 for the fiscal years ended March 31, 2023 March 31, 2024 and 2022, 2023, respectively.

LEGAL MATTERS

From time to time, claims are made against us in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties or injunctions prohibiting us from selling one or more products or engaging in other activities.

The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on our results of operations for that period or future periods. We are not presently a party to any pending or threatened legal proceedings.

9. SUBSEQUENT EVENTS

Management has evaluated events subsequent to March 31, 2023 March 31, 2024 through the date that the accompanying consolidated financial statements were filed with the Securities and Exchange Commission for transactions and other events which may require adjustment of and/or disclosure in such financial statements.

Sales Under 2022 ATM Agreement Public Offering

Subsequent to March 31, 2023 On May 17, 2024, we raised net proceeds of $1,086,119, net of $27,999 in commissions closed a public offering pursuant to Wainwright and $5,846 in other offering expense, through the sale of 1,778,901 which we sold an aggregate of: (i) 2,450,000 shares of our common stock and accompanying Class A warrants to purchase up to 2,450,000 shares of common stock and Class B warrants to purchase up to 2,450,000 shares of common stock, at an average a combined public offering price of $0.61 $0.58 per share under and accompanying warrants; and (ii) in lieu of common stock, pre-funded warrants to purchase 5,650,000 shares of common stock and accompanying Class A warrants to purchase up to 5,650,000 shares of common stock and Class B warrants to purchase up to 5,650,000 shares of common stock, at a combined public offering price of $0.579 per pre-funded warrant and accompanying warrants, which is equal to the 2022 ATM Agreement. public offering price per share of common stock, and accompanying warrants less the $0.001 per share exercise price of each such pre-funded warrant.
The Class A and Class B warrants each have an exercise price of $0.58 per share, are immediately exercisable, and, in the case of Class A warrants, will expire on May 17, 2029, and in the case of Class B warrants, will expire on May 19, 2025. The exercise price of the Class A and Class B warrants is also subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in such warrants. Maxim Group LLC acted as the exclusive placement agent for the offering.
The gross proceeds from the offering, before deducting the placement agent's fees and other offering expenses, were approximately $4.7 million. The Company intends to use the net proceeds from this offering for general corporate purposes, which may include clinical trial expenses, research and development expenses, capital expenditures and working capital.
In June 2024, holders of Class A and Class B warrants exercised 295,000 shares and 2,875,000 shares, respectively, for total proceeds of $1,838,600.

RSU GRANTS Grants

In April 2023, 2024, the Compensation Committee Board approved, pursuant to the terms of the Director Compensation Policy, the grant of the annual RSUs under the Director Compensation Policy to each of the three four non-employee directors of the Company then serving on the Board. The Director Compensation Policy provides for a grant of stock options or $50,000 worth of RSUs at the beginning of each fiscal year for current non-employee directors then serving on the Board, and for a grant of stock options or $75,000 worth of RSUs for a newly elected non-employee director, with each RSU priced at the average for the closing prices for the five days preceding and including the date of grant, or $0.43 $1.52 per share for the April 2023 2024 RSU grants. As a result, in April 2023 2024 the three four eligible directors were each was granted an RSU in the amount of 116,279 32,894 shares under the 2020 Plan. The RSUs are subject to vesting in four equal installments, with 25% of the restricted stock units vesting on each of June 30, 2023 June 30, 2024, September 30, 2023 September 30, 2024, December 31, 2023 December 31, 2024, and March 31, 2024 March 31, 2025, subject in each case to the director's Continuous Service (as defined in the 2020 Plan), through such dates. Vesting will terminate upon the director's termination of Continuous Service prior to any vesting date.

Exhibit 10.18

AMENDMENT NO. 1 TO

EXECUTIVE EMPLOYMENT AGREEMENT

This **AMENDMENT NO. 1 TO EXECUTIVE EMPLOYMENT AGREEMENT** (this "***Amendment***") is made and entered into as of May 1, 2023 (the "***Effective Date***") by and between Aethlon Medical, Inc., a Delaware corporation (the "***Company***"), and Lee D. Arnold, Ph.D., an individual resident in the State of California (the "***Employee***") (the Company and the Employee are hereinafter sometimes individually referred to as a "***Party***" and together referred to as the "***Parties***").

WHEREAS, Employee and the Company previously entered into that certain Executive Employment Agreement dated February 1, 2023 (the "***Employment Agreement***"); and

WHEREAS, Employee and the Company have agreed to amend certain terms of the Employment Agreement in accordance with the terms hereof.

NOW THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth, the adequacy and sufficiency of which is hereby acknowledged, the Company and Employee agree as follows:

1. Section 1.2 of the Employment Agreement. Effective as of the Effective Date, Section 1.2 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

"**Duties and Location.** Employee shall perform such duties as are customarily associated with the position of Chief Scientific Officer and such other duties as are assigned to Employee by the Company. During the term of Employee's employment with the Company, Employee will devote Employee's best efforts and perform Employee's duties within a part-time commitment of four full-time days per week, although Employee's job duties may require that Employee work additional hours. Employee will work from the Company's office in San Diego, California at least two full-time days per week, provided that Employee may work remotely from his residence for the remaining two day(s) per week. Subject to the terms of this Agreement, the Company reserves the right to (i) reasonably require Employee to perform Employee's duties at places other than Employee's primary office location from time to time and to require reasonable business travel, and (ii) modify Employee's job title and duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time."

2. Section 2.1 of the Employment Agreement. Effective as of the Effective Date, Section 2.1 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

"**Base Salary.** For services to be rendered hereunder, Employee shall receive a base salary at the rate of $305,333 per year, less standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule."

3. Acknowledgments. Employee expressly consents to the revised compensation, terms and benefits under this Amendment. In consideration of the compensation, terms and benefits provided to Employee by this Amendment and as part of Employee's continued employment, Employee agrees and acknowledges that there are no circumstances as of the date of this Amendment that constitute, and nothing contemplated in this Amendment shall be deemed for any purpose to be or to create, an involuntary termination without Cause or a Good Reason resignation right, including for purposes of Section 8 of the Employment Agreement, or any other severance or change in control plan, agreement or policy maintained by the Company. Employee further hereby expressly waives any claim or right Employee may have (if any) to assert that this Amendment, or any other condition or occurrence, forms the basis for a without Cause termination or Good Reason resignation for any purpose, including for purposes of Section 8 of the Employment Agreement, or any other severance or change in control plan, agreement or policy maintained by the Company.

4. Effect of Amendment; Entire Agreement. Except as modified herein, the terms and conditions of the Employment Agreement shall remain unchanged and in full force and effect. The Employment Agreement, as modified by this Amendment, sets forth the entire understanding between the parties with regard to the subject matter hereof and supersedes any prior oral discussions or written communications and agreements. This Amendment cannot be modified or amended except in writing signed by Executive and a duly authorized member of the Company's Board of Directors.

5. Governing Law. This Amendment shall be governed by the laws of the State of California, without regard to any conflicts of law principles thereof that would call for the application of the laws of any other jurisdiction.

6. Counterparts. This Amendment may be executed in counterparts which shall be deemed to be part of one original, and facsimile and electronic image copies of signatures (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000) or other transmission method shall be equivalent to original signatures.

[Signature Page to Follow]

IN WITNESS WHEREOF, each of the Parties has executed this Amendment as of the date first above written.

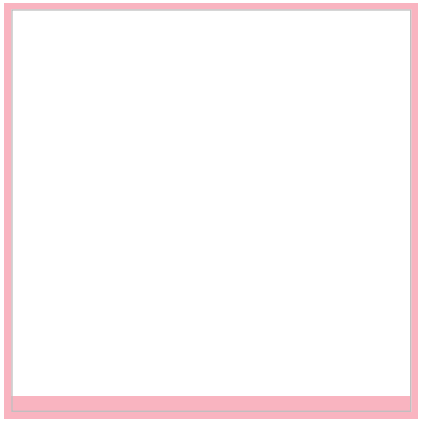

Exhibit 21.1

List of Subsidiaries

Subsidiary	Percentage Owned by Aethlon Medical, Inc.	Jurisdiction of Incorporation
Aethlon Medical Australia Pty Ltd	100%	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-267504, 333- 248820, 333-248820, 333-230445, 333-182902, 333-168483, 333-168481, 333-164939, 333-160532, 333-145290, 333-127911, 333-114017 and 333-49896), Form S-3 (File No. 333-259909), and Form S-1 (File Nos. 333-234712, 333-201334, 333-219589 and 333-219589) 333-278188) of Aethlon Medical, Inc. of our report dated June 28, 2023 June 27, 2024, relating to the consolidated financial statements of Aethlon Medical, Inc. and subsidiary appearing which appears in the this Annual Report on Form 10-K of Aethlon Medical, Inc. and subsidiary for the year ended March 31, 2023 March 31, 2024.

BAKER TILLY US, LLP

/s/ Baker Tilly US, LLP

San Diego, California
June 28, 2023 27, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE RULES 13a-14(a)/15d-14(a), UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles J. Fisher, Jr., M.D. certify that:

1. I have reviewed this Annual Report on Form 10-K of Aethlon Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(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.

Date: June 28, 2023

/s/ CHARLES J. FISHER
CHARLES J. FISHER, JR.
CHIEF EXECUTIVE OFFICER

(PRINCIPAL EXECUTIVE OFFICER)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a), AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James B. Frakes certify that:

1. I have reviewed this Annual Report on Form 10-K of Aethlon Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us me 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 my 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 my 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 my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 28, 2023 June 27, 2024

/s/ JAMES B. FRAKES
JAMES B. FRAKES FRAKES.
INTERIM CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
(PRINCIPAL FINANCIAL OFFICER) Principal Executive and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
AND SECTION 1350 OF CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE (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 of Aethlon Medical, Inc., or the Registrant, on Form 10-K for the fiscal year ended March 31, 2023 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof, I, Charles J. Fisher, Jr., M.D., James B. Frakes, Interim Chief Executive Officer and Chief Financial Officer of the Registrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Annual Report on Form 10-K, to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and

2. The information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Aethlon Medical, Inc.

Dated: June 28, 2023 June 27, 2024

/s/ CHARLES J. FISHER JAMES B. FRAKES
Charles J. Fisher, Jr., M.D. James B. Frakes
Interim Chief Executive Officer and Chief Financial Officer
Principal Executive and Financial Officer
Aethlon Medical, Inc.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aethlon Medical, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 97.1

Exhibit 32.2AETHLON MEDICAL, INC.

CERTIFICATION PURSUANT TO RULE 13a-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

AND SECTION 1350 OF CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE (18 U.S.C. SECTION 1350),
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002INCENTIVE COMPENSATION RECOUPMENT POLICY

1. In connection with **INTRODUCTION**

The Compensation Committee (the "***Compensation Committee***") of the Annual Report Board of Directors (the "***Board***") of Aethlon Medical, Inc., a Nevada corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. **EFFECTIVE DATE**

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. **DEFINITIONS**

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the Registrant, on Form 10-K officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the fiscal year ended March 31, 2023 as filed Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission Commission.

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the date hereof, I, James B. Frakes, Chief Financial Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) **Impracticability of Recovery.** Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the Registrant, certify, pursuant applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to 18 U.S.C. recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 1350, 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) **Sources of Recoupment.** To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) **No Indemnification of Covered Officers.** Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) **Indemnification of Administrator.** Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) **No "Good Reason" for Covered Officers.** Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as adopted pursuant a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. **Administration**

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. **Severability**

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. **No Impairment of Other Remedies**

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 906 304 of the Sarbanes-Oxley Act of 2002 that: ("***SOX 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

1. The Annual Report on Form 10-K, to which this Certification is attached as Exhibit 32.2, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as

8. amended, and **Amendment; Termination**

2. The information contained Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Aethlon Medical, Inc. its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

Dated: June 28, 2023

/s/ JAMES B. FRAKES
James B. Frakes
Chief Financial Officer
Aethlon Medical, Inc.

9. **Successors**

This certification accompanies Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. **Required Filings**

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

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AETHLON MEDICAL, INC.
INCENTIVE COMPENSATION RECOUPMENT POLICY
FORM 10-K OF EXECUTIVE ACKNOWLEDGMENT

I, the undersigned, agree and acknowledge that I am bound by, and subject to, which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aethlon Medical, Inc. under Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the Securities Act event of 1933, as amended, any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Aethlon Medical, Inc. (the "***Company***") to which I am a party, or the Securities Exchange Act terms of 1934, as amended (whether made before any compensation plan, program or after agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the date terms of the Form 10-K), irrespective Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any general incorporation language contained in such filing. enforcement of the Policy by the Company.

Agreed and Acknowledged:

EXECUTIVE OFFICER
Signature: _____
Print Name: _____
Title: _____
Date: _____

AETHLON MEDICAL, INC.
By: _____
Print Name: _____
Title: _____
Date: _____

DISCLAIMER

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