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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, 2021

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.)
9635 Granite Ridge Drive, Suite 100 San Diego, California (Address of principal executive office)	92123 (Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (858) 459-7800

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, $.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. ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of September 30, 2020 was approximately $16.2 million, computed by reference to the closing sale price of the common stock of $1.35 per share on the Nasdaq Capital Market on September 30, 2020. 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 21, 2021 was 15,365,490.

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 2021 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, 2021.

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PART I

CAUTIONARY NOTICE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K, or Form 10-K, 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 Form 10-K 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 Form 10-K 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.

ITEM 1. DESCRIPTION OF BUSINESS

Unless otherwise indicated or the context otherwise requires, references to the "Company", "Aethlon", "we", "us" and "our" refer to Aethlon Medical, Inc., combined with its majority-owned subsidiary, Exosome Sciences, Inc.

Overview and Corporate History

We are a medical technology company focused on developing products to diagnose and treat life and organ threatening diseases. The Aethlon Hemopurifier®, or Hemopurifier, is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier is designed to deplete the presence of circulating tumor-derived exosomes that promote immune suppression, seed the spread of metastasis and inhibit the benefit of leading cancer therapies. 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 life-threatening viruses that are not addressed with approved therapies.

We believe the Hemopurifier can be a substantial advance in the treatment of patients with advanced and metastatic cancer through the clearance of exosomes that promote the growth and spread of tumors through multiple mechanisms. We are currently conducting a clinical trial in patients with advanced and metastatic head and neck cancer. We are initially focused on the treatment of solid tumors, including head and neck cancer, gastrointestinal cancers and other cancers. As we advance our clinical trials, we are in close contact with our clinical sites to navigate and assess the impact of the COVID-19 global pandemic on our clinical trials and current timelines.

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, which will enroll 10 to 12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. This study, which is being conducted at the UPMC Hillman Cancer Center in Pittsburgh, PA, has been approved by the Institutional Review Board, or IRB, and is in the process of recruiting and treating patients.

We also believe 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 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, 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.

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 is designed to enroll up to 40 subjects at up to 20 centers in the U.S. Subjects will have established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU, and will have acute lung injury and/or severe or life threatening disease, among other criteria. Endpoints for this study, in addition to safety, will include reduction in circulating virus as well as clinical outcomes (NCT # 04595903). The initial sites for this trial, Hoag Memorial Hospital Presbyterian in Newport Beach, CA and Hoag Hospital – Irvine in Irvine, CA and Loma Linda Hospital in Loma Linda, CA, have completed clinical trial agreements, and have received IRB approval in the case of the Hoag hospitals, and are preparing to open for patient enrollment. Under Single Patient Emergency Use regulations, the Company has also treated two patients with COVID-19 with the Hemopurifier.

We are also the majority owner of Exosome Sciences, Inc., or ESI, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. Included among ESI's activities is the advancement of a TauSome™ biomarker candidate to diagnose chronic traumatic encephalopathy, or CTE, in the living. ESI previously documented TauSome levels in former NFL players to be nine times higher than same age-group control subjects. Through ESI, we are also developing exosome based biomarkers in patients with, or at risk for, a number of cancers. We consolidate ESI's activities in our consolidated financial statements.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we plan to 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 more recently will help protect the proprietary nature of the Hemopurifier treatment technology.

In addition to the foregoing, we are monitoring closely the impact of the COVID-19 global pandemic on our business and have taken steps designed to protect the health and safety of our employees while continuing our operations. Given the level of uncertainty regarding the duration and impact of the COVID-19 pandemic on capital markets and the U.S. economy, we are unable to assess the impact of the worldwide spread of SARS-CoV-2 and the resulting COVID-19 pandemic on our timelines and future access to capital. We are continuing to monitor the spread of COVID-19 and its potential impact on our operations. The full extent to which the COVID-19 pandemic will impact our business, results of operations, financial condition, clinical trials, and preclinical research will depend on future developments that are highly uncertain, including actions taken to contain or treat COVID-19 and their effectiveness, as well as the economic impact on national and international markets.

We were formed on March 10, 1999. Our executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. Our website address is www.aethlonmedical.com.

The Mechanism of the Hemopurifier

The Hemopurifier is an affinity hemofiltration device designed for the single-use removal of 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 application, 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 binds to a glycosylated, or sugar substituted, membrane, which exosomes and most infectious viruses share.

The Hemopurifier - Clinical Trials In Viral Infections

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 multiple other outside labs including the Centers for Disease Control, or CDC, the United States Army Medical Research Institute of Infectious Diseases, or USAMRIID, Battelle Memorial Research Institute and others, we have demonstrated that the mini-Hemopurifier can bind and clear multiple different glycosylated, or containing sugar molecules on their membranes, viruses. These viruses include HIV, hepatitis C, or HCV, Dengue, West Nile, multiple strains of influenza, Ebola, Chikungunya, 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 Early Feasibility Study conducted in the U.S. under an FDA approved Investigational Device Exemption, or IDE.

On March 13, 2017, we concluded an FDA-approved early feasibility study 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 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 is designed to enroll up to 40 subjects at up to 20 centers in the U.S. Subjects will have established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU, and will have acute lung injury and/or severe or life threatening disease, among other criteria. Endpoints for this study, in addition to safety, will include reduction in circulating virus as well as clinical outcomes (NCT # 04595903). The initial sites for this trial, Hoag Memorial Hospital Presbyterian in Newport Beach, CA and Hoag Hospital – Irvine in Irvine, CA and Loma Linda Hospital in Loma Linda, CA, have completed clinical trial agreements, and have received IRB approval in the case of the Hoag hospitals, and are preparing to open for patient enrollment.

Under Single Patient Emergency Use regulations, the Company has also treated two patients with COVID-19 with the Hemopurifier. The Company recently published a manuscript reviewing case studies covering those 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 (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 (CRRT). The patient ultimately expired three hours after being placed on CRRT because of the advanced stage of the patient's disease.

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 U.S. 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 a Breakthrough Designation by the FDA "… 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, twelve 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 twelve treated patients.

Of these twelve 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

While hepatitis C is no longer a major commercial opportunity in developed markets due to the wide availability of curative, oral direct acting anti-viral agents, we continue to investigate potential viral targets for the Hemopurifier. Recently, however, our primary focus has been on the evaluation of the Hemopurifier in cancer, where we have shown in non-clinical studies 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."

On October 4, 2019, the FDA approved our IDE application to initiate an 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, which will enroll 10 to 12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. This study, which is being conducted at the UPMC Hillman Cancer Center in Pittsburgh, PA, has been approved by the IRB and is in the process of recruiting and treating patients.

Exosome Sciences, Inc. – Majority Owned Biomarker Discovery Company

We are the majority owner of Exosome Sciences, Inc., or ESI, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening disease conditions that may be current or future therapeutic targets for Aethlon Medical. At present, the priority of ESI is directed toward exosomal biomarkers to diagnose and monitor cancer and neurological disorders.

Since it began operations in 2013, ESI researchers disclosed the discovery of an exosomal biomarker that may be associated with neurodegenerative diseases that involve the abnormal accumulation of tau protein in the brain. These diseases, known as tauopathies, are a family of 21 different neurological disorders that include Alzheimer's disease and Chronic Traumatic Encephalopathy, or CTE. Related to CTE, the ESI team was invited to participate in a National Institutes of Health, or NIH, funded research study with The Boston University CTE Center. In the study, ESI researchers investigated an exosomal tau biomarker, or TauSome, as a candidate to diagnose and monitor CTE in living individuals. At the present time, CTE can only be diagnosed through post-mortem brain autopsy.

The results of the study indicated that TauSome levels in the blood of former professional American football players, a high CTE risk group, were significantly higher as compared to same-age group control subjects who did not participate in activities that involved repetitive head trauma. Additionally, high TauSome levels also correlated with poor performance in cognitive decline testing. These results were published in an article entitled "Preliminary Study of Plasma Exosomal Tau as a Potential Biomarker for Chronic Traumatic Encephalopathy" in the *Journal of Alzheimer's Disease* on April 12, 2016.

To further validate these observations, ESI has initiated a follow-on study to evaluate TauSome levels in up to 200 former professional football players and control subjects. If fully enrolled, the study would be the largest study to date related to the advancement of a candidate biomarker to diagnose and monitor CTE in the living. Enrollment of study participants began in March 2018 at the Translational Genomics Research Institute, or TGEN, in Phoenix, AZ. Kendall Van Keuren-Jensen, Ph.D., Co-Director of TGEN's Center for Noninvasive Diagnostics is the principal investigator at this site location. Dr. Van Keuren-Jensen is neurodegenerative disease thought leader whose research includes discovery and detection of biomarkers for central nervous system disorders. Additional site locations are anticipated.

In September 2019, we announced that ESI had entered into a collaboration with the Hoag Hospital Presbyterian in Newport Beach, California to identify and characterize potential early disease markers for cancer diagnostics, cancer progression and treatment resistance. The Principal Investigator on this study is Michael Demeure, M.D., program director of Precision Medicine at Hoag. Samples from patients at Hoag will be analyzed by ESI scientists to identify and characterize exosomal "liquid biopsy" markers of cancer incidence and progression. We believe that our recently announced NCI-SBIR Phase II contract to develop a benchtop instrument to isolate and characterize exosomes could substantially expand the capabilities of the ESI programs.

U.S. GOVERNMENT CONTRACTS

We have recognized revenue under the following three government contracts/grants over the past two years:

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 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 is $1,860,561 and runs for the period from September 16, 2019 through September 15, 2021.

The work to be performed pursuant to this Award Contract focuses on melanoma exosomes. This work follows from our completion of a phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018. Following on the phase I work, the deliverables in the phase II program involve the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

During the fiscal year ended March 31, 2021, we completed the milestones relevant to the first nine months of the fiscal year. As a result, we recorded $436,427 of government contract revenue on the Phase 2 Melanoma Cancer Contract in the fiscal year ended March 31, 2021. During the three month period ended March 31, 2021, we did not complete all of the milestones relevant to that time period, as a result, we recorded $114,849 as deferred revenue related to the Phase 2 Melanoma Cancer Contract.

Breast Cancer Grant

In the fiscal year ended March 31, 2021, we completed and submitted the final reports applicable to this NCI grant (number 1R43CA232977-01). The title of this Small Business Innovation Research, or SBIR, Phase I grant is "The Hemopurifier Device for Targeted Removal of Breast Cancer Exosomes from the Blood Circulation," or the Breast Cancer Grant.

This NCI Phase I grant period originally ran from September 14, 2018 through August 31, 2019. In August 2019, we applied for and received a no cost, twelve month extension on this grant; through August 31, 2020. The total amount of the firm grant was $298,444. The grant called for two subcontractors to work with us. Those subcontractors were University of Pittsburgh and Massachusetts General Hospital.

During the fiscal year ended March 31, 2021, we recorded the remaining $188,444 of revenue related to the Breast Cancer Grant, as we achieved two of the three milestones related to the Breast Cancer Grant. We concluded in our final report to the SBIR that our pre-clinical results demonstrated that our work under the grant provided support that the Hemopurifier has the capacity to clear exosomes from breast cancer patients. That amount previously was recorded as deferred revenue.

As of March 31, 2021, we received all of the funds allocated to the Breast Cancer Grant and have submitted the final reports applicable to this grant.

Subaward with University of Pittsburgh

In 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 is $256,750. We recorded $34,233 of revenue related to this subaward in the fiscal year ended March 31, 2021.

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 $2,072,000 and $927,000 in the fiscal years ended March 31, 2021 and 2020, 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 issued patents and pending applications worldwide. We currently have five issued U.S. patents and 35 issued patents in countries outside of the United States. In addition, we have 11 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 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:

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	10/2/29
8,288,172	Extracorporeal removal of microvesicular particles	10/16/12	Owned	3/30/29
7,226,429	Method for removal of viruses from blood by lectin affinity hemodialysis	6/5/07	Owned	1/20/24
10,022,483	Method for removal of viruses from blood by lectin affinity hemodialysis	7/17/18	Owned	1/20/24

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
16/506,864	Brain specific exosome based diagnostics and extracorporeal therapies	7/09/19	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
16/883,624	Plasma exosomal tau as a biomarker for chronic traumatic encephalopathy	5/26/20	Owned

Foreign Patents

PATENT #	PATENT NAME	ISSUANCE DATE	OWNED OR LICENSED	EXPIRATION DATE
3110977	Brain specific exosome based diagnostics and extracorporeal therapies (Denmark)	5/16/18	Owned	9/12/36
3110977	Brain specific exosome based diagnostics and extracorporeal therapies (France)	5/16/18	Owned	9/12/36
3110977	Brain specific exosome based diagnostics and extracorporeal therapies (Germany)	5/16/18	Owned	9/12/36
3110977	Brain specific exosome based diagnostics and extracorporeal therapies (Ireland)	5/16/18	Owned	9/12/36
3110977	Brain specific exosome based diagnostics and extracorporeal therapies (Great Britain)	5/16/18	Owned	9/12/36
3110977	Brain specific exosome based diagnostics and extracorporeal therapies (Sweden)	5/16/18	Owned	9/12/36
3110977	Brain specific exosome based diagnostics and extracorporeal therapies (Netherlands)	5/16/18	Owned	9/12/36
3110977	Brain specific exosome based diagnostics and extracorporeal therapies (Switzerland)	5/16/18	Owned	9/12/36
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
1993600	Extracorporeal removal of microvesicular particles (Germany)	4/24/19	Owned	1/20/24
1993600	Extracorporeal removal of microvesicular particles (Switzerland)	4/24/19	Owned	1/20/24
1993600	Extracorporeal removal of microvesicular particles (Spain)	4/24/19	Owned	1/20/24
1993600	Extracorporeal removal of microvesicular particles (France)	4/24/19	Owned	1/20/24
1993600	Extracorporeal removal of microvesicular particles (Great Britain)	4/24/19	Owned	1/20/24
1993600	Extracorporeal removal of microvesicular particles (Italy)	4/24/19	Owned	1/20/24
1993600	Extracorporeal removal of microvesicular particles (Netherlands)	4/24/19	Owned	1/20/24
1993600	Extracorporeal removal of microvesicular particles (Sweden)	4/24/19	Owned	1/20/24
1126138	Extracorporeal removal of microvesicular particles (Hong Kong)	6/19/20	Owned	1/20/24
3517151	Extracorporeal removal of microvesicular particles (Europe – not yet validated)	4/21/21	Owned	1/20/24
3366784	Brain specific exosome based diagnostics and extracorporeal therapies (Great Britain)	11/13/19	Owned	9/12/36
3366784	Brain specific exosome based diagnostics and extracorporeal therapies (France)	11/13/19	Owned	9/12/36
3366784	Brain specific exosome based diagnostics and extracorporeal therapies (Germany)	11/13/19	Owned	9/12/36
3366784	Brain specific exosome based diagnostics and extracorporeal therapies (Netherlands)	11/13/19	Owned	9/12/36

Foreign Patent Applications

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
DE 112016001400.7	Methods of delivering regional citrate anticoagulation (RCA) during extracorporeal blood treatments	10/23/17	Owned
8139/DELNP/2008	Extracorporeal removal of microvesicular particles (exosomes) (India)	3/9/07	Owned
3061952	Extracorporeal removal of microvesicular particles (Canada)	11/18/19	Owned
2939652	Brain specific exosome based diagnostics and extracorporeal therapies (Canada)	8/12/06	Owned
16867003.2	Plasma exosomal tau as a biomarker for chronic traumatic encephalopathy	11/16/16	Owned

International Patent Applications

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
PCT/US2021/ 026377	Devices and methods for treating a coronavirus infection and symptoms thereof	4/08/21	Owned

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 U.S. as of October 2012. The agreement provided for an upfront payment of 53 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 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.

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 FDA's Center for Devices and Radiological Health, or 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 (beginning January 1, 2022) 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 U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, PPACA, 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 PPACA-mandated medical device tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, the Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by two percent through fiscal year 2030. However, COVID-19 relief legislation suspended the two percent Medicare sequester from May 1, 2020 through December 31, 2021. These reductions may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Furthermore, the healthcare industry in the U.S. 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. 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.

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 U.S. 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 U.S., 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

Manufacturing of our Hemopurifier occurs in collaboration with two contract manufacturers based in California under Good Manufacturing Practice, or GMP, regulations promulgated by the FDA. Our contract manufacturers are registered with the FDA. To date, our manufacture of the Hemopurifier has been limited to quantities necessary to support our clinical studies.

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 are currently assembled by Aethlon personnel in a GMP manufacturing facility provided by Life Science Outsourcing, Inc, or LSO. In the future, we plan to bring 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 and stored at LSO prior to use in manufacturing. Specifically, the Hemopurifier contains three critical components with limited available suppliers. 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. The GNA lectin is sourced from Vector Laboratories Inc. and also is available from other suppliers; however, Sigma Aldrich is the only approved back up supplier at this time. A business interruption at any of these sources could have a material impact on our ability to manufacture the Hemopurifier.

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

We have ten full-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, 2021 and March 31, 2020, in the amounts of $659,104, and $650,187, respectively, primarily from our contracts with the NIH. Our revenues, from research grants, continue to be insufficient to cover our cost of operations. It is possible that we may not be able to enter into future government contracts beyond our current contract with the NIH. Future profitability, if any, will require the successful commercialization of our Hemopurifier technology, other products that may emerge from our potential diagnostic products or from additional government contract or grant income. 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.

We will require additional financing to sustain our operations.

We will require significant additional financing for our operations and for expected additional future clinical trials in the U.S., as well as to fund all of our 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. If the financing we may require to sustain our working capital needs is unavailable to us on reasonable terms, or at all, we may be unable to support our research and FDA development activities, including our planned clinical trials. The failure to implement our research and clearance activities would have a material adverse effect on our ability to commercialize our products or continue our business.

We also will need to raise additional funds through debt or equity financings to achieve our business objectives and to satisfy our cash obligations, which may dilute the ownership of our existing stockholders.

We will need to raise additional funds through debt and/or equity financings in order to complete our ultimate business objectives, including funding working capital to support development and regulatory clearance of our potential products. We also may 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 sales of additional equity or convertible debt securities could result in dilution of the equity interests of our existing stockholders, which could be substantial. Also, 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.

Risks Related to Our Business Operations

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 neurodegenerative diseases 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 potential diagnostic products, and obtain FDA and other regulatory approvals necessary for commercializing them, 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 U.S.

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 U.S. 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 dependent in part on our executive officers.

Our success depends to a critical extent on the continued services 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., and our Chief Business Officer, Guy Cipriani. If any of these key executive officers were 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 our business plan and the diversion of limited working capital. The unique knowledge and expertise of these individuals would be difficult to replace within the biotechnology field. 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 either 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 ten full-time employees, consisting of our Chief Executive Officer, our Chief Financial Officer, a Chief Medical Officer, a Chief Business Officer, a Vice President, Manufacturing and Product Development, a Vice President, Clinical Operations, a Project Manager, and three research scientists. 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, including to mitigate the material weakness in our internal control over financial reporting described above. 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 cannot assure you that we will 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, we will be unable to commercialize our products on a large-scale in a timely manner, if at all, and our business could fail.

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 difficult to obtain. 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 U.S. 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 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 U.S. 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 completing our planned clinical trials could jeopardize our ability to obtain regulatory approval.

Our business prospects will depend on our ability to complete studies, clinical trials, including our ongoing Early Feasibility trial in 10 to 12 patients in head and neck cancer and our study in Covid-19 patients, 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:

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

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.

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, 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 U.S., 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. The COVID-19 pandemic could also potentially affect the business of the FDA and comparable authorities in other countries, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates.

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.

Delays, interruptions or the cessation of production by our third-party suppliers of important materials or delays in qualifying new materials, may prevent or delay our ability to manufacture or process 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 may be required if these materials become unavailable from our current suppliers. Although there may be other suppliers that have equivalent materials that would be available to us, FDA review of any alternate suppliers, if required, could take several months or more to obtain, if able to be obtained at all. Any delay, interruption or cessation of production by our third-party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay our ability to manufacture our Hemopurifiers. 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 to us or to any trial sites, we are working to resolve the issue, and concurrently are working to identify alternative suppliers for this component. We believe that our current Hemopurifier inventory is sufficient for the conduct of our current ongoing clinical trials, but it is possible that the need for our Hemopurifiers could increase or the resolution of the issue with one of our current suppliers and identification of an alternative supplier could take longer than expected. Although we intend to procure alternative supply sources for our component and our current supplier intends to correct their issue, we can provide no assurance that we will do so in a timely manner. Any such delays could limit our ability to meet demand for the Hemopurifier and delay our ongoing clinical trials, which would 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 and our product revenues.

We currently outsource most of the manufacturing of our Hemopurifier. 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. The manufacture of our products may 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;
- inclement weather and 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.

If efficient manufacture and supply of our Hemopurifier is interrupted, we may experience delayed shipments or supply constraints. If we are at any time unable to provide an uninterrupted supply of our products for our clinical trials, our ongoing clinical trials may be delayed, which could materially and adversely affect our business, results of operations and financial conditions.

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, 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 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 the much of the day-to-day conduct of conducting clinical trials and manufacturing our current product candidates. 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. It is possible that the current COVID-19 epidemic might constrain the ability of needed third-party vendors to provide services that we require.

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 product candidates 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 product candidates and any other or future product candidates that we may develop 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 under development 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 or Institutional Biosafety Committee, which may delay or make impossible clinical testing of a product candidate. The Institutional Review Board 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 manufacture, sales and marketing of 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 recently 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 U.S., 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 (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 studies.

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 U.S. 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 U.S. 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 U.S. 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 and Ebola. We do have preclinical data suggesting that it could clear a closely related coronavirus (MERS).

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's plan is to enroll up to 40 subjects at up to 20 centers in the U.S. Subjects will have established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU, and will have acute lung injury and/or severe or life threatening disease, among other criteria. Endpoints for this study, in addition to safety, will include reduction in circulating virus as well as clinical outcomes (NCT # 04595903). The initial sites for this trial, Hoag Memorial Hospital Presbyterian in Newport Beach, CA and Hoag Hospital – Irvine in Irvine, CA and Loma Linda Hospital in Loma Linda, CA, have completed clinical trial agreements, and have received IRB approval in the case of the Hoag hospitals, and are preparing to open for patient enrollment. Under Single Patient Emergency Use regulations, the Company has also treated two patients with COVID-19 with the Hemopurifier.

Additionally, we have a very limited supply of Hemopurifiers and therefore any use in this pandemic will be only investigational in a very small number of patients, even if it appears that the device can help those patients.

Thus, we may not be able to demonstrate the effectiveness of our treatment countermeasures through controlled human efficacy studies. Additionally, a change in government policies could impair our ability to obtain regulatory approval and the FDA may not approve any of our product candidates.

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 U.S. 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 or new 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 once 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 (beginning January 1, 2022) 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 are subject to stringent and changing privacy laws, 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 could lead to government enforcement actions (that could include fines and penalties), a disruption of our clinical trials or commercialization of our products, private litigation, harm to our reputation, or other adverse effects on our business or prospects.

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share personal information and other information, including information we collect in connection with clinical trials, or "Process" or "Processing", as necessary to operate our business, for legal and marketing purposes, and for other business-related purposes.

There are numerous federal, state, local and international laws, regulations and guidance regarding privacy, information security and Processing, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent. We are, or may become, subject to these laws, regulations, and guidance, and we are also subject to the terms of our external and internal privacy and security policies, representations, certifications, standards, publications, frameworks, and contractual obligations to third parties related to privacy, information security and Processing, or Data Protection Obligations.

If we fail, or are perceived to have failed, to address or comply with 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 each, a Material Adverse Impact. 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.

The California Consumer Privacy Act of 2018, CCPA, is an example of the increasingly stringent data protection legislation in the United States. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches and statutory damages ranging from $100 to $750 per violation, which is expected to increase data breach class action litigation and result in significant exposure to costly legal judgements and settlements. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how they are interpreted.

The European Union's General Data Protection Regulation, or GDPR, is an example of the type of data protection legislation being passed in international jurisdictions. The GDPR requires covered businesses to, among other requirements, provide detailed disclosures, contractually commit to data protection measures in our contracts, maintain adequate data security measures, notify regulators and affected individuals of certain data breaches and meet extensive privacy governance and documentation requirements. Companies that violate the GDPR can face private litigation, restrictions on data processing, and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. In addition, the GDPR includes restrictions on cross-border data transfers. A Recent decision by the Court of Justice of the European Union, or the "Schrems II" ruling, however, has created substantial uncertainty regarding how to legally transfer personal data from Europe to the United States. There are few, if any, viable options for us or our vendors to legally transfer personal data from Europe to the United States, which could materially impact our business.

If our security measures, or those maintained on our behalf, are compromised, or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, this could result in a Material Adverse Impact.

In the ordinary course of our business, we 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 whom we rely to help us operate our business. If we, our service providers, partners, or other relevant third parties 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 compromise related to the security, confidentiality, integrity of our (or their) information technology, software, services, communications or data (any, a "Security Breach"), it may result in a Material Adverse Impact (as defined above), including the diversion of funds to address the breach, and interruptions, delays, or outages in our operations and development programs.

Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase. In addition to threats from traditional computer "hackers," threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing) and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). We may also be the subject of phishing attacks, viruses, malware installation, server malfunction, software or hardware failures, loss of data or other computer assets, or other similar issues.

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 security measures or those of third parties upon whom we rely will be effective in protecting against Security Incidents.

Applicable Data Protection Obligations (as defined above) may require us to notify relevant stakeholders of Security Breaches, including affected individuals, partners, collaborators, regulators, law enforcement agencies and others. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to Material Adverse Impacts. There can be no assurances that any limitations or exclusions of liability in our contracts would be adequate or would otherwise 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 insurance coverage, if any, will 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 Material Adverse Impacts arising out of our Processing operations, privacy and security practices, or Security Breaches that we may experience. 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 premium increases or the imposition of large excess or deductible or co-insurance requirements), could have a Material Adverse Impact.

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 U.S. 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 U.S., 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 any of our potential products, including the Hemopurifier, be approved for commercialization, adverse changes in reimbursement policies and procedures by payors 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 U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, PPACA, among other things, reduced and/or limited Medicare reimbursement to certain providers. However, on December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when a decision will be made or how the Supreme Court will rule. The Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by two percent through fiscal year 2030. However, COVID-19 relief legislation suspended the two percent Medicare sequester from May 1, 2020 through December 31, 2021. These reductions may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Furthermore, the healthcare industry in the U.S. 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. Legislation could be adopted in the future that limits payments for our products from governmental payors. It is possible that additional governmental action is 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. 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 the Tax Cuts and Jobs Act of 2017, as modified by the CARES Act, 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 in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act of 2017 or the CARES Act. 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. We believe we have not experienced an ownership change in the past three years, however, we could experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. 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. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023.

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 damages arising from hazardous materials. Our product liability policy has a $5,000,000 limit of liability that would cover certain releases of hazardous substances away from our facilities. For our facilities, our property policy provides $25,000 in coverage for contaminant clean-up or removal and $50,000 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 10 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.

Our business is subject to risks arising from the recent COVID-19 pandemic.

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, communities and business operations, as well as the U.S. and global economy and financial markets.

International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. In response, we have implemented a work from home policy for all non-laboratory employees, following the guidelines or directives issued by federal, state and local government agencies in the U.S.

To date, we do not currently anticipate any interruptions in supply. In addition, while we are continuing the process of getting our clinical trial underway, we expect that COVID-19 precautions may directly or indirectly impact the timeline for the trial. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, clinical trials and manufacturing and supply chains, including:

- further delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and interruption in global shipping that may affect the transport of clinical trial materials;

- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- delays in receiving feedback or approvals from the FDA or other regulatory authorities with respect to future clinical trials or regulatory submissions;

- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA to accept data from clinical trials in affected geographies; and

- difficulties launching or commercializing products, including due to reduced access to doctors as a result of social distancing protocols.

In addition, the spread of COVID-19 has had and may continue to impact the trading price of shares of our common stock and could further negatively impact our ability to raise additional capital on a timely basis or at all.

The COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 may impact our business, including our clinical trials, manufacturing and supply chains and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the continued geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, continued business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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 Galanthus nivalis agglutinin, or GNA, is sourced from Vector Laboratories, Inc. and also is available from other suppliers; however, Sigma Aldrich is the only approved back up supplier at this time. A business interruption at any of these sources, including interruption resulting from the coronavirus pandemic, could have a material impact on our ability to manufacture the Hemopurifier.

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.

Compliance with laws, regulations, and related interpretations and related legal claims or other regulatory enforcement actions could impact our business, and we face additional risks and uncertainties related to any potential actions resulting from the Securities and Exchange Commission's, or the SEC, ongoing investigation, or any other investigation or action.

On February 7, 2020, the SEC issued an Order of Suspension of Trading, or SEC Order, temporarily suspending trading in our stock for a period of ten days. The SEC Order stated that the suspension was due to concerns regarding the accuracy and adequacy of information in the marketplace that appeared to be disseminated by third party promotors and recent and unusual market activity since at least January 22, 2020. Although our stock resumed trading upon expiration of the SEC Order, we are unable to predict the outcome of the SEC investigation or any other actions the SEC may take in connection therewith. Furthermore, the Company's reputation may be negatively impacted. As a result, the potential impact to the Company's business, if any, cannot be determined.

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 market place 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 five pending U.S. patent applications. We also have 33 issued foreign patents and have applied for six additional international patents. Our issued patents begin to expire in 2024, with the last of these patents expiring in 2036, 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 U.S. 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.

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 is likely to continue 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 subjects us to additional risks. 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 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 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 U.S. Government contractor, we are 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, 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 recent 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 impact our results of operations and liquidity, and 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 our government contract 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

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, or Nasdaq, such as the minimum stockholders' equity requirement or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. For example, in May 2019 we received a letter from Nasdaq indicating that Nasdaq had determined that we had failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2). Nasdaq Listing Rule 5550(a)(2) requires that companies listed on the Nasdaq Capital Market maintain a minimum closing bid price of at least $1.00 per share. In July 2019, we received another letter from Nasdaq indicating that Nasdaq has determined that we have failed to comply with the minimum stockholder's equity requirement of Nasdaq Listing Rule 5550(b)(1). Nasdaq Listing Rule 5550(b)(1) requires that companies listed on the Nasdaq Capital Market maintain a minimum of $2,500,000 in stockholder's equity. If we fail to maintain compliance with these, or any other of the continued listing requirements of The Nasdaq Capital Market, Nasdaq may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with Nasdaq's listing requirements, but any such action taken by us may not be successful.

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 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, including the effects of the ongoing pandemic; 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. If our common stock is subject to the "penny stock" rules promulgated under the Exchange Act, 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 June 10, 2021, the high and low closing sale prices for a share of our common stock were $10.79 and $1.29, 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 of the 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 30,000,000 shares of common stock. We have reserved for issuance 2,836,062 of those shares of common stock for outstanding restricted stock units, stock options and warrants. As of March 31, 2021, we had issued and outstanding 12,150,597 shares of common stock. As a result, as of March 31, 2021 we had 15,013,341 shares of common stock available for issuance to new investors or for use to satisfy indebtedness or pay service providers.

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 2. PROPERTIES

We currently lease approximately 2,600 square feet of executive office space at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123 under a 39-month gross plus utilities lease that commenced on December 1, 2014 and expires on August 31, 2021. The current rental rate under the lease extension is $8,265 per month.

We also rent approximately 1,700 square feet of laboratory space at 11585 Sorrento Valley Road, Suite 109, San Diego, California 92121 at the rate of $6,148 per month on a one-year lease that originally was to expire on November 30, 2020. In December 2020, we entered into a short-term lease extension running from December 1, 2020 through the completion date of our construction of our planned new laboratory space which is adjacent to our current laboratory.

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. The agreement carries a term of 63 months and we will commence paying rent when we take occupancy of those spaces, which is expected to occur in the third calendar quarter of 2021. For the initial year of the lease, the rental rate will be $13,385.55 per month. Thereafter, the base rent will increase each year.

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

We have no disclosure applicable to this item.

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 67 record holders of our common stock at June 21, 2021. 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. SELECTED FINANCIAL DATA

As a Smaller Reporting Company, we are not required to furnish information under this Item 6.

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

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

Overview

We are a medical technology company focused on developing products to diagnose and treat life and organ threatening diseases. The Aethlon Hemopurifier is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier is designed to deplete the presence of circulating tumor-derived exosomes that promote immune suppression, seed the spread of metastasis and inhibit the benefit of leading cancer therapies. 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 life-threatening viruses that are not addressed with approved therapies.

We believe the Hemopurifier can be a substantial advance in the treatment of patients with advanced and metastatic cancer through the clearance of exosomes that promote the growth and spread of tumors through multiple mechanisms. We are currently preparing for the initiation of clinical trials in patients with advanced and metastatic cancers. We are initially focused on the treatment of solid tumors, including head and neck cancer, gastrointestinal cancers and other cancers. As we advance our clinical trials, we are in close contact with our clinical sites to navigate and assess the impact of the COVID-19 global pandemic on our clinical trials and current timelines.

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, which will enroll 10-12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. This study is being conducted at the UPMC Hillman Cancer Center in Pittsburgh, PA, is in the process of recruiting and treating patients.

We also believe 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 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, and the reconstructed Spanish flu virus of 1918. In several cases, these validations were conducted in collaboration with leading government or non-government research institutes.

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's plan is to enroll up to 40 subjects at up to 20 centers in the U.S. Subjects will have established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU, and will have acute lung injury and/or severe or life threatening disease, among other criteria. Endpoints for this study, in addition to safety, will include reduction in circulating virus as well as clinical outcomes (NCT # 04595903). The initial sites for this trial, Hoag Memorial Hospital Presbyterian in Newport Beach, CA and Hoag Hospital – Irvine in Irvine, CA and Loma Linda Hospital in Loma Linda, CA, have completed clinical trial agreements, and have received IRB approval in the case of the Hoag hospitals, and are preparing to open for patient enrollment. Under Single Patient Emergency Use regulations, the Company has also treated two patients with COVID-19 with the Hemopurifier.

We are also the majority owner of Exosome Sciences, Inc., or ESI, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. Included among ESI's activities is the advancement of a TauSome™ biomarker candidate to diagnose chronic traumatic encephalopathy, or CTE, in the living. ESI previously documented TauSome levels in former NFL players to be nine times higher than same age-group control subjects. Through ESI, we are also developing exosome based biomarkers in patients with, or at risk for, a number of cancers. We consolidate ESI's activities in our consolidated financial statements.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we plan to 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 more recently will help protect the proprietary nature of the Hemopurifier treatment technology.

We were formed on March 10, 1999. Our executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. Our website address is www.aethlonmedical.com.

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

COVID-19 Update

In March 2020, the World Health Organization declared COVID-19 a global pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets.

We are monitoring closely the impact of the COVID-19 global pandemic on our business and have taken steps designed to protect the health and safety of our employees while continuing our operations, including clinical trials. Given the level of uncertainty regarding the duration and impact of the COVID-19 pandemic on capital markets and the U.S. economy, we are unable to assess the impact of the worldwide spread of SARS-CoV-2 and the resulting COVID-19 pandemic on our future access to capital. Further, while we have not experienced significant disruptions to our manufacturing supply chain, business, results of operations, financial condition, clinical trials, or preclinical research to date, we are unable to assess the potential impact this pandemic could have on our manufacturing supply chain, business, results of operations, financial condition, clinical trials, or preclinical research in the future.

As we continue to actively advance our clinical trials, we remain in close contact with our clinical sites and are assessing the impact of COVID-19 on our trials, expected timelines and costs on an ongoing basis. We will assess any potential delays in our ability to timely ship clinical trial materials, including internationally, due to transportation interruptions. The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, impact on our clinical trials, employees and vendors, all of which are uncertain and cannot be predicted. Given these uncertainties, we cannot reasonably estimate the related impact to our business, operating results and financial condition, if any.

Fiscal Years Ended March 31, 2021 and 2020

Results of Operations

Government Contract Revenues

We recorded government contract revenue in the fiscal years ended March 31, 2021 and 2020. This revenue resulted from work performed under our government contracts with the NIH and our subaward with the University of Pittsburgh as follows:

	Fiscal Year Ended 3/31/21	Fiscal Year Ended 3/31/20	Change in Dollars
Phase 2 Melanoma Cancer Contract	$ 436,427	$ 620,187	$ (183,760)
Breast Cancer Grant	188,444	30,000	158,444
Subaward with University of Pittsburgh	34,233	–	34,233
Total Government Contract and Grant Revenue	$ 659,104	$ 650,187	$ 8,917

We have recognized revenue under the following three government contracts/grants over the past two years:

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 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 is $1,860,561 and runs for the period from September 16, 2019 through September 15, 2021.

The work to be performed pursuant to this Award Contract focuses on melanoma exosomes. This work follows from our completion of a phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018. Following on the phase I work, the deliverables in the phase II program involve the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

During the fiscal year ended March 31, 2021, we completed the milestones relevant to the first nine months of the fiscal year. As a result, we recorded $436,427 of government contract revenue on the Phase 2 Melanoma Cancer Contract in the fiscal year ended March 31, 2021. Of the total revenue recognized during the current period relating to this grant, a total of $117,849 was invoiced to the NCI during the three months ended December 31, 2020 and we recorded $318,578 which had previously been recognized as deferred revenue.

During the three month period ended March 31, 2021, we did not complete all of the milestones relevant to that time period, as a result, we recorded $114,849 as deferred revenue related to the Phase 2 Melanoma Cancer Contract.

Breast Cancer Grant

In the fiscal year ended March 31, 2021, we completed and submitted the final reports applicable to this NCI grant (number 1R43CA232977-01). The title of this Small Business Innovation Research, or SBIR, Phase I grant is "The Hemopurifier Device for Targeted Removal of Breast Cancer Exosomes from the Blood Circulation," or the Breast Cancer Grant.

This NCI Phase I grant period originally ran from September 14, 2018 through August 31, 2019. In August 2019, we applied for and received a no cost, twelve month extension on this grant; through August 31, 2020. The total amount of the firm grant was $298,444. The grant called for two subcontractors to work with us. Those subcontractors were University of Pittsburgh and Massachusetts General Hospital.

During the fiscal year ended March 31, 2021, we recorded the remaining $188,444 of revenue related to the Breast Cancer Grant, as we achieved two of the three milestones related to the Breast Cancer Grant. We concluded in our final report to the SBIR that our pre-clinical results demonstrated that our work under the grant provided support that the Hemopurifier has the capacity to clear exosomes from breast cancer patients. That amount previously was recorded as deferred revenue.

As of March 31, 2021, we received all of the funds allocated to the Breast Cancer Grant and have submitted the final reports applicable to this grant.

Subaward with University of Pittsburgh

In 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 is $256,750. We recorded $34,233 of revenue related to this subaward in the fiscal year ended March 31, 2021.

Operating Costs and Expenses

Consolidated operating expenses were $8,549,023 for the fiscal year ended March 31, 2021, compared to $6,580,175 for the fiscal year ended March 31, 2020, an increase of $1,968,848. The $1,968,848 increase was due to increases in payroll and related expenses of $1,152,342 and in general and administrative expense of $907,867, which were partially offset by a decrease of $91,361 in professional fees.

The $1,152,342 increase in fiscal year ended March 31, 2021 in our payroll and related expenses was due to an increase in cash-based compensation of $1,216,919, which was partially offset by a decrease in our stock-based compensation of $64,577. Approximately $444,729 of the increase in cash-based compensation related to an accrual for severance payments to our former Chief Executive Officer.

The $907,867 increase in fiscal year ended March 31, 2021 in our general and administrative expenses primarily arose from increases of $460,817 in our clinical trial expenses and $469,304 in laboratory supplies.

The $91,361 decrease in fiscal year ended March 31, 2021 in our professional fees primarily arose from decreases of $295,022 in legal fees and $116,536 in accounting fees, which were partially offset by increases of $179,457 in scientific consulting fees, $94,548 in recruiting fees and $58,966 in contract labor costs.

Other Expense

In the fiscal year ended March 31, 2021, we recognized other expenses of $1,580, compared to $450,053 of other expense in the fiscal year ended March 31, 2020. The following table breaks out the various components of our other expense over the fiscal years ended March 31, 2021 and 2020:

	Components of Other Expense in Fiscal Year Ended		
	March 31, 2021	March 31, 2020	Change
Loss on debt extinguishment	$ –	$ 447,011	$ (447,011)
(Gain) on share for warrant exchanges	–	(51,190)	51,190
Interest and other debt expenses	1,580	54,232	(52,652)
Total other expense	$ 1,580	$ 450,053	$ (448,473)

Loss on Debt Extinguishment

During the fiscal year ended March 31, 2020, we reduced the conversion price on our outstanding convertible notes from $45.00 per share to $10.20 per share. The modification of the convertible notes was evaluated under ASC 470-50-40 and the instruments were determined to be substantially different, and the transaction qualified for extinguishment accounting. Under the extinguishment accounting we recorded a loss on debt extinguishment of $447,011. There was no comparable loss on debt extinguishment in the fiscal year ended March 31, 2021.

Gain on Common Stock for Warrant Cancellation

During the fiscal year ended March 31, 2020, we agreed with seven accredited investors to issue an aggregate of 3,992 shares of our common stock to these investors in exchange for the cancellation of outstanding warrants then held by the investors to purchase an aggregate of 39,900 shares of our common stock. We measured the fair value of the shares issued and the fair value of the warrants exchanged for those shares and recorded a gain of $51,190 on those exchanges based on the changes in fair value between the instruments exchanged. There was no comparable gain on common stock for warrant cancellation in the fiscal year ended March 31, 2021.

Interest and Other Debt Expenses

Our interest and other debt expense decreased by $52,652 in the fiscal year ended March 31, 2021, from the fiscal year ended March 31, 2020. The following table breaks out the various components of our interest expense over the fiscal years ended March 31, 2021 and 2020:

	Components of Interest Expense and Other Debt Expenses in Fiscal Year Ended		
	March 31, 2021	March 31, 2020	Change
Interest expense and financing charges	$ 1,580	$ 23,945	$ (22,365)
Amortization of note discounts	–	30,287	(30,287)
Total interest and other debt expenses	$ 1,580	$ 54,232	$ (52,652)

As noted in the above table, the factors in the $52,652 overall decrease in fiscal year ended March 21, 2021 in interest and other debt expenses were a $30,287 decrease in the amortization of note discounts and a $22,365 decrease in interest expense in fiscal year ended March 31, 2021 as the result of paying off our convertible notes.

As a result of the above factors, our net loss before noncontrolling interests increased to $7,891,499 for the fiscal year ended March 31, 2021, from $6,380,041 for the fiscal year ended March 31, 2020.

Liquidity and Capital Resources

At March 31, 2021, we had a cash balance of $9,861,575 and working capital of $8,976,512. This compares to a cash balance of $9,604,780 and working capital of $8,973,393 at March 31, 2020. We expect our existing cash as of March 31, 2021 to be sufficient to fund the Company's operations for at least twelve months from the issuance date of this Form 10-K.

The primary source of our increase in cash during the fiscal year ended March 31, 2021 resulted from our Common Stock Sales Agreement with H.C. Wainwright & Co., LLC, or Wainwright, entered into originally in 2016. The cash raised from that activity is described below:

Common Stock Sales Agreement with Wainwright

On June 28, 2016, we entered into a Common Stock Sales Agreement, or the 2016 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 2016 Agreement. The 2016 Agreement provided for the sale of shares of our common stock having an aggregate offering price of up to $12,500,000.

On March 30, 2020, we executed Amendment No. 2 to the 2016 Agreement with Wainwright, effective as of the same date. The amendment provides that references in the 2016 Agreement to the registration statement shall refer to the registration statement on Form S-3 (File No. 333-237269), originally filed with the SEC on March 19, 2020, declared effective by the SEC on March 30, 2020.

Subject to the terms and conditions set forth in the 2016 Agreement, Wainwright agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares under the 2016 Agreement from time to time, based upon our instructions. We provided Wainwright with customary indemnification rights under the 2016 Agreement, and Wainwright is entitled to a commission at a fixed rate equal to three percent of the gross proceeds per share sold. In addition, we agreed to pay certain expenses incurred by Wainwright in connection with the 2016 Agreement, including up to $50,000 of the fees and disbursements of their counsel. The 2016 Agreement will terminate upon the sale of all of the shares under the 2016 Agreement, unless terminated earlier by either party as permitted under the 2016 Agreement.

As of March 31, 2021, no further sales will be made under the 2016 Agreement.

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

The offering was registered under the Securities Act of 1933, as amended, or 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 may 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 Offering Agreement, Wainwright agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares under the Offering Agreement from time to time, based upon our instructions. We provided Wainwright with customary indemnification rights under the Offering Agreement, and Wainwright is entitled to a commission at a fixed rate equal 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 Offering Agreement. The Offering Agreement will terminate upon the written termination by either party as permitted thereunder.

Sales of the shares, if any, under the 2016 Agreement and the Offering Agreement will be 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. We have no obligation to sell any of the shares, and, at any time, we may suspend offers under the 2016 Agreement and the Offering Agreement or terminate the Agreement.

In the fiscal year ended March 31, 2021, we raised aggregate net proceeds of $7,260,869, net of $224,825 in commissions to Wainwright and $8,472 in other offering expenses, under the 2016 Agreement through the sale of 2,685,600 shares at an average price of $2.70 per share of net proceeds.

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.

As a result of the COVID-19 pandemic and actions taken to slow its spread, 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 unemployment rates 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.

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):

	(In thousands) For the year ended	
	March 31, 2021	March 31, 2020
Cash (used in) provided by:		
Operating activities	$ (6,765)	$ (5,198)
Investing activities	(60)	(152)
Financing activities	7,128	11,126
Net increase in cash	$ 303	$ 5,776

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 $6,765,000 in fiscal 2021, compared to net cash used in operating activities of approximately $5,198,000 in fiscal 2020, an increase of approximately $1,567,000. The primary factors in this $1,567,000 increase in cash used in operations was a $1,511,000 increase in our net loss.

Net Cash Used in Investing Activities

During the fiscal years ended March 31, 2121 and 2020, we purchased approximately $60,000 and $152,000 of equipment, respectively.

Net Cash from Financing Activities

Net cash generated from financing activities decreased from approximately $11,126,000 in the fiscal year ended March 31, 2020 to approximately $7,128,000 in the fiscal year ended March 31, 2021.

In the fiscal year ended March 31, 2021, we raised approximately $7,261,000 from the issuance of common stock, which was partially offset by the use of approximately $133,000 to pay for the tax withholding on the issuance of restricted stock units. In the fiscal year ended March 31, 2020, we raised approximately $12,160,000 from the issuance of common stock. We used approximately $993,000 to pay off our convertible notes in the fiscal year ended March 31, 2020 and we also used approximately $41,000 to pay for the tax withholding on restricted stock units issued in the fiscal year ended March 31, 2020.

Recent Events

RSU Grants

On April 1, 2021, pursuant to the terms of the Company's 2012 Non-Employee Directors Compensation Program, as amended, or the Directors Plan, the Compensation Committee of the Board granted RSUs under the Company's 2020 Equity Incentive Plan, or the 2020 Plan, to each non-employee director of the Company. The Director's Plan provides for a grant of $50,000 worth of RSUs at the beginning of each fiscal year, 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 RSU's are 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.

Sales Under ATM Facility

In June 2021, we raised aggregate net proceeds of $4,947,785, net of $126,922 in commissions to Wainwright and $2,154 in other offering expenses, under the Offering Agreement described above through the sale of 626,000 shares of our common stock at an average purchase price of $8.11 per share of gross proceeds.

Registered Direct Financing

In June 2021, we sold an aggregate of 1,380,555 shares of our common stock at a purchase price per share of $9.00, for aggregate gross proceeds to us of approximately $12.425 million, before deducting fees payable to Maxim Group LLC, the placement agent and other offering expenses. These shares were sold pursuant to a securities purchase agreement entered into by the Company with certain institutional investors, The shares of common stock were issued in this offering 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) (the "Registration Statement") and a prospectus supplement thereunder.

Warrant Exercises

In June 2021, pursuant to the exercise of outstanding warrants held by institutional investors, we issued 531,167 shares of our common stock and received proceeds in the amount of $820,938.

Also in June 2021, pursuant to the exercise on a cashless, net exercise basis, of 874,664 outstanding warrants, we issued 675,554 shares of our common stock. The difference of 199,110 outstanding warrants were cancelled in connection with the exercise.

Critical Accounting Policies

Use of 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 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.

Revenue Recognition

Our revenues consist entirely of amounts earned under contracts and grants with the National Institutes of Health, or NIH. During the fiscal years ended March 31, 2021 and 2020, we recognized revenues totaling $659,104 and $650,187, 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 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

We often grant 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.

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, 2021 or March 31, 2020.

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.

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 effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Convertible Notes Payable and Warrants

In July 2019, we paid off our then outstanding convertible notes in the amount of $992,591. There were no convertible notes outstanding as of March 31, 2021 or 2020.

Restricted Stock Unit Grants to Non-Employee Directors

In 2012, as amended through October 30, 2020, our Board of Directors established the Non-Employee Directors Compensation Program, to provide for cash and equity compensation for persons serving as non-employee directors of the Company. Under this program, each new director receives either stock options or a grant of restricted stock units, or RSUs, as well as an annual grant of RSUs at the beginning of each fiscal year. The 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 3, 2020, pursuant to the terms of the Company's Non-Employee Directors Compensation Program, the Compensation Committee of the Board of Directors granted RSUs to each non-employee director of the Company. The Non-Employee Directors Compensation Program provided for a grant of RSUs with a grant date fair value of $35,000, priced at the average of the closing prices for the five trading days ending on the date of grant, which was $1.41 per share, so that the total number of RSUs to be granted to each non-employee director for fiscal year 2020 would be 24,822 shares of our common stock. On April 3, 2020, each eligible director was granted an RSU for 23,893 shares under the Company's 2010 Stock Plan, or the 2010 Plan, as the number of shares that remained available for grant under the 2010 Plan was not sufficient for each director's full RSU grant. The Compensation Committee also granted to each eligible director a contingent grant under our 2020 Equity Incentive Plan, or the 2020 Plan, for the remaining portion of the annual RSU grants, or 929 RSU's to each eligible director, contingent upon stockholder approval of the 2020 Plan at the Company's 2020 Annual Meeting of Stockholders, or the Annual Meeting. These grants are subject to vesting as follows: 50% of the RSUs subject to the grants will vest on December 31, 2020 and 50% of the RSUs will vest on March 31, 2021, subject in each case to the continuous service of each director, through such vesting dates, as well as approval of the 2020 Plan by the stockholders at the Annual Meeting, which was obtained at the Annual Meeting.

In June 2020, 29,866 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 11,947 of the vested RSUs being cancelled in exchange for $24,251 in aggregate cash proceeds to those independent directors.

In September 2020, 29,866 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 11,947 of the vested RSUs being cancelled in exchange for $16,128 in aggregate cash proceeds to those independent directors.

Also in September 2020, our stockholders approved the 2020 Plan at the Annual Meeting, at which point the grants of 929 RSUs to each of our eligible independent directors for a total of 4,645 RSUs were considered effective and no longer contingent as of that date.

In December 2020, 32,189 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 12,876 of the vested RSUs being cancelled in exchange for $31,802 in aggregate cash proceeds to those independent directors.

In March 2021, 32,189 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 12,875 of the vested RSUs being cancelled in exchange for $26,136 in aggregate cash proceeds to those independent directors.

There were no vested RSUs outstanding as of March 31, 2021.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a Smaller Reporting Company, we are not required to furnish information under this Item 7A.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements listed in the accompanying Index to Financial Statements are attached hereto and filed as a part of this Report under Item 15.

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 Securities Exchange Act of 1934, as amended, or 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 principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosures.

In designing and evaluating the disclosure controls and procedures, we recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we were required to apply our 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 report under the supervision and with the participation of our management, including our 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 report, our disclosure controls and procedures were effective.

Internal Control over Financial Reporting

(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 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, 2021. 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 effective as of March 31, 2021.

(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, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

We have no disclosure applicable to this item.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Except as set forth below, the information required by this item will be contained in our Definitive Proxy Statement to be filed with the SEC in connection with our 2021 Annual Meeting of Stockholders, the Proxy Statement, within 120 days after the end of the fiscal year ended March 31, 2021, and is incorporated herein by reference.

On February 23, 2005, the Board of Directors approved a "Code of Business Conduct and Ethics," or the Code, which applies to our principal executive officer, our principal financial officer, our principal accounting officer and persons performing similar tasks. On February 6, 2020, the Board of Directors adopted an amended Code, which supersedes the Company's existing Code previously adopted by the Board of Directors. Our Code is available on our company website at www.aethlonmedical.com. If we make any substantive amendments to, or grant any waivers from, the Code of Business Conduct and Ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained 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 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 our Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be contained in our Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS ANDFINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report on Form 10-K:

1. Consolidated Financial Statements for the years ended March 31, 2021 and 2020:
   - Report of Independent Registered Public Accounting Firm
   - Consolidated Balance Sheets
   - Consolidated Statements of Operations
   - Consolidated Statements of Equity
   - Consolidated Statements of Cash Flows
   - Notes to Consolidated Financial Statements

2. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	SEC File No.	Exhibit Number	Date	
3.1	Articles of Incorporation.	S-3	333-211151	3.1	May 5, 2016	
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 Common Stock Purchase Warrant dated August 29, 2012.	8-K	000-21846	4.1	September 6, 2012	
4.3	Form of Common Stock Purchase Warrant dated October, November and December 2012.	10-Q	000-21846	4.1	February 13, 2013	
4.4	Form of Common Stock Purchase Warrant dated June 14, 2013.	10-Q	000-21846	4.1	August 13, 2013	
4.5	Form of Common Stock Purchase Warrant dated June 24, 2014.	8-K	000-21846	4.1	June 30, 2014	
4.6	Form of Common Stock Purchase Warrant dated July 24, 2014.	8-K	000-21846	4.1	July 28, 2014	
4.7	Form of Common Stock Purchase Warrant dated August and September 2014.	10-Q	000-21846	4.3	November 10, 2014	

4.10	Form of Warrant Agreement dated March 27, 2017.	8-K	001-37487	4.1	March 22, 2017
4.11	Form of Warrant dated _____, 2017.	S-1/A	333-219589	4.29	September 18, 2017
4.12	Form of Placement Agent Warrant dated _____, 2017.	S-1/A	333-219589	4.30	September 22, 2017
4.13	Form of Warrant to Purchase Common Stock.	S-1/A	333-234712	4.14	December 11, 2019
4.14	Form of Underwriter Warrant.	S-1/A	333-234712	4.15	December 11, 2019
4.15	Form of Common Stock Purchase Warrant.	8-K	001-37487	4.1	January 17, 2020
4.16	Description of Aethlon Medical, Inc.'s Securities.	10-K	001-37487	4.16	June 25, 2020
10.1	Amended 2010 Stock Incentive Plan. ++	8-K	001-37487	10.1	March 30, 2016
10.2	Standard Industrial Net Lease, by and between Glenborough Aventine, LLC and Aethlon Medical, Inc., dated September 28, 2009.	10-Q	000-21846	10.6	November 16, 2009
10.3	Second Amendment to Standard Industrial Net Lease, by and between AGP Sorrento Business Complex and Aethlon Medical, Inc., dated October 10, 2014.	S-1	333-201334	10.52	December 31, 2014
10.4	Office Lease, by and between T-C Stonecrest LLC and Aethlon Medical, Inc., dated November 13, 2014.	8-K/A	000-21846	10.1	November 19, 2014
10.5	UCI Clinical Trial Agreement, by and between The Regents of the University of California, on behalf of its Irvine campus and Aethlon Medical, Inc., dated March 24, 2015.	8-K	000-21846	10.1	April 15, 2015
10.8	Third Amendment to Standard Industrial Net Lease, by and between AGP Sorrento Business Complex, L.P. and Aethlon Medical, Inc., dated October 21, 2015.	10-Q	001-37487	10.5	November 16, 2015
10.9	Common Stock Sales Agreement, by and between H.C. Wainwright & Co., LLC and Aethlon Medical, Inc., dated June 28, 2016.	8-K	001-37487	10.1	June 28, 2016

10.10	Amendment No. 1 to Common Stock Sales Agreement, by and between H.C. Wainwright & Co., LLC and Aethlon Medical, Inc., dated June 28, 2016.	8-K	001-37487	10.1	August 12, 2019	
10.11	Amendment No. 2 to Common Stock Sales Agreement, by and between H.C. Wainwright & Co., LLC and Aethlon Medical, Inc., dated March 30, 2020.	10-Q	001-37487	10.1	August 11, 2020	
10.12	Aethlon Medical, Inc. Amended and Restated Non-Employee Directors Compensation Policy, as Modified on October 30, 2020.					X
10.13	Fourth Amendment to Standard Industrial Net Lease, by and between AGP Sorrento Business Complex, L.P. and Aethlon Medical, Inc., dated October 5, 2016.	10-K	001-37487	10.80	June 28, 2017	
10.14	Form of Securities Purchase Agreement, by and among each purchaser identified on the signature pages therein and Aethlon Medical, Inc., dated March 22, 2017. ++	8-K	001-37487	10.1	March 22, 2017	
10.15	Form of Securities Purchase Agreement, by and among each purchaser identified on the signature pages therein and Aethlon Medical, Inc., dated September _____, 2017. ++	S-1	333-220490	10.84	September 15, 2017	
10.16	Fifth Amendment to Standard Industrial Net Lease, by and between AGP Sorrento Business Complex, L.P. and Aethlon Medical, Inc., dated October 16, 2017.	10-Q	001-37487	10.1	November 2, 2017	
10.17	Sixth Amendment to Standard Industrial Net Lease, by and between AGP Sorrento Business Complex, L.P. and Aethlon Medical, Inc., dated September 18, 2018.	10-Q	001-37487	10.1	November 6, 2018	
10.18	Employment Agreement, by and between Aethlon Medical, Inc. and James Frakes, dated December 12, 2018. ++	10-Q	001-37487	10.3	February 11, 2019	
10.19	Form of Indemnification Agreement for Officers and Directors. ++	10-Q	001-37487	10.4	February 11, 2019	
10.20	Form of Option Grant Agreement for Officers and Directors. ++	10-Q	001-37487	10.5	February 11, 2019	

10.21	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for Directors. ++	10-Q	001-37487	10.6	February 11, 2019
10.22	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for Executives. ++	10-Q	001-37487	10.7	February 11, 2019
10.23	Seventh Amendment to Standard Industrial Net Lease, by and between Aethlon Medical, Inc. and San Diego Inspire 1, LLC., dated September 9, 2019.	10-Q	001-37487	10.1	November 1, 2019
10.24	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
10.25	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
10.26	Form of Securities Purchase Agreement, by and between Aethlon Medical, Inc. and the Purchasers thereto, dated January 17, 2020.	8-K	001-37487	10.1	January 17, 2020
10.27	Aethlon Medical, Inc. 2020 Equity Incentive Plan, Form of Restricted Stock Grant, Form of Option Grant and Agreement.	8-K	001-37487	10.1	September 15, 2020
10.28	Separation Agreement between the Company and Dr. Rodell, dated October 30, 2020.	8-K	001-37487	10.1	November 3, 2020
10.29	Employment Agreement between the Company and Dr. Fisher, dated October 30, 2020.	8-K	001-37487	10.2	November 3, 2020
10.30	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
10.31	Eighth Amendment to Standard Industrial Net Lease, by and between the Company and San Diego Inspire 1, LLC., effective December 7, 2020.	10-Q	001-37487	10.4	February 10, 2021

10.32	Executive Employment Agreement between the Company and Guy Cipriani, dated January 1, 2021.	10-Q	001-37487	10.5	February 10, 2021	
10.33	Executive Employment Agreement between the Company and Steven P. LaRosa, MD, dated January 4, 2021.	10-Q	001-37487	10.6	February 10, 2021	
10.34	At the Market Offering Agreement, March 22, 2021, by and between Aethlon Medical, Inc. and H.C. Wainwright & CO., LLC.	8-K	001-37487	1.1	March 22, 2021	
21.1	List of Subsidiaries.	S-1	333-201334	21.1	December 31, 2014	
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of our Chief Executive Officer, pursuant to Securities Exchange Act rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.					X
31.2	Certification of our Chief Financial Officer, pursuant to Securities Exchange Act rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.					X
32.1	Statement of our Chief Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).					X
32.2	Statement of our Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Schema Document					X
101.CAL	XBRL Calculation Linkbase Document					X
101.DEF	XBRL Definition Linkbase Document					X
101.LAB	XBRL Label Linkbase Document					X
101.PRE	XBRL Presentation Linkbase Document					X

++Indicates management contract or compensatory plan.

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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 24th day of June, 2021.

By: /s/ CHARLES J. FISHER, JR., M.D.
Charles J. Fisher, Jr., M.D.
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 Timothy C. Rodell, 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 and agents, and each of them, 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 and agents, or any of them, or their 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, 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, JR., MD Charles J. Fisher, Jr., MD	Chief Executive Officer, Principal Executive Officer and Director	June 24, 2021
/s/ JAMES B. FRAKES James B. Frakes	Chief Financial Officer and Principal Accounting Officer	June 24, 2021
/s/ EDWARD G. BROENNIMAN Edward G. Broenniman	Chairman and Director	June 24, 2021
/s/ CHETAN S. SHAH Chetan S. Shah	Director	June 24, 2021
/s/ SABRINA MARTUCCI JOHNSON Sabrina Martucci Johnson	Director	June 24, 2021
/s/ GUY CIPRIANI Guy Cipriani	SVP and Chief Business Officer and Director	June 24, 2021

AETHLON MEDICAL, INC. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2021 and 2020, the related consolidated statements of operations, 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, 2021 and 2020, 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.

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.

Baker Tilly US, LLP

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

San Diego, California
June 24, 2021

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	March 31, 2021	March 31, 2020
ASSETS		
CURRENT ASSETS		
Cash	$ 9,861,575	$ 9,604,780
Accounts receivable	149,082	206,729
Prepaid expenses and other current assets	341,081	229,604
TOTAL CURRENT ASSETS	10,351,738	10,041,113
Property and equipment, net	160,976	140,484
Right-of-use lease asset	40,363	136,426
Patents, net	56,954	57,504
Restricted cash	46,726	–
Deposits	12,159	12,159
TOTAL ASSETS	$ 10,668,916	$ 10,387,686
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 337,678	$ 285,036
Due to related parties	118,520	111,707
Deferred revenue	114,849	100,000
Lease liability, current portion	42,543	98,557
Other current liabilities	761,636	472,420
TOTAL CURRENT LIABILITIES	1,375,226	1,067,720
Lease liability, less current portion	–	42,540
TOTAL LIABILITIES	1,375,226	1,110,260
COMMITMENTS AND CONTINGENCIES (Note 11)		
STOCKHOLDERS' EQUITY		
Common stock, $0.001 par value, 30,000,000 shares authorized at March 31, 2021 and 2020; 12,150,597 and 9,366,873 issued and outstanding at March 31, 2021 and 2020, respectively	12,152	9,368
Additional paid-in capital	129,331,542	121,426,563
Accumulated deficit	(119,913,090)	(112,026,381)
TOTAL AETHLON MEDICAL, INC. STOCKHOLDERS' EQUITY BEFORE NONCONTROLLING INTERESTS	9,430,604	9,409,550
NONCONTROLLING INTERESTS	(136,914)	(132,124)
TOTAL STOCKHOLDERS' EQUITY	9,293,690	9,277,426
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 10,668,916	$ 10,387,686

See accompanying notes to the consolidated financial statements.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended March 31,	
	2021	2020
REVENUES:		
Government contract and grant revenue	$ 659,104	$ 650,187
Total revenues	659,104	650,187
OPERATING COSTS AND EXPENSES		
Professional fees	2,637,664	2,729,025
Payroll and related expenses	3,454,941	2,302,599
General and administrative	2,456,418	1,548,551
Total operating expenses	8,549,023	6,580,175
OPERATING LOSS	(7,889,919)	(5,929,988)
OTHER EXPENSE		
Loss on debt extinguishment	–	447,011
(Gain) on share for warrant exchanges	–	(51,190)
Interest and other expenses	1,580	54,232
Total other expense	1,580	450,053
NET LOSS BEFORE NONCONTROLLING INTERESTS	(7,891,499)	(6,380,041)
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	(4,790)	(6,093)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (7,886,709)	$ (6,373,948)
Basic and diluted net loss per share attributable to common stockholders	$ (0.65)	$ (1.87)
Weighted average number of common shares outstanding - basic and diluted	12,090,884	3,414,840

See accompanying notes to the consolidated financial statements.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF EQUITY
FOR THE YEARS ENDED MARCH 31, 2021 AND 2020

	ATTRIBUTABLE TO AETHLON MEDICAL, INC.					
	COMMON STOCK		ADDITIONAL PAID IN	ACCUMULATED	NON-CONTROLLING	TOTAL
	SHARES	AMOUNT	CAPITAL	DEFICIT	INTERESTS	EQUITY
BALANCE - MARCH 31, 2019	1,266,979	$ 1,267	$ 108,076,275	$ (105,652,433)	$ (126,031)	$ 2,299,078
Issuances of common stock for cash under at the market program	161,149	162	895,869	–	–	896,031
Loss on debt extinguishment	–	–	447,011	–	–	447,011
Issuances of common stock for cash under warrant exercises	2,700,000	2,700	3,804,462	–	–	3,807,162
Issuance of common shares upon vesting of restricted stock units.	12,393	12	(40,950)	–	–	(40,938)
Proceeds from the issuance of common stock in public offerings, net	5,218,712	5,219	7,451,096	–	–	7,456,315
Issuances of common stock upon warrant exchanges	3,992	4	(51,194)	–	–	(51,190)
Par value of DTC roundup of shares following reverse split	3,946	4	(4)	–	–	–
Adjustment	(298)	–	–	–	–	–
Stock-based compensation expense	–	–	843,998	–	–	843,998
Net loss	–	–	–	(6,373,948)	(6,093)	(6,380,041)
BALANCE - MARCH 31, 2020	9,366,873	$ 9,368	$ 121,426,563	$ (112,026,381)	$ (132,124)	$ 9,277,426
Issuances of common stock for cash under at the market program	2,685,600	2,686	7,258,183	–	–	7,260,869
Issuance of common shares upon vesting of restricted stock units and net stock option exercise	98,124	98	(132,625)	–	–	(132,527)
Stock-based compensation expense	–	–	779,421	–	–	779,421
Net loss	–	–	–	(7,886,709)	(4,790)	(7,891,499)
BALANCE - MARCH 31, 2021	12,150,597	$ 12,152	$ 129,331,542	$ (119,913,090)	$ (136,914)	$ 9,293,690

See accompanying notes to the consolidated financial statements.

AETHLON MEDICAL, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED MARCH 31, 2021 AND 2020

	2021	2020
Cash flows from operating activities:		
Net loss	$ (7,891,499)	$ (6,380,041)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	39,939	26,366
Gain on share for warrant exchanges	–	(51,190)
Loss on debt extinguishment	–	447,011
Stock based compensation	779,421	843,998
Amortization of debt discount and deferred financing costs	–	30,287
Non-cash rent expense	(2,491)	964
Changes in operating assets and liabilities:		
Accounts receivable	57,647	(206,729)
Prepaid expenses and other current assets	(111,477)	(19,562)
Accounts payable and other current liabilities	341,858	(16,765)
Deferred revenue	14,849	100,000
Due to related parties	6,813	28,053
Net cash used in operating activities	(6,764,940)	(5,197,608)
Cash flows from investing activities:		
Purchases of property and equipment	(59,881)	(151,665)
Net cash used in investing activities	(59,881)	(151,665)
Cash flows from financing activities:		
Tax withholding payments or tax equivalent payments for net share settlement of restricted stock units	(132,527)	(40,938)
Principal repayments of notes payable	–	(992,591)
Net proceeds from the issuance of common stock and exercise of warrants	7,260,869	12,159,508
Net cash provided by financing activities	7,128,342	11,125,979
Net increase in cash and restricted cash	303,521	5,776,706
Cash and restricted cash at beginning of year	9,604,780	3,828,074
Cash and restricted cash at end of year	$ 9,908,301	$ 9,604,780
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ –	$ 83,332
Supplemental information of non-cash investing and financing activities:		
Issuance of shares under vested restricted stock units, net stock option exercises and unvested share issuance for services	$ 98	$ 12
Issuance of common stock upon warrant exchanges	$ –	$ 51,190
Initial recognition of right-of-use lease asset and lease liability	$ –	$ 228,694
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets:		
Cash and cash equivalents	$ 9,861,575	$ 9,604,780
Restricted cash	$ 46,729	$ –
Cash and restricted cash	$ 9,908,301	$ 9,604,780

See accompanying notes to the consolidated financial statements.

1. ORGANIZATION, LIQUIDITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION

Aethlon Medical, Inc. and its subsidiary (collectively, "Aethlon", the "Company", "we" or "us"), is a medical technology company focused on developing products to diagnose and treat life and organ threatening diseases. The Aethlon Hemopurifier is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier is designed to deplete the presence of circulating tumor-derived exosomes that promote immune suppression, seed the spread of metastasis and inhibit the benefit of leading cancer therapies. 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 life-threatening viruses that are not addressed with approved therapies.

We believe the Hemopurifier can be a substantial advance in the treatment of patients with advanced and metastatic cancer through the clearance of exosomes that promote the growth and spread of tumors through multiple mechanisms. We are currently preparing for the initiation of clinical trials in patients with advanced and metastatic cancers. We are initially focused on the treatment of solid tumors, including head and neck cancer, gastrointestinal cancers and other cancers. As we advance our clinical trials, we are in close contact with our clinical sites to navigate and assess the impact of the COVID-19 global pandemic on our clinical trials and current timelines.

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, which will enroll 10 to12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. This study, which is being conducted at the UPMC Hillman Cancer Center in Pittsburgh, PA, is in the process of recruiting and treating patients.

We also believe the Hemopurifier can be a 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 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, 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.

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's plan is to enroll up to 40 subjects at up to 20 centers in the U.S. Subjects will have established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, or ICU, and will have acute lung injury and/or severe or life threatening disease, among other criteria. Endpoints for this study, in addition to safety, will include reduction in circulating virus as well as clinical outcomes (NCT # 04595903). The initial sites for this trial, Hoag Memorial Hospital Presbyterian in Newport Beach, CA and Hoag Hospital – Irvine in Irvine, CA and Loma Linda Hospital in Loma Linda, CA, have completed clinical trial agreements, and have received IRB approval in the case of the Hoag hospitals, and are preparing to open for patient enrollment. Under Single Patient Emergency Use regulations, the Company has also treated two patients with COVID-19 with the Hemopurifier.

We are also the majority owner of Exosome Sciences, Inc., or ESI, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. Included among ESI's activities is the advancement of a TauSome™ biomarker candidate to diagnose chronic traumatic encephalopathy, or CTE, in the living. ESI previously documented TauSome levels in former NFL players to be nine times higher than same age-group control subjects. Through ESI, we are also developing exosome based biomarkers in patients with, or at risk for, a number of cancers. We consolidate ESI's activities in our consolidated financial statements.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we plan to 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 more recently will help protect the proprietary nature of the Hemopurifier treatment technology.

In addition to the foregoing, we are monitoring closely the impact of the COVID-19 global pandemic on our business and have taken steps designed to protect the health and safety of our employees while continuing our operations. Given the level of uncertainty regarding the duration and impact of the COVID-19 pandemic on capital markets and the U.S. economy, we are unable to assess the impact of the worldwide spread of SARS-CoV-2 and the resulting COVID-19 pandemic on our timelines and future access to capital. We are continuing to monitor the spread of COVID-19 and its potential impact on our operations. The full extent to which the COVID-19 pandemic will impact our business, results of operations, financial condition, clinical trials, and preclinical research will depend on future developments that are highly uncertain, including actions taken to contain or treat COVID-19 and their effectiveness, as well as the economic impact on national and international markets.

Our executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. Our website address is www.aethlonmedical.com.

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

REVERSE STOCK SPLIT

Effective October 14, 2019, the Company completed a 1-for-15 reverse stock split. Accordingly, 15 shares of outstanding common stock then held by 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 30,000,000 shares. 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, 2018. All shares and per share amounts have been revised accordingly.

LIQUIDITY AND GOING CONCERN

Management expects existing cash as of March 31, 2021 and additional cash raised in June 2021 to be sufficient to fund the Company's operations for at least twelve months from the issuance date of these consolidated financial statements.

PRINCIPLES OF CONSOLIDATION

The accompanying consolidated financial statements include the accounts of Aethlon Medical, Inc. and its majority-owned (80% ownership) and controlled subsidiary, Exosome Sciences, Inc., or ESI. All significant intercompany balances and transactions have been eliminated in consolidation. The Company has classified the (20% ownership) noncontrolling interests in ESI as part of consolidated net loss in the fiscal years ended March 31, 2021 and 2020 and includes the accumulated amount of noncontrolling interests as part of equity.

The losses at ESI during the fiscal year ended March 31, 2021 reduced the noncontrolling interests on our consolidated balance sheet by $4,790 from $(132,124) at March 31, 2020 to $(136,914) at March 31, 2021.

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. As of March 31, 2021 and 2020, we had no assets that were classified as cash equivalents.

CONCENTRATIONS OF CREDIT RISKS

Cash is maintained at one financial institution in checking accounts. Accounts at this institution are secured by the Federal Deposit Insurance Corporation up to $250,000. Our March 31, 2021 cash balances were approximately $9,712,000 over such insured amount. We do not believe that the Company is exposed to any significant risk with respect to its cash.

All of our accounts receivable at March 31, 2021 and all of our revenue in the fiscal years ended March 31, 2021 and 2020 related to our government contracts.

Restricted Cash

To comply with the terms of our new laboratory and office lease, we caused our bank to issue a standby letter of credit, or the L/C, in the amount of $46,726 in favor of the landlord. The L/C is in lieu of a security deposit. In order to support the L/C, we agreed to have our bank withdraw $46,726 from our operating accounts and to place that amount in a restricted certificate 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.

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, 2021 and 2020.

LOSS PER SHARE

Basic loss per share is computed by dividing net income 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, 2021 and 2020, a total of 2,836,062 and 2,072,492 potential common shares, consisting of shares underlying outstanding stock options, restricted stock units, warrants and convertible notes payable were excluded as their inclusion would be antidilutive.

SEGMENTS

Historically, we operated in one segment that was based on our development of therapeutic devices. However, in the December 2013 quarter, we initiated the operations of ESI to develop diagnostic tests. As a result, we now operate in two segments, Aethlon for therapeutic applications and ESI for diagnostic applications (See Note 9).

We record discrete financial information for ESI and our chief operating decision maker reviews ESI's operating results in order to make decisions about resources to be allocated to the ESI segment and to assess its performance.

DEFERRED FINANCING COSTS

Costs related to the issuance of debt are capitalized as a deduction to our convertible notes based on the new accounting standard on imputation of interest, and amortized to interest expense over the life of the related debt using the effective interest method. There was no amortization related to our deferred financing costs in the fiscal years ended March 31, 2021 and 2020.

REVENUE RECOGNITION

Our revenues consist entirely of amounts earned under contracts and grants with the National Institutes of Health, or NIH. During the fiscal years ended March 31, 2021 and 2020, we recognized revenues totaling $659,104 and $650,187, 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 three government contracts/grants over the past two years:

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 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 is $1,860,561 and runs for the period from September 16, 2019 through September 15, 2021.

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

During the fiscal year ended March 31, 2021, we completed the milestones relevant to the first nine months of the fiscal year. As a result, we recorded $436,427 of government contract revenue on the Phase 2 Melanoma Cancer Contract in the fiscal year ended March 31, 2021. Of the total revenue recognized during the current period relating to this grant, a total of $117,849 was invoiced to the NCI during the three months ended December 31, 2020 and we recorded $318,578 which had previously been recognized as deferred revenue.

During the three month period ended March 31, 2021, we did not complete all of the milestones relevant to that time period, as a result, we recorded $114,849 as deferred revenue related to the Phase 2 Melanoma Cancer Contract.

Breast Cancer Grant

In the fiscal year ended March 31, 2021, we completed and submitted the final reports applicable to this NCI grant (number 1R43CA232977-01). The title of this Small Business Innovation Research, or SBIR, Phase I grant is "The Hemopurifier Device for Targeted Removal of Breast Cancer Exosomes from the Blood Circulation," or the Breast Cancer Grant.

This NCI Phase I grant period originally ran from September 14, 2018 through August 31, 2019. In August 2019, we applied for and received a no cost, twelve month extension on this grant; through August 31, 2020. The total amount of the firm grant was $298,444. The grant called for two subcontractors to work with us. Those subcontractors were University of Pittsburgh and Massachusetts General Hospital. As of December 31, 2020, we have received all of the funds allocated to the Breast Cancer Grant.

During the fiscal year ended March 31, 2021, we recorded the remaining $188,444 of revenue related to the Breast Cancer Grant, as we achieved two of the three milestones related to the Breast Cancer Grant. We concluded in our final report to the SBIR that our pre-clinical results demonstrated that our work under the grant provided support that the Hemopurifier has the capacity to clear exosomes from breast cancer patients. That amount previously was recorded as deferred revenue.

As of March 31, 2021, we received all of the funds allocated to the Breast Cancer Grant and have submitted the final reports applicable to this grant.

Subaward with University of Pittsburgh

In 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 is $256,750. We recorded $34,233 of revenue related to this subaward in the fiscal year ended March 31, 2021.

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 5).

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, 2021 and 2020:

	Fiscal Years Ended	
	March 31, 2021	March 31, 2020
Vesting of Stock Options and Restricted Stock Units	$ 779,421	$ 843,998
Total Stock-Based Compensation Expense	$ 779,421	$ 843,998
Weighted average number of common shares outstanding – basic and diluted	12,090,884	3,414,840
Basic and diluted loss per common share	$ (0.06)	$ (0.25)

We record share-based compensation expenses for awards of stock options and restricted stock units, or 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 SARs 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, 2020 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

We grant warrants 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.

BENEFICIAL CONVERSION FEATURE OF CONVERTIBLE NOTES PAYABLE

The convertible feature of certain notes payable provides for a rate of conversion that is below market value. Such feature is normally characterized as a Beneficial Conversion Feature, or BCF. We measure the estimated fair value of the BCF in circumstances in which the conversion feature is not required to be separated from the host instrument and accounted for separately, and record that value in the consolidated financial statements as a discount from the face amount of the notes. Such discounts are amortized to interest expense over the term of the notes. As of March 31, 2021, we did not have any unamortized debt discount relating to BCF.

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development costs are expensed as incurred. We incurred approximately $2,072,000 and $927,000 of research and development expenses for the years ended March 31, 2021 and 2020, 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 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 and early adoption is permitted. 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 of $228,694 on its balance sheet as of April 1, 2019. The lease liabilities represent the present value of the remaining lease payments of the Company's corporate headquarters lease (see Note 13), discounted using the Company's incremental borrowing rate as of April 1, 2019. The corresponding right-of-use lease assets are recorded based on the lease liabilities and the cumulative difference between rent expense and amounts paid under its corporate headquarters lease. The Company also elected the short-term lease recognition exemption for its laboratory lease. For the laboratory lease that qualified as short-term, the Company did not recognize ROU assets or lease liabilities at adoption.

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, 2021	March 31, 2020
Furniture and office equipment, at cost	$ 585,910	$ 526,029
Accumulated depreciation	(424,934)	(385,545)
	$ 160,976	$ 140,484

Depreciation expense for the fiscal years ended March 31, 2021 and 2020 was $39,389 and $17,202, respectively.

3. PATENTS, NET

Patents, net consist of the following:

	March 31, 2021	March 31, 2020
Issued patents	$ 157,442	$ 157,442
Accumulated amortization	(154,691)	(154,141)
Issued patents, net of accumulated amortization	2,751	3,301
Patents pending	54,203	54,203
Patents, net	$ 56,954	$ 57,504

Amortization expense for our capitalized issued patents for each of the fiscal years ended March 31, 2021 and 2020 was $550 and $9,164, respectively. As several patents expired during the fiscal year ended March 31, 2020 and 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 5 years.

4. CONVERTIBLE NOTES PAYABLE

We paid off our convertible notes in full in July 2019. We also paid $83,332 of accrued interest during the fiscal year ended March 31, 2020. The following table shows the activity related to our convertible notes during the fiscal year ended March 31, 2020:

Total Convertible Notes Payable at March 31, 2019	$ 992,591
Less Principal Payments in Cash on Convertible Notes During the Fiscal Year Ended March 31, 2020	(992,591)
Total Convertible Notes Payable at March 31, 2020	$ –

During the fiscal year ended March 31, 2020, we recorded interest expense of $23,759 related to the contractual interest rates of our convertible notes and interest expense of $30,287 related to the amortization of the note discount, for a total interest expense of $54,046 related to our convertible notes in the fiscal year ended March 31, 2020.

5. EQUITY TRANSACTIONS

ISSUANCES OF COMMON STOCK AND WARRANTS

Equity Transactions in the Fiscal Year Ended March 31, 2021.

Common Stock Sales Agreement with H.C. Wainwright

On June 28, 2016, we entered into a Common Stock Sales Agreement, or the 2016 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 2016 Agreement. The 2016 Agreement provided for the sale of shares of our common stock having an aggregate offering price of up to $12,500,000.

On March 30, 2020, we executed Amendment No. 2 to the 2016 Agreement with Wainwright, effective as of the same date. The amendment provides that references in the 2016 Agreement to the registration statement shall refer to the registration statement on Form S-3 (File No. 333-237269), originally filed with the SEC on March 19, 2020, declared effective by the SEC on March 30, 2020.

Subject to the terms and conditions set forth in the 2016 Agreement, Wainwright agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares under the 2016 Agreement from time to time, based upon our instructions. We provided Wainwright with customary indemnification rights under the 2016 Agreement, and Wainwright is entitled to a commission at a fixed rate equal to three percent of the gross proceeds per share sold. In addition, we agreed to pay certain expenses incurred by Wainwright in connection with the 2016 Agreement, including up to $50,000 of the fees and disbursements of their counsel. The 2016 Agreement will terminate upon the sale of all of the shares under the 2016 Agreement, unless terminated earlier by either party as permitted under the 2016 Agreement.

As of March 31, 2021, no further sales will be made under the 2016 Agreement.

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

The offering has been registered under the Securities Act of 1933, as amended, or 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 may 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 Offering Agreement, Wainwright agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares under the Offering Agreement from time to time, based upon our instructions. We provided Wainwright with customary indemnification rights under the Offering Agreement, and Wainwright is entitled to a commission at a fixed rate equal 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 Offering Agreement. The Offering Agreement will terminate upon the written termination by either party as permitted thereunder.

Sales of the shares, if any, under the 2016 Agreement and the Offering Agreement will be 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. We have no obligation to sell any of the shares, and, at any time, we may suspend offers under the 2016 Agreement and the Offering Agreement or terminate the Agreement.

In the fiscal year ended March 31, 2021, we raised aggregate net proceeds of $7,260,869, net of $224,825 in commissions to Wainwright and $8,472 in other offering expenses, under the Agreement, through the sale of 2,685,600 shares at an average price of $2.70 per share of net proceeds.

Restricted Stock Unit Grants to Non-Employee Directors

In 2012, as amended through October 30, 2020, our Board of Directors established the Non-Employee Directors Compensation Program, to provide for cash and equity compensation for persons serving as non-employee directors of the Company. Under this program, each new director receives either stock options or a grant of restricted stock units, or RSUs, as well as an annual grant of RSUs at the beginning of each fiscal year. The 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 3, 2020, pursuant to the terms of the Company's Non-Employee Directors Compensation Program, the Compensation Committee of the Board of Directors granted RSUs to each non-employee director of the Company. The Non-Employee Directors Compensation Program provided for a grant of RSUs with a grant date fair value of $35,000, priced at the average of the closing prices for the five trading days ending on the date of grant, which was $1.41 per share, so that the total number of RSUs to be granted to each non-employee director for fiscal year 2020 would be 24,822 shares of our common stock. On April 3, 2020, each eligible director was granted an RSU for 23,893 shares under the Company's 2010 Stock Plan, or the 2010 Plan, as the number of shares that remained available for grant under the 2010 Plan was not sufficient for each director's full RSU grant. The Compensation Committee also granted to each eligible director a contingent grant under our 2020 Equity Incentive Plan, or the 2020 Plan, for the remaining portion of the annual RSU grants, or 929 RSU's to each eligible director, contingent upon stockholder approval of the 2020 Plan at the Company's 2020 Annual Meeting of Stockholders, or the Annual Meeting. These grants are subject to vesting as follows: 50% of the RSUs subject to the grants will vest on December 31, 2020 and 50% of the RSUs will vest on March 31, 2021, subject in each case to the continuous service of each director, through such vesting dates, as well as approval of the 2020 Plan by the stockholders at the Annual Meeting, which was obtained at the Annual Meeting.

In June 2020, 29,866 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 11,947 of the vested RSUs being cancelled in exchange for $24,251 in aggregate cash proceeds to those independent directors.

In September 2020, 29,866 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 11,947 of the vested RSUs being cancelled in exchange for $16,128 in aggregate cash proceeds to those independent directors.

Also in September 2020, our stockholders approved the 2020 Plan at the Annual Meeting, at which point the grants of 929 RSUs to each of our eligible independent directors for a total of 4,645 RSUs were considered effective and no longer contingent as of that date (See Note 9).

In December 2020, 32,189 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 12,876 of the vested RSUs being cancelled in exchange for $31,802 in aggregate cash proceeds to those independent directors.

In March 2021, 32,189 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 12,875 of the vested RSUs being cancelled in exchange for $26,136 in aggregate cash proceeds to those independent directors.

There were no vested RSUs outstanding as of March 31, 2021.

Restricted Stock Grant to Consultant

In February 2021, our Board of directors approved a restricted stock grant of 7,758 shares to an investor relations consultant. Those shares were valued at $18,000 based on our closing price on the date of the approval. The shares will vest quarterly over a twelve month period and were issued under our 2020 Stock Plan. During the twelve months ended March 31, 2021, we recorded non-cash stock-based compensation expense of $1,500 related to this grant.

Equity Transactions in the Fiscal Year Ended March 31, 2020.

December 2019 Public Offering

On December 13, 2019, we entered into an underwriting agreement with H.C. Wainwright and Co., or Wainwright, as representative of the several underwriters named therein, relating to the public offering, issuance and sale of 3,333,334 shares of common stock (which includes pre-funded warrants to purchase shares of common stock in lieu thereof), and common warrants to purchase up to an aggregate of 3,333,334 shares of common stock, at a public offering price of $1.50 per share and common warrant. Each share of common stock (or pre-funded warrant in lieu thereof) was sold together with a common warrant to purchase one share of common stock. The common warrants have an exercise price of $1.50 per share, were immediately exercisable, and will expire five years from the date of issuance. The offering closed on December 17, 2019.

The gross proceeds of the December 2019 Public Offering were approximately $5 million, prior to deducting underwriting discounts and commissions and estimated offering expenses and excluding the exercise of any common warrants and the underwriter's option to purchase additional securities. The net proceeds from the December 2019 Public Offering were $4,091,437.

Subsequent to the completion of the December 2019 Public Offering and prior to March 31, 2020, all of the holders of pre-funded warrants exercised their pre-funded warrants in full.

In the event of a Fundamental Transaction (a transfer of ownership of the Company as defined in the common warrants issued in the December 2019 Public Offering) within our control, the holders of the unexercised common stock warrants exercisable for $1.50 per share, are entitled to receive cash consideration equal to a Black-Scholes valuation, as defined in the warrant. If such Fundamental Transaction is not within our control, the warrant holders would only be entitled to receive the same form of consideration (and in the same proportion) as the holders of our common stock, hence these warrants are classified as a component of permanent equity.

January 2020 Registered Direct Offering and Private Placement

On January 16, 2020, we engaged Wainwright to act as our exclusive placement agent in connection with the private placement and a concurrent registered direct offering, or together, the Offering, of an aggregate of 1,885,378 shares of our common stock at a purchase price per share of $2.00, or the Shares, for aggregate gross proceeds to us of approximately $3.77 million, before deducting fees payable to Wainwright and other estimated offering expenses payable by us. We also entered into a securities purchase agreement, or the Purchase Agreement with certain institutional investors, or the Purchasers, pursuant to which we agreed to sell and issue to the Purchasers warrants, or the Purchase Warrants, to purchase up to an aggregate of 942,689 shares of our common stock, or the Purchase Warrant Shares. We agreed to pay Wainwright a cash fee of 6.0% of the aggregate gross proceeds in the Offering, excluding the proceeds, if any, from the exercise of the Purchase Warrants. We paid Wainwright an additional 1.0% of the aggregate gross proceeds in the Offering as a management fee and also paid Wainwright an additional $70,000 for certain expenses in connection with the Offering. In addition, Wainwright received placement agent warrants on substantially the same terms as the Purchase Warrants in an amount equal to 3.0% of the aggregate number of Shares sold in the offering, or 56,561 shares of Common Stock, at an exercise price of $2.50 per share and a term expiring on January 17, 2025, or the Placement Agent Warrants, and the shares of common stock issuable thereunder, or the Placement Agent Warrant Shares.

On January 22, 2020, the Company closed the Offering and issued the Purchase Warrants to the Purchasers. The Purchase Warrants are exercisable immediately at an exercise price of $2.75 per share and will expire five and one-half years from the issuance date.

The net proceeds from the January 2020 Registered Direct Offering and Private Placement were $3,364,878.

Common Stock Sales Agreement with H.C. Wainwright

In the fiscal year ended March 31, 2020, we raised aggregate net proceeds of $896,031 (net of $27,896 in commissions to H.C. Wainwright and $5,929 in other offering expenses) under this Agreement through the sale of 161,149 shares at an average price of $5.56 per share of net proceeds.

Warrant Exercises

In fiscal year ended March 31, 2020, investors that participated in the December 2019 public offering exercised 2,700,000 warrants for aggregate cash proceeds to us of $3,807,162.

Restricted Stock Unit Grants to Non-Employee Directors

In 2012, as amended through October 30, 2020, our Board of Directors established the Non-Employee Directors Compensation Program, to provide for cash and equity compensation for persons serving as non-employee directors of the Company. Under this program, each new director receives either stock options or a grant of restricted stock units, or RSUs, as well as an annual grant of RSUs at the beginning of each fiscal year. The RSUs are subject to vesting and represent the right to be issued on a future date shares of our common stock for upon vesting.

In April 2019, pursuant to the Non-Employee Directors Compensation Program, we issued RSUs with a value of $35,000, in accordance with the terms of the plan, to each of our non-employee directors, as the stock-based compensation element of their overall directors' compensation, for the fiscal year ending March 31, 2020. Those grants were based on the closing price of our common stock on the grant date, or $14.25 per share, resulting in 2,456 RSUs being issued to each of our five non-employee directors, for a total of 12,280 RSUs. All of the RSUs were subject to vesting in equal quarterly installments on June 30, 2019, September 30, 2019, December 31, 2019 and March 31, 2020.

During the fiscal year ended March 31, 2020, 12,280 vested RSUs held by our outside directors were exchanged into the same number of shares of our common stock. As four of our five independent directors elected to return 40% of their RSUs in exchange for cash in order to pay their withholding taxes on the share issuances, 3,926 of the RSUs were cancelled and we paid $11,230 in cash to those independent directors.

In addition, during the fiscal year ended March 31, 2020, 8,793 vested RSUs then held by our executive officers were exchanged into the same number of shares of our common stock. As our executives elected to net settle a portion of their RSU's in exchange for the Company paying the related withholding taxes on the share issuance, 4,657 of the RSUs were cancelled and we issued a net 4,136 shares to our executives.

There were no vested RSUs outstanding as of March 31, 2020.

Common Stock for Warrant Cancellation

During the fiscal year ended March 31, 2020, we agreed with seven accredited investors to issue an aggregate of 3,992 shares of our common stock to these investors in exchange for the cancellation of outstanding warrants then held by the investors to purchase an aggregate of 39,900 shares of our common stock. We measured the fair value of the shares issued and the fair value of the warrants exchanged for those shares and recorded a gain of $51,190 on those exchanges based on the changes in fair value between the instruments exchanged.

WARRANTS:

We did not issue any warrants during the fiscal year ended March 31, 2021. During the fiscal year ended March 31, 2020, we issued 4,432,585 warrants in association with our December 2019 Public Offering and our January 2020 Registered Direct Financing and associated private placement (see Note 6). All of those warrants had a five year term and had exercise prices as follows:

Financing	Warrants Issued	Exercise Price
December 2019 Public Offering – Investors' Warrants	3,333,334	$1.50
December 2019 Public Offering – Placement Agents' Warrants	100,000	$1.875
January 2020 Registered Direct – Investors' Warrants	942,689	$2.75
January 2020 Registered Direct – Placement Agents' Warrants	56,562	$2.50

Based on the above assumptions, we valued the warrants issued during the fiscal year ended March 31, 2020 as follows:

- The 999,251 warrants issued in our January 2020 Registered Direct Financing were valued at $2,388,776 and we classified that fair value as equity.
- The 3,433,334 warrants issued in our December 2019 public offering were valued at $3,021,334 and we classified that fair value as equity.

A summary of the aggregate warrant activity for the years ended March 31, 2021 and 2020 is presented below:

	Fiscal Year Ended March 31,			
	2021		2020	
	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Outstanding, beginning of year	2,021,368	$ 5.21	342,992	$ 27.00
Granted	–	N/A	4,432,585	$ 1.79
Adjustment for reverse split	–	N/A	73	N/A
Exercised	–	N/A	(2,700,000)	$ 1.50
Cancelled/Forfeited	(29,395)	$ 91.17	(54,282)	$ 91.23
Outstanding, end of year	1,991,973	$ 5.23	2,021,368	$ 5.21
Exercisable, end of year	1,991,973	$ 5.23	2,021,368	$ 5.21
Weighted average estimated fair value of warrants granted		N/A		$ 1.22

The following outlines the significant weighted average assumptions used to estimate the fair value of warrants granted in the fiscal year ended March 31, 2020 utilizing the Binomial Lattice option pricing model:

	Fiscal Year Ended March 31, 2020
Risk free interest rate	1.57% - 1.71%
Average expected life	5 years
Expected volatility	148.6% - 233.0%
Expected dividends	None

The expected volatility was based on the historic volatility. The expected life of options granted was based on the "simplified method" as described in the SEC's guidance due to changes in the vesting terms and contractual life of current option grants compared to our historical grants.

The detail of the warrants outstanding and exercisable as of March 31, 2021 is as follows:

	Warrants Outstanding			Warrants Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Exercise Price
$2.75 or Below	1,732,585	3.80	$ 2.23	1,732,585	$ 2.23
$16.50 - $59.25	249,985	1.43	$ 23.24	249,985	$ 23.24
$64.50 - $135.00	9,403	0.58	$ 77.62	9,403	$ 77.62
	1,991,973			1,991,973	

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 common shares for issuance under the 2020 Plan pursuant to stock option grants, RSUs or other forms of stock-based compensation.

2010 STOCK INCENTIVE PLAN

In August 2010, we adopted the 2010 Stock Incentive 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 4,667 common shares for issuance under the 2010 Stock Incentive Plan.

On January 26, 2016, our Board of Directors approved an amendment to the 2010 Stock Incentive Plan to increase the total number of shares of common stock authorized for issuance under the plan to 211,333 shares, subject to amendment of our Articles of Incorporation to increase our authorized common stock. On March 29, 2016, at which our stockholders approved the Amended 2010 Stock Incentive Plan and an amendment of our Articles of Incorporation to increase our authorized common stock to 30,000,000 shares. On March 31, 2016, we filed a Certificate of Amendment to our Articles of Incorporation to effect the increase in our authorized common stock. As a result of such amendment, the Amended 2010 Stock Incentive Plan became effective on March 31, 2016.

Effective October 14, 2019, we completed a 1-for-15 reverse stock split. Accordingly, 15 shares of outstanding common stock then held by 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 30,000,000 shares.

No future grants will be made under the 2010 Stock Incentive Plan.

2012 NON-EMPLOYEE DIRECTORS COMPENSATION PROGRAM

In 2012, as amended through October 30, 2020, our Board of Directors established the Non-Employee Directors Compensation Program, to provide for cash and equity compensation for persons serving as non-employee directors of the Company. Under this program, each new director receives either stock options or a grant of restricted stock units, or RSUs, as well as an annual grant of RSUs at the beginning of each fiscal year. The 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 3, 2020, pursuant to the terms of the Company's Non-Employee Directors Compensation Program, the Compensation Committee of the Board of Directors granted RSUs to each non-employee director of the Company. The Non-Employee Directors Compensation Program provided for a grant of RSUs with a grant date fair value of $35,000, priced at the average of the closing prices for the five trading days ending on the date of grant, which was $1.41 per share, so that the total number of RSUs to be granted to each non-employee director for fiscal year 2020 would be 24,822 shares of our common stock. On April 3, 2020, each eligible director was granted an RSU for 23,893 shares under the Company's 2010 Stock Plan, or the 2010 Plan, as the number of shares that remained available for grant under the 2010 Plan was not sufficient for each director's full RSU grant. The Compensation Committee also granted to each eligible director a contingent grant under our 2020 Equity Incentive Plan, or the 2020 Plan, for the remaining portion of the annual RSU grants, or 929 RSU's to each eligible director, contingent upon stockholder approval of the 2020 Plan at the Company's 2020 Annual Meeting of Stockholders, or the Annual Meeting. These grants were subject to vesting as follows: 50% of the RSUs subject to the grants vested on December 31, 2020 and 50% of the RSUs vested on March 31, 2021, subject in each case to the continuous service of each director, through such vesting dates, as well as approval of the 2020 Plan by the stockholders at the Annual Meeting, which was obtained at the Annual Meeting.

In June 2020, 29,866 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 11,947 of the vested RSUs being cancelled in exchange for $24,251 in aggregate cash proceeds to those independent directors.

In September 2020, 29,866 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 11,947 of the vested RSUs being cancelled in exchange for $16,128 in aggregate cash proceeds to those independent directors.

Also in September 2020, our stockholders approved the 2020 Plan at the Annual Meeting, at which point the grants of 929 RSUs to each of our eligible independent directors for a total of 4,645 RSUs were considered effective and no longer contingent as of that date.

In December 2020, 32,189 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 12,876 of the vested RSUs being cancelled in exchange for $31,802 in aggregate cash proceeds to those independent directors.

In March 2021, 32,189 vested RSUs held by our non-employee directors were exchanged into the same number of shares of our common stock. All five 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 12,875 of the vested RSUs being cancelled in exchange for $26,136 in aggregate cash proceeds to those independent directors.

There were no vested RSUs outstanding as of March 31, 2021.

STAND-ALONE GRANTS

From time to time our Board of Directors grants common stock or options to purchase common stock or warrants exercisable to common stock to selected officers, employees and consultants as equity compensation to such persons on a stand-alone basis outside of any of our formal stock plans. The terms of these grants are individually negotiated.

STOCK OPTION ACTIVITY

From February 2020 through May 2020, our compensation committee granted options to purchase 521,476 shares of our common stock that were contingent upon stockholder approval of the 2020 Plan. Upon approval of the 2020 Plan at the Annual Meeting, these option grants were considered effective and no longer contingent as of that date.

The 2020 Plan approved by our stockholders at the 2020 Annual Meeting of Stockholders, authorizes up to 1,842,556 shares for issuance pursuant to stock option grants, RSUs or other forms of stock-based compensation. No future grants will be made under the 2010 Plan.

Effective as of October 30, 2020, we issued an option to purchase 239,122 shares of our common stock pursuant to the 2020 Plan to our Chief Executive Officer, in connection with the appointment of Dr. Fisher as our Chief Executive Officer.

In connection with the Separation Agreement and pursuant to Dr. Rodell's employment agreement with the Company, the vesting was accelerated on 50% of outstanding and unvested options to purchase shares of our common stock held by Dr. Rodell as of the Separation Date of October 30, 2020, such that the accelerated stock options were fully vested and exercisable as of the Separation Date.

In December 2020, Dr. Rodell elected to net exercise a portion of his stock options. As a result, we issued Dr. Rodell an aggregate of 15,896 shares of our common stock and we paid the estimated withholding taxes of $34,209 related to the net exercise.

Options outstanding that were vested as of March 31, 2021 and options that are expected to vest subsequent to March 31, 2021 are as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years
Vested	58,954	$ 20.06	7.35
Expected to vest	785,135	$ 1.79	9.19
Total	844,089		

The following is a summary of the stock options outstanding at March 31, 2021 and 2020 and the changes during the years then ended:

	Fiscal Year Ended March 31,			
	2021		2020	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding, beginning of year	51,124	$ 44.12	59,111	$ 56.85
Granted	1,011,860	$ 1.71	–	$ N/A
Exercised	(15,896)	$ 1.28	–	$ N/A
Cancelled/Forfeited	(202,999)	$ 6.76	(7,987)	$ 138.75
Outstanding, end of year	844,089	$ 3.07	51,124	$ 44.12
Exercisable, end of year	58,954	$ 20.06	25,197	$ 70.08
Weighted average estimated fair value of options granted		$ 1.58		$ N/A

The detail of the options outstanding and exercisable as of March 31, 2021 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
$1.28 - $1.68	479,814	9.25 years	$ 1.34	--	$ N/A
$2.45 - $2.52	329,766	9.00 years	$ 2.50	24,445	$ 2.45
$18.75 - $142.50	34,509	5.88 years	$ 32.53	34,509	$ 32.53
	844,089			58,954	

We recorded stock-based compensation expense related to restricted stock unit issuances and to options granted totaling $779,421 and $843,998 for the fiscal years ended March 31, 2021 and 2020, 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, 2021 and 2020.

Our total stock-based compensation for fiscal years ended March 31, 2021 and 2020 included the following:

	Fiscal Year Ended	
	March 31, 2021	March 31, 2020
Vesting of restricted stock units	$ 175,000	$ 678,028
Vesting of restricted shares issued for services	1,500	–
Vesting of stock options	602,921	165,970
Total Stock-Based Compensation	$ 779,421	$ 843,998

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, 2021 was insignificant.

On March 31, 2021, our outstanding stock options had no intrinsic value since the closing price on that date of $2.03 per share was below the weighted average exercise price of our outstanding stock options.

At March 31, 2021, there was approximately $2,668,000 of unrecognized compensation cost related to share-based payments, which is expected to be recognized over a weighted average period of 4.44 years.

6. RELATED PARTY TRANSACTIONS

DUE TO RELATED PARTIES

Historically, certain of our officers and other related parties have advanced us funds, agreed to defer compensation and/or paid expenses on our behalf to cover working capital deficiencies. There were no such related party transactions during the fiscal year ended March 31, 2021, except that we had accrued unpaid Board fees of $52,000 owed to our outside directors as of March 31, 2021.

Due to related parties were comprised of the following items:

	March 31, 2021	March 31, 2020
Accrued board fees	$ 52,000	$ 69,750
Accrued vacation	66,520	41,957
Total due to related parties	$ 118,520	$ 111,707

7. OTHER CURRENT LIABILITIES

Other current liabilities were comprised of the following items:

	March 31, 2021	March 31, 2020
Accrued separation expenses for former executive (see Note 11)	$ 284,270	$ –
Accrued professional fees	477,366	472,420
Total other current liabilities	$ 761,636	$ 472,420

8. INCOME TAXES

For the years ended March 31, 2021 and 2020, we had no income tax expense due to our net operating losses and 100% deferred tax asset valuation allowance.

At March 31, 2021 and 2020, 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, 2021 and 2020 are shown below:

	YEAR ENDED MARCH 31,	
	2021	2020
Deferred tax assets:		
Capitalized research and development	$ 3,442,000	$ 3,442,000
Net operating loss carryforwards[1]	19,921,000	18,384,000
Stock compensation	1,399,000	1,181,000
Total deferred tax assets	24,762,000	23,007,000
Total deferred tax liabilities	–	–
Net deferred tax assets	24,762,000	23,007,000
Valuation allowance for deferred tax assets	(24,762,000)	(23,007,000)
Net deferred tax assets	$ –	$ –

At March 31, 2021, we had tax net operating loss carryforwards for federal and state purposes approximating $77 million and $60 million, portions of which began to expire in the year 2021.

The provision for income taxes on earnings subject to income taxes differs from the statutory federal rate for the years ended March 31, 2021 and 2020 due to the following:

	2021	2020
Income taxes (benefit) at federal statutory rate of 21.00%	$ (1,657,000)	$ (1,340,000)
State income tax, net of federal benefit	(551,000)	(446,000)
Tax effect on non-deductible expenses and credits	1,000	122,000
True up items	25,000	42,000
Expiration of net operating loss carryforwards	427,000	222,000
Change in valuation allowance	1,755,000	1,400,000
	$ –	$ –

(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, 2021 and 2020, we did not recognize any interest or penalties relating to tax matters.

At and for the years ended March 31, 2021 and 2020, management does not believe the Company has any uncertain tax positions. Accordingly, there are no unrecognized tax benefits at March 31, 2021 or March 31, 2020.

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.

9. SEGMENTS

We operate our businesses principally through two reportable segments: Aethlon, which represents our therapeutic business activities, and ESI, which represents our diagnostic business activities. Our reportable segments have been determined based on the nature of the potential products being developed. We record discrete financial information for ESI and our chief operating decision maker reviews ESI's operating results in order to make decisions about resources to be allocated to the ESI segment and to assess its performance.

Aethlon's revenue is generated primarily from government contracts to date and ESI does not yet have any revenues. We have not included any allocation of corporate overhead to the ESI segment.

The following tables set forth certain information regarding our segments:

	Fiscal Years Ended March 31,	
	2021	2020
Revenues:		
Aethlon	$ 659,104	$ 650,187
ESI	–	–
Total Revenues	$ 659,104	$ 650,187
Operating Losses:		
Aethlon	$ (7,865,967)	$ (5,899,523)
ESI	(23,952)	(30,465)
Total Operating Loss	$ (7,889,919)	$ (5,929,988)
Net Losses:		
Aethlon	$ (7,867,547)	$ (6,349,576)
ESI	(23,952)	(30,465)
Net Loss Before Non-Controlling Interests	$ (7,891,499)	$ (6,380,041)
Cash:		
Aethlon	$ 9,861,378	$ 9,604,583
ESI	197	197
Total Cash	$ 9,861,575	$ 9,604,780
Total Assets:		
Aethlon	$ 10,668,719	$ 10,387,489
ESI	197	197
Total Assets	$ 10,668,916	$ 10,387,686
Capital Expenditures:		
Aethlon	$ 59,881	$ 151,665
ESI	–	–
Capital Expenditures	$ 59,881	$ 151,665
Depreciation and Amortization:		
Aethlon	$ 39,939	$ 26,366
ESI	–	–
Total Depreciation and Amortization	$ 39,939	$ 26,366
Interest Expense:		
Aethlon	$ 1,580	$ 54,232
ESI	–	–
Total Interest Expense	$ 1,580	$ 54,232

10. SUBSEQUENT EVENTS

Management has evaluated events subsequent to March 31, 2021 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 ATM FACILITY

In June 2021, we raised aggregate net proceeds under the 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.

REGISTERED DIRECT FINANCING

In June 2021, we sold an aggregate of 1,380,555 shares of our common stock at a purchase price per share of $9.00, for aggregate gross proceeds to us of approximately $12.425 million, before 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 June 2021, 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 June 2021, 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 EXERCISE

In June 2021, a former employee paid us $22,969 to exercise 9,375 stock options.

RSU GRANTS

On April 1, 2021, pursuant to the terms of the Company's 2012 Non-Employee Directors Compensation Program, as amended, or the Directors Plan, the Compensation Committee of the Board granted RSUs under the Company's 2020 Plan to each non-employee director of the Company. The Director's Plan provides for a grant of $50,000 worth of RSUs at the beginning of each fiscal year, 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 RSU's are 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.

CONTINGENT BONUS AWARDS

Pursuant to the terms of the Executive Employment Agreement, dated October 30, 2020, between the Company and Charles J. Fisher, Jr., M.D., or the Employment Agreement, the Company's Chief Executive Officer, Dr. Fisher is entitled to a cash bonus equal to 50% of his annual base salary upon achievement of certain qualified events, or a Qualifying Event, as set forth in the Employment Agreement, as well as a stock option grant of a number of shares of common stock, pursuant to the 2020 Plan, such that Dr. Fisher's equity holdings in the Company after the additional grant will equal 3% of the Company, on a fully diluted basis. Based on the market capitalization of the Company and the Company's recent registered direct financing, the Company believes, subject to approval of the Compensation Committee of the Company's Board of Directors, that in June 2021 a Qualifying Event has occurred and that Dr. Fisher has earned the cash bonus award in the amount of $215,000 and an additional stock option grant under the terms of the Employment Agreement.

11. 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, 2021:

SEPARATION AGREEMENT

On October 30, 2020, we entered into a Separation Agreement with Timothy Rodell, M.D., our former Chief Executive Officer, or the Separation Agreement. Under this agreement, we agreed to pay Dr. Rodell a total of $444,729 and to cover his medical insurance costs over a twelve-month period that began on November 1, 2020, all in accordance with the terms of his employment agreement with the Company. We also paid Dr. Rodell accrued vacation in the amount of $20,260 in November 2020.

The total expense accrued at March 31, 2021 relating to the Separation Agreement, was $284,270 (see Note 7).

LEASE COMMITMENTS

We currently lease approximately 2,600 square feet of executive office space at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123 under a 39-month gross plus utilities lease that commenced on December 1, 2014 and expires on August 31, 2021. The current rental rate under the lease extension is $8,265 per month.

We also rent approximately 1,700 square feet of laboratory space at 11585 Sorrento Valley Road, Suite 109, San Diego, California 92121 at the rate of $6,148 per month on a one-year lease that originally was to expire on November 30, 2020. In December 2020, we entered into a short-term lease extension running from December 1, 2020 through the completion date of our construction of our planned new laboratory space which is adjacent to our current laboratory.

Rent expense, which is included in general and administrative expenses, approximated $192,000 and $178,000 for the fiscal years ended March 31, 2021 and 2020, respectively.

Future minimum lease payments under the Granite Ridge Lease as of March 31, 2021, are as follows:

April 1, 2021 through August 31, 2021	$	43,670
Less: discount		(1,127)
Total lease liability	$	42,543

During the fiscal year ended March 31, 2020, we adopted ASU Topic 842 on April 1, 2019 utilizing the alternative transition method allowed for under this guidance. As a result, we recorded lease liabilities and right-of-use lease assets of $228,694 on our balance sheet as of April 1, 2019. The lease liabilities represent the present value of the remaining lease payments of our corporate headquarters lease, discounted using our incremental borrowing rate as of April 1, 2019. The corresponding right-of-use lease assets are recorded based on the lease liabilities and the cumulative difference between rent expense and amounts paid under its corporate headquarters lease. We also elected the short-term lease recognition exemption for its laboratory lease. For the laboratory lease that qualified as short-term, we did not recognize right-of-use assets or lease liabilities at adoption.

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. The agreement carries a term of 63 months and we will commence paying rent when we take occupancy of those spaces, which is expected to occur in the third quarter of 2021. Upon taking occupancy of the space, we will record lease liabilities and right-of-use lease assets related to this agreement on our balance sheet. We estimate that the present value of the contractual payments under the lease agreement to be approximately $806,000.

In addition, the new lease agreement required us to post a standby letter of credit in favor of the landlord in the amount of $46,726 in lieu of a security deposit. We arranged for our bank to issue the standby letter of credit in the fiscal year ended March 31, 2021 and transferred a like amount to a restricted certificate of deposit which secured the bank's risk in issuing that letter of credit. We have classified that restricted certificate of deposit on our balance sheet as restricted cash.

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.

EXHIBIT 10.12

AETHLON MEDICAL, INC.

AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY
OCTOBER 30, 2020

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Aethlon Medical, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Amended and Restated Non-Employee Director Compensation Policy for his or her Board service. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy is effective as of October 30, 2020 (the "***Effective Date***") and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board. This policy supersedes and replaces any prior agreement or program that provides for compensation terms as of the Effective Date.

Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

For Eligible Directors who are serving on the Board as of the Effective Date the annual cash compensation shall be deemed effective as of the later of (i) the Effective Date, or (ii) the date such member of the Board was appointed or elected to the Board or to the board of directors of a wholly-owned subsidiary of the Company.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $35,000
   b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $30,000

2. Annual Committee Chair Service Retainer:
   a. Chair of the Audit Committee: $15,000
   b. Chair of the Compensation Committee: $15,000
   c. Chair of the Nominating and Corporate Governance Committee: $8,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
   Member of the Audit Committee: $7,500
   Member of the Compensation Committee: $7,500
   Member of the Nominating and Corporate Governance Committee: $5,000

Equity Compensation

1. New Eligible Directors: A new eligible director will receive an initial grant of restricted stock units with a grant date fair value of $75,000 or, at the discretion of the Board, options to acquire shares of common stock. Restricted stock units granted under this provision will be valued based on the average of the closing prices of the common stock for the five trading days preceding and including the date of grant and will vest at a rate determined by the Board in its discretion, typically in equal quarterly installments over one year. Options granted under this provision will be valued at the exercise price, which will be based on the average of the closing prices of the common stock for the five trading days preceding and including the date of grant. Such options will have a term of ten years and will vest at a rate determined by the Board in its discretion.

2. Existing Eligible Directors: At the beginning of each fiscal year, each existing eligible director will receive a grant of restricted stock units with a grant date fair value of $50,000 or, at the discretion of the Board, options to acquire shares of common stock. Restricted stock units granted under this provision will be valued based on the average of the closing prices of the common stock for the five trading days preceding and including the date of grant and will vest at a rate determined by the Board in its discretion, typically in equal quarterly installments over one year. Options granted under this provision will be valued at the exercise price, which will be based on the average of the closing prices of the common stock for the five trading days preceding and including the date of grant. Such options will have a term of ten years and will vest at a rate determined by the Board in its discretion.

Additional Requirements

In making any future changes to compensation payable to Non-Employee Directors, the Board or Compensation Committee will evaluate the practices of the peer group of companies that serve as references for executive compensation benchmarking, as well as then current general best practices regarding director compensation. The Compensation Committee will review this Policy on at least a biennial basis and engage an independent compensation consultant to assist in such review. Furthermore, the Company will not permit compensation to be paid to Non-Employee Directors for their service as such, other than as provided for in this Policy, unless there are extraordinary circumstances as determined by the Compensation Committee or the Board. All payments to Non-Employee Directors will be disclosed in accordance with applicable law, regulations and exchange or national market system requirements.

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. 333-248820, 333-230445, 333-182902, 333-168483, 333-168481, 333-164939, 333-160532, 333-145290, 333-127911, 333-114017 and 333-49896) and Form S-1 (File Nos. 333-234712, 333-201334 and 333-219589) of Aethlon Medical, Inc. of our report dated June 24, 2021 relating to the consolidated financial statements of Aethlon Medical, Inc. and subsidiary appearing in the Annual Report on Form 10-K of Aethlon Medical, Inc. and subsidiary for the year ended March 31, 2021.

/s/ Baker Tilly LLP

San Diego, California
June 24, 2021

EXHIBIT 31.1

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

I, Charles J. Fisher, Jr., 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 24, 2021

/s/ CHARLES J. FISHER, JR.
CHARLES J. FISHER, JR., M.D.
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 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 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 24, 2021

/s/ JAMES B. FRAKES
JAMES B. FRAKES
CHIEF FINANCIAL OFFICER
(PRINCIPAL FINANCIAL OFFICER)

EXHIBIT 32.1

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

In connection with the Annual Report of Aethlon Medical, Inc. (the "Registrant") on Form 10-K for the fiscal year ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof, I, Charles J. Fisher, Jr., Chief Executive 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 fully complies with the requirements of Section 13(a) or Section 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 24, 2021

/s/ CHARLES J. FISHER, JR., M.D.
Charles J. Fisher, Jr., M.D.
Chief Executive Officer
Aethlon Medical, Inc.

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Aethlon Medical, Inc. and will be retained by Aethlon Medical, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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 the Registrant 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 32.2

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

In connection with the Annual Report of Aethlon Medical, Inc. (the "Registrant") on Form 10-K for the fiscal year ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof, I, James B. Frakes, 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 fully complies with the requirements of Section 13(a) or Section 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 24, 2021

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

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Aethlon Medical, Inc. and will be retained by Aethlon Medical, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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 the Registrant 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.