AETHLON MEDICAL INC Form S-8 March 21, 2019

Table of Contents

As filed with the Securities and Exchange Commission on March 21, 2019

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-8

REGISTRATION STATEMENT

Under

The Securities Act of 1933

Aethlon Medical, Inc.

(Exact name of Registrant as specified in its charter)

Nevada13-3632859(State or other jurisdiction of(I.R.S. Employer)

incorporation or organization) Identification Number) 9635 Granite Ridge Drive, Suite 100 San Diego, California 92123

(Address, including zip code, of Registrant's principal executive offices)

2010 Stock Incentive Plan

(Full title of the plans)

James B. Frakes 9635 Granite Ridge Drive, Suite 100 San Diego, California 92123 (858) 459-7800

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Julie Robinson

Cooley LLP

4401 Eastgate Mall San Diego, CA 92121-1909 (858) 550-6092

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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of Securities

Amount

Proposed

Proposed

to be Registered	to be	Maximum	Maximum Aggregate	Amount of Registration
	Registered(1)	Offering Price Per Share(2)	Offering Price	Fee
Common Stock, par value \$0.0001 per share 2010 Stock Incentive Plan	3,000,000 shares	\$1.01	\$3,030,000.00	\$367.24

Pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended, this Registration Statement shall also cover any additional shares of the Registrant's Common Stock that become issuable under the 2010 Stock

(1)Incentive Plan or restricted stock unit awards set forth herein by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without receipt of consideration that increases the number of outstanding shares of the Registrant's Common Stock.

Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(h) and Rule

(2) 457(c) promulgated under the Securities Act of 1933, as amended. The offering price per share and the aggregate offering price are based upon the average of the high and low prices of the Registrant's Common Stock as reported on The Nasdaq Capital Market on March 15, 2019.

Explanatory Note

This Registration Statement on Form S-8 (this "Registration Statement") registers an aggregate of 3,000,000 shares of common stock, par value 0.0001 per share, of Aethlon Medical, Inc. ("Common Stock"), that may be issued and sold under the Aethlon Medical, Inc. 2010 Stock Incentive Plan ("2010 Plan"), consisting of certain shares previously issued as restricted stock units granted to employees through transactions by the Registrant not involving any public offering, in accordance with the exemption under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), (formerly Section 4(2) but redesignated Section 4(a)(2) by the Jumpstart Our Business Startups Act (the "JOBS Act")).

This Registration Statement also includes a prospectus (the "Reoffer Prospectus") prepared in accordance with General Instruction C of Form S-8 and in accordance with the requirements of Part I of Form S-3. This Reoffer Prospectus may be used for reofferings and resales of shares of Common Stock that may be deemed to be "control securities" under the Securities Act, and the rules and regulations promulgated thereunder that have been or may be acquired by certain of our "affiliates" pursuant to outstanding restricted stock units under our 2010 Plan, being the Selling Stockholders identified in the Reoffer Prospectus. The number of shares of Common Stock included in the Reoffer Prospectus represents the total number of shares of Common Stock that may be acquired by the Selling Stockholders pursuant to restricted stock unit awards made to the Selling Stockholders in accordance with Section 4(a)(2) of the Securities Act, and does not necessarily represent a present intention to sell any or all such shares of Common Stock.

Part I

INFORMATION REQUIRED IN SECTION 10(A) PROSPECTUS

This Registration Statement relates to two separate prospectuses.

<u>Section 10(a)</u> Prospectus: Items 1 and 2, from this page, and the documents incorporated by reference pursuant to Part II, Item 3 of this prospectus, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

<u>Reoffer Prospectus</u>: The material that follows Item 2, beginning on Page 6 through Page 34, up to but not including Part II of this Registration Statement, beginning on Page II-1, of which the reoffer prospectus is a part, constitutes a "reoffer prospectus," prepared in accordance with the requirements of Part I of Form S-3 under the Securities Act. Pursuant to Instruction C of Form S-8, the reoffer prospectus may be used for reoffers or resales of common stock which are deemed to be "control securities" or "restricted securities" under the Securities Act that have been acquired by the selling stockholders named in the reoffer prospectus.

Item 1. Plan Information.

Aethlon Medical, Inc. will provide each participant (the "Recipient") with documents that contain information related to the 2010 Plan and other information including, but not limited to, the disclosure required by Item 1 of Form S-8, which information is not filed as a part of this Registration Statement. The foregoing information and the documents incorporated by reference in response to Item 3 of Part II of this Registration Statement taken together constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act. A Section 10(a) prospectus will be given to each Recipient who receives common stock covered by this Registration Statement, in accordance with Rule 428(b)(1) under the Securities Act.

Item 2. Registrant Information and Employee Plan Annual Information.*

We will provide to each Recipient a written statement advising it of the availability of documents incorporated by reference in Item 3 of Part II of this Registration Statement and of documents required to be delivered pursuant to Rule 428(b) under the Securities Act without charge and upon written or oral notice. The statement will include the

address and telephone number to which any requests for documents should be directed.

Information required by Part I to be contained in Section 10(a) prospectus is omitted from the Registration Statement in accordance with Rule 428 under the Securities Act, and Note to Part I of Form S-8.

REOFFER PROSPECTUS

Aethlon Medical, Inc.

9635 Granite Ridge Drive, Suite 100 San Diego, California 92123 (858) 459-7800

957,716 SHARES OF COMMON STOCK

This reoffer prospectus relates to 957,716 shares of our common stock, par value \$0.001 per share ("Common Stock"), that may be offered and resold from time to time by the selling stockholders named in this reoffer prospectus for their own account. Eligible participants in our 2010 Plan consist of employees, directors, officers and consultants of our company or its related entities. The selling stockholders are "affiliates" of our company (as defined in Rule 405 under the Securities Act).

The selling stockholders may offer and sell their shares of Common Stock at various times and in various types of transactions, including sales in the open market, sales in negotiated transactions and sales by a combination of these methods. Shares may be sold at the market price of the Common Stock at the time of a sale, at prices relating to the market price over a period of time, or at prices negotiated with the buyers of shares. The shares may be sold through underwriters or dealers which the selling stockholders may select. If underwriters or dealers are used to sell the shares, we will name them and describe their compensation in a prospectus supplement. For a description of the various methods by which the selling stockholders may offer and sell their Common Stock described in this prospectus, see the section entitled "Plan of Distribution" of this prospectus. We will receive no part of the proceeds from sales made under this prospectus. The selling stockholders will bear all sales commissions and similar expenses. Any other expenses incurred by us in connection with the registration and offering and not borne by the selling stockholders will be borne by us.

The shares of Common Stock will be issued pursuant to awards granted to the selling stockholders and will be "control securities" under the Securities Act before their sale under this prospectus. This prospectus has been prepared for the purposes of registering the shares under the Securities Act to allow for future sales by selling stockholders on a continuous or delayed basis to the public without restriction.

Our Common Stock is traded on The Nasdaq Capital Market under the symbol "AEMD." On March 20, 2019, the last reported sale price for our Common Stock was \$0.98 per share.

Our business and an investment in our securities involve a high degree of risk. Before making any investment in our securities, you should read and carefully consider risks described in the <u>"Risk Factors</u>" section beginning on page 4 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is March 21, 2019

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with information that is different from that contained in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The selling stockholders are offering to sell and seeking offers to buy these securities only in jurisdictions where offers and sales are permitted. You should assume that the information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our Common Stock. Our business, financial condition, results of operations and prospects may have changed since that date. We are not making an offer of any securities in any jurisdiction where the offer is not permitted.

TABLE OF CONTENTS

	Page
Prospectus Summary	1
Risk Factors	2
Special Note Regarding Forward-Looking Statements	21
Use of Proceeds	22
Determination of Offering Price	22
Selling Stockholders	22
Plan of Distribution	23
Description of Capital Stock	24
Legal Matters	26
Experts	26
Material Changes	26
Incorporation of Certain Information By Reference	26
Where You Can Find Additional Information	27
Disclosure of Commission Position on Indemnification for Securities Act Liabilities	27

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that should be considered before investing in our Common Stock. Potential investors should read the entire prospectus carefully, including the more detailed information regarding our business provided below in the "Description of Business" section and the risks of purchasing our Common Stock discussed under the "Risk Factors" section below.

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to "Aethlon," "the company," "we," "us," "our" and similar references refer to Aethlon Medical, Inc., a corporation incorporated under the laws of the State of Nevada, and its wholly owned subsidiary.

All brand names or trademarks appearing in this prospectus are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this prospectus is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Overview

Aethlon Medical, Inc. is a medical technology company focused on addressing unmet needs in global health and biodefense. The Aethlon Hemopurifier® is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier depletes 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 ("FDA") has designated the Hemopurifier as a "Breakthrough Device" related to the following two indications:

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

We believe the Hemopurifier can be a part of the broad-spectrum treatment of life-threatening highly glycosylated viruses that are not addressed with an already approved treatment countermeasure objective set forth by the U.S. Government to protect citizens from bioterror and pandemic threats. In small-scale or early feasibility human studies, the Hemopurifier has been administered to individuals infected with HIV, hepatitis-C, and Ebola. Additionally, the Hemopurifier has been validated 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. Domestically, we are

focused on the clinical advancement of the Hemopurifier through investigational device exemptions ("IDEs") approved by the FDA. We recently concluded a feasibility study to demonstrate the safety of our device in health-compromised individuals infected with a viral pathogen.

We are also the majority owner of Exosome Sciences, Inc. ("ESI"), a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. Included among ESI's endeavors is the advancement of a TauSomeTM biomarker candidate to diagnose chronic traumatic encephalopathy ("CTE") in the living. ESI previously documented TauSome levels in former NFL players to be nine times higher than same age-group control subjects.

Successful outcomes of human trials will also be required by the regulatory agencies of certain foreign countries where we intend 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.

About This Offering

1

This prospectus relates to the public offering, which is not being underwritten, by the selling stockholders listed in this prospectus, of up to 957,716 shares of our Common Stock. The shares offered by this prospectus may be sold by the selling stockholders from time to time in the open market, through negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices. We will receive none of the proceeds from the sale of the shares by the selling stockholders. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

RISK FACTORS

Selected Risks Associated with an Investment in Shares of Our Common Stock

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 prospectus 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. At December 31, 2018, we had a cash balance of \$4,824,901 and working capital of \$3,079,243. Our revenues, from research grants, continue to be insufficient to cover our cost of operations. Additionally, our contracts with the Defense Advanced Research Projects Agency ("DARPA"), have now ended, and we cannot be assured when, if at all, we will be able to enter into future government contracts beyond our current contract with the National Institutes of Health ("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 one or more of our 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 be unavailable to us on reasonable terms, or at all, we may be unable to support our research and FDA clearance 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 products and potentially to repay our outstanding convertible notes due July 1, 2019. 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. Our competitors are developing vaccine candidates, which could compete with the Hemopurifier medical device we are developing. 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;
- \cdot are better tolerated;
- ·are more adaptable to various modes of dosing;
- \cdot 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 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 Aethlon 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 Interim Chief Executive Officer, Timothy Rodell, MD, and our Chief Financial Officer, James B. Frakes. If one or both 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 six full-time employees, consisting of our Interim Chief Executive Officer, our Chief Financial Officer, two research scientists and an executive assistant. 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 grow rapidly which will 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 product candidates are in the pre-clinical and clinical stages of development and have 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 they believe 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 their 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;
- \cdot product recalls; and
- \cdot 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, 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; and • different interpretations of our pre-clinical and clinical data, which could initially lead to inconclusive results.

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

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;
- \cdot withdrawing 510(k) clearances or premarket approvals that have already been granted;
- ·refusal to grant export approval for our products; or
- ·criminal prosecution.

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

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

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

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, 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 almost all 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 generally rely on third-party consultants or other vendors to manage and implement the day-to-day conduct of our operations, including conducting clinical trials and manufacturing our current product candidates and any future product candidates that we may develop. Accordingly, we are and will continue to be dependent on the timeliness and effectiveness of their efforts. Our dependence on third parties includes key suppliers and third-party service providers supporting the development, manufacture and regulatory approval of our products 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 lead product candidate are conducted by our management team, but all other activities are the responsibility of third-party vendors.

If a clinical research organization that we utilize is unable to allocate sufficient qualified personnel to our studies in a timely manner or if the work performed by it does not fully satisfy the requirements of the FDA or other regulatory agencies, we may encounter substantial delays and increased costs in completing our development efforts. Any manufacturer that we select may encounter difficulties in the manufacture of new products in commercial quantities, including problems involving product yields, product stability or shelf life, quality control, adequacy of control procedures and policies, compliance with FDA regulations and the need for further FDA approval of any new manufacturing processes and facilities. If any of these occur, the development and commercialization of our 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 rely on only one source for the manufacture of the clinical or commercial supplies of any of our product candidates or products, any production problems or supply constraints with that manufacturer could adversely impact the development or commercialization of that product candidate or product.

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 develop, market and sell our current product candidates or any future product candidates under development successfully 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 our current product candidates 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 current product candidates 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 current product candidates 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 may be used in connection with medical procedures in which it is important that those products function with precision and accuracy. If our products 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 either premarket approval, or 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 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:

 \cdot our inability to demonstrate safety or effectiveness to the FDA's satisfaction;

·insufficient data from our preclinical studies and clinical trials 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 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 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. 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 any products that we are developing or may develop will be subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad. In the future, we may conduct clinical trials to support approval of new products. 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 may be subject, directly or indirectly, 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 or 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 and other healthcare professionals 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.

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 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 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 drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement can differ significantly from payor to payor. If CMS or other agencies limit coverage or decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors for any products that we develop.

Should our products 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. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act. The Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by two percent through fiscal year 2027. 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. 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.

Should our products be approved for commercialization, our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

PPACA currently imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the U.S. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to \$20 billion over the next decade. The Internal Revenue Service issued final regulations implementing the tax in December 2012, which requires, among other things, bi-monthly payments and quarterly reporting.

The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on Dec. 18, 2015, included a two-year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. This moratorium was then extended by an additional two years in January 2018. Currently, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device until January 1, 2020, unless the moratorium is further extended.

Once we market products, if this regulation is not repealed, we will be subject to this or any future excise tax on our sales of certain medical devices in the U.S. We anticipate that primarily all of our sales, once commenced, of medical devices in the U.S. will be subject to this 2.3% excise tax.

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, who inspect 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 \$3,000,000 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.

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 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 seven pending U.S. patent applications. We also have 26 issued foreign patents and have applied for nine additional international patents. Our issued patents begin to expire in 2019, with the last of these patents expiring in 2029, 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.

13

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, 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. Such 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 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, 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;

·failure to 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;

·general market conditions;

·domestic or international terrorism and other factors; and

 \cdot 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 Securities and Exchange Commission'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 Securities and Exchange Commission's, or 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 \cdot 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 Securities and Exchange Commission 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 them, which may result in losses to you.

The market for our common shares 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 January 31, 2019, the high and low closing sale prices of a share of our common stock were \$0.93 and \$1.90, respectively. The volatility in our share price is attributable to a number of factors. First, as noted above, trading in our common shares 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 shares: actual or anticipated variations in our quarterly or annual operating results; 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 directors and officers own or control approximately 6.8% of our outstanding common shares which may limit your ability to propose new management or influence the overall direction of the business; this concentration of control may also discourage potential takeovers that could otherwise provide a premium to you.

As of January 31, 2019, our officers and directors beneficially owned or controlled approximately 6.8% of our outstanding common shares, assuming the exercise of all outstanding options, restricted stock units and warrants held by our officers and directors. These persons will have the ability to substantially influence all matters submitted to our stockholders for approval and to control our management and affairs, including extraordinary transactions such as mergers and other changes of corporate control, and going private transactions.

A large number of our common shares are issuable upon exercise of outstanding convertible securities which, if exercised or converted, would be dilutive to your holdings.

As of January 31, 2019, there were outstanding purchase options and warrants entitling the holders to purchase 6,076,690 common shares at a weighted average exercise price of \$2.19 per share. Additionally, as of January 31, 2019, we had reserved 2,272,393 shares of common stock for issuance under our equity compensation plans.

The exercise price for all of our outstanding options and warrants, or the conversion price of our convertible notes, may be less than your cost to acquire our common shares. In the event of the exercise or conversion of these securities, you could suffer substantial dilution of your investment in terms of your percentage ownership in us as well as the book value of your common shares. In addition, the holders of the convertible notes, common share purchase options or warrants may sell common shares in tandem with their exercise or conversion of those securities to finance that exercise or conversion, or may resell the shares purchased in order to cover any income tax liabilities that may arise from their exercise of the options or warrants or conversion of the notes.

Our issuance of additional common shares, or convertible securities, would be dilutive to your holdings.

We are entitled under our articles of incorporation to issue up to 30,000,000 shares of common stock. We have reserved for issuance 6,659,789 of those shares of common stock for outstanding restricted stock units, options, warrants and convertible notes. As of February 18, 2019, we had issued and outstanding 18,960,505 shares of common stock. As a result, as of February 18, 2019 we had 4,379,706 common shares 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 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 issuance of additional shares of common stock in satisfaction of services, or to repay indebtedness, would be dilutive to your holdings.

Subject to compliance with Nasdaq rules, our Board of Directors may generally issue shares of common stock to pay for debt or services, without further approval by our stockholders based upon such factors that our Board of Directors may deem relevant at that time. For the past four fiscal years, ending March 31, 2018, we issued a total of 1,102,741 shares of common stock to pay for debt to reduce our obligations. In the fiscal year ended March 31, 2018, we issued 120,922 shares of common stock to pay for debt to reduce our obligations.

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 by-laws also require us to indemnify our officers and directors. 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.

Risks Related to This Offering

We may experience volatility in our stock price, which could negatively affect your investment, and you may not be able to resell your shares at or above the offering price.

The offering price of our common stock may vary from the market price of our common stock after the offering. If you purchase shares of common stock, you may not be able to resell those shares at or above your purchase price. The market price of our common stock may fluctuate significantly in response to a number of factors, some of which are beyond our control, including: a quarterly variations in operating results; changes in financial estimates by securities analysts; changes in market valuations of other similar companies; announcements by us or our competitors of new products or of significant technical innovations, contracts, acquisitions, strategic partnerships or joint ventures; additions or departures of key personnel; any deviations in net sales or in losses from levels expected by securities analysts; and future sales of common stock. In addition, the stock market has recently experienced extreme volatility that has often been unrelated to the performance of particular companies. These market fluctuations may cause our stock price to fall regardless of our performance.

Corporate information

On March 10, 1999, Aethlon, Inc., a California corporation, Hemex, Inc., a Delaware corporation and the accounting predecessor to Aethlon, Inc., and Bishop Equities, Inc., a publicly traded Nevada corporation, completed an Agreement and Plan of Reorganization structured to result in Bishop Equities, Inc.'s acquisition of all of the outstanding common shares of Aethlon, Inc. and Hemex, Inc. Under the plan's terms, Bishop Equities, Inc. issued shares of its common stock to the stockholders of Aethlon, Inc. and Hemex, Inc. such that Bishop Equities, Inc. then owned 100% of each company. Upon completion of the transaction, Bishop Equities, Inc. was renamed Aethlon Medical, Inc. In 2009, we formed Exosome Sciences, Inc., which today is a majority-owned subsidiary focused on identifying and monitoring neurological conditions and cancer. We commenced formal operations of Exosome in 2013.

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

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 information on our website is not incorporated by reference into this prospectus and should not be considered to be a part of this prospectus. Our internet address is included in this prospectus as an inactive textual reference only.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus and the documents incorporated by reference are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company's or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

the initiation, progress, timing, costs and results of preclinical studies and any clinical trials for our Hemopurifier and any other product candidates;

our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

our ability to further improve our process development capabilities and viral vector technology;

the timing or likelihood of regulatory filings and approvals;

our plans to explore potential applications of our gene therapy platform in other indications in ophthalmology and rare diseases;

our expectations regarding the clinical effectiveness and safety and tolerability of our product candidates;

our commercialization, marketing and manufacturing capabilities and strategy;

the pricing and reimbursement of our product candidates, if approved;

our expectation regarding the potential market sizes for our product candidates;

our intellectual property position;

the potential benefits of our strategic collaborations, our plans with respect to our strategic collaborations and our plans with respect to and our ability to enter into strategic arrangements;

developments and projections relating to our competitors and our industry;

our expectations regarding the time during which we will be an "emerging growth company" under the JOBS Act; and the safety, efficacy and projected development timeline and commercial potential of any product candidates.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "experimants," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss in greater detail many of these risks under the heading "Risk Factors" contained, or incorporated by reference, in this prospectus. Also, these forward-looking statement. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should read this prospectus together with the documents we have filed with the SEC that are incorporated by reference completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

USE OF PROCEEDS

The shares of Common Stock offered hereby are being registered for the account of the selling stockholders named in this prospectus. As a result, all proceeds from the sales of the Common Stock will go to the selling stockholders and we will not receive any proceeds from the resale of the Common Stock by the selling stockholders.

DETERMINATION OF OFFERING PRICE

The selling security holders may sell the common shares issued to them from time-to-time at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. See "Plan of Distribution" below for more information.

SELLING STOCKHOLDERS

The table below sets forth information concerning the resale of the shares by the selling stockholders. We will not receive any proceeds from the resale of the shares by the selling stockholders.

The table below sets forth, as of January 31, 2019, (i) the name of each person who is offering the resale of shares by this prospectus and their position with us; (ii) the number of shares (and the percentage, if 1% or more) of Common Stock beneficially owned (as such term is defined in Rule 13d-3 under the Exchange Act) by each person; (iii) the number of shares that each selling stockholder may offer for sale from time to time pursuant to this prospectus, whether or not such selling stockholder has a present intention to do so; and (iv) the number of shares (and the percentage, if 1% or more) of Common Stock each person will own after the offering, assuming they sell all of the shares offered. Unless otherwise indicated, beneficial ownership is direct and the person indicated has sole voting and investment power. Unless otherwise indicated, the address for each selling stockholder listed in the table below is c/o Aethlon Medical, Inc., 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123.

The table below has been prepared based upon the information furnished to us by the selling stockholders as of January 31, 2019, and we have not independently verified this information. The selling stockholders identified below may have sold, transferred or otherwise disposed of some or all of their shares since the date on which the information in the following table is presented in transactions exempt from or not subject to the registration requirements of the Securities Act. Information concerning the selling stockholders may change from time to time and, if necessary, we will amend or supplement this prospectus accordingly. We cannot give an estimate as to the number of shares of Common Stock that will actually be held by the selling stockholders upon termination of this offering because the selling stockholders may offer some or all of their Common Stock under the offering contemplated by this prospectus or acquire additional shares of Common Stock. The total number of shares that may be sold hereunder will not exceed the number of shares offered hereby. Please read the section entitled "Plan of Distribution" in this prospectus.

Selling Stockholder	Shares of Common Stock Beneficially Owned Prior to this Offering (1)	Percentage of Common Stock Beneficially Owned Before Resale (1)(4)	Shares of Common Stock Offered for Resale in this Offering(2)	Shares of Common Stock Beneficially Owned After this Offering (3)	Percentage of Common Stock Beneficially Owned After Resale (1)(4)
Edward G. Broenniman, Director (5)	112,967	*	80,465	112,967	*
Charles J. Fisher, Jr., MD, Chairman and Director (6)	51,568	*	79,990	51,568	*
James B. Frakes, Chief Financial Officer (7)	62,564	*	74,971	62,564	*
Sabrina Martucci Johnson, Director (8)	44,043	*	67,449	44,043	*
James A. Joyce, Former President (9)	484,946	2.5%	574,376	484,946	2.5%
Chetan Shah, Director (10)	453,700	2.4%	80,465	453,700	2.4%
Total			957,716		

* Less than 1%

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of Common Stock underlying options currently exercisable, or exercisable, or restricted stock units that vest, within 60 days after January 31, 2019, (as used in this section, the "Determination Date"), are deemed outstanding for purposes of computing the beneficial ownership of the person

(1) Determination Date), are deemed outstanding for purposes of computing the beneficial ownership of the person holding such options and/or restricted stock units but are not deemed outstanding for computing the beneficial ownership of any other person. Except where we had knowledge of such ownership, the number presented in this column may not include shares held in street name or through other entities over which the selling stockholder has voting and dispositive power.

The shares being offered are issuable pursuant to restricted stock units outstanding on the Determination Date and

(2) that may be acquired more than 60 days from the Determination Date. As a result, not all of the shares are not beneficially owned as of the Determination Date.
 Assumes all of the shares of Common Stock being offered are sold in the offering, that shares of Common Stock

Assumes all of the shares of Common Stock being offered are sold in the offering, that shares of Common Stock beneficially owned by such selling stockholder on the Determination Date but not being offered pursuant to this (3)

- ⁽³⁾ prospectus (if any) are not sold, and that no additional shares are purchased or otherwise acquired other than pursuant to the RSUs relating to the shares being offered.
- Percentages are based on the 18,935,638 shares of Common Stock issued and outstanding as of the Determination Date.

Includes 12,000 stock options exercisable at \$12.50 per share, 9,211 stock options exercisable at \$3.80 per share,

- (5) 8,537 stock options exercisable at \$4.10 per share and 3,684 stock options exercisable at \$9.50 per share. Also includes shares underlying 8,933 restricted stock units that will vest within 60 days of January 31, 2019.
- (6) Includes shares underlying 8,933 restricted stock units that will vest within 60 days of January 31, 2019. Includes 10,000 stock options exercisable at \$12.50 per share, 10,000 stock options exercisable at \$5.00 per share
- (7) and 5,000 stock options exercisable at \$9.50 per share. Also includes shares underlying 10,907 restricted stock units that will vest within 60 days of January 31, 2019.
- (8) Includes shares underlying 8,933 restricted stock units that will vest within 60 days of January 31, 2019. Includes 90,000 stock options exercisable at \$12.50 per share, 40,000 stock options exercisable at \$5.00 per share
- (9) and 30,000 stock options exercisable at \$9.50 per share. Also includes shares underlying 39,625 restricted stock units that will vest within 60 days of January 31, 2019.
 Includes warrants to purchase 109,322 shares of common stock at exercise prices ranging from \$4.65 per share to
- (10) \$6.60 per share, and 7,521 stock options exercisable at \$4.10 per share and 3,684 stock options exercisable at \$9.50 per share. Also includes shares underlying 8,933 restricted stock units which vest within 60 days of February 17, 2019.

PLAN OF DISTRIBUTION

The shares of Common Stock covered by this reoffer prospectus are being registered by Aethlon for the account of the selling stockholders. The shares of Common Stock offered may be sold from time to time directly by or on behalf of each selling stockholder in one or more transactions on The Nasdaq Capital Market or any other stock exchange on which the Common Stock may be li