

AETHLON MEDICAL INC  
Form 424B5  
March 22, 2017

PROSPECTUS SUPPLEMENT

**Filed Pursuant to Rule 424(b)(5)**

**Registration No. 333-211151**

**Amendment No. 1 to**

**PROSPECTUS SUPPLEMENT**

**(To Prospectus dated May 12, 2016)**

**Aethlon Medical, Inc.**

**\$9,532,294**

**Common Stock**

We have entered into a sales agreement with H.C. Wainwright & Co., LLC, or H.C. Wainwright, relating to shares of our common stock, par value \$0.001 per share, offered by this prospectus supplement and the accompanying underlying prospectus. Under the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to \$12,500,000 from time to time at prevailing market prices through H.C. Wainwright as our sales agent. We are hereby reducing the remaining aggregate offering price shares we will sell under the sales agreement to \$9,532,294. This Amendment No. 1 to Prospectus Supplement (originally dated June 23, 2016) amends the offering amount hereunder to \$9,532,294, and no other changes are made, other than updating for documents incorporated by reference.

Our common stock is listed on the Nasdaq Capital Market under the symbol "AEMD." On March 17, 2017, the last reported sale price for our common stock on the Nasdaq Capital Market was \$4.17 per share.

H.C. Wainwright, as our sales agent, may sell our common stock under this prospectus supplement and the accompanying prospectus, in sales deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made from time to time directly on or

through the Nasdaq Capital Market, on any other existing trading market for our common stock, to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or in any other method permitted by law. H.C. Wainwright will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our common stock in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75,000,000. Calculated in accordance with General Instruction I.B.6 of Form S-3, as of June 23, 2016, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was approximately \$39,784,259 based upon 6,479,521 shares of our outstanding stock held by non-affiliates at the per share price of \$6.14, the closing sale price of our common stock on June 23, 2016. One-third of our public float, calculated in accordance with General Instruction I.B.6 of Form S-3 as of June 23, 2016, is equal to approximately \$13,261,420. Other than the securities offered by this prospectus supplement and the accompanying prospectus, we have not offered any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on and includes the date of the underlying prospectus other than \$955,206 of common stock sold under our at the market offering facility to which this prospectus, as amended, applies and \$680,400 principal amount of convertible notes and \$574,088 of warrants (if fully exercised) registered for resale from our December 30, 2016 placement of notes and warrants.

H.C. Wainwright will be entitled to compensation at a fixed commission rate equal to three percent (3.0%) of the gross proceeds per share sold. In connection with the sale of the common stock on our behalf, H.C. Wainwright may be deemed to be an "underwriter" within the meaning of the Securities Act, and the compensation of H.C. Wainwright may be deemed to be underwriting commissions or discounts.

**INVESTING IN OUR SECURITIES INVOLVES RISKS. YOU SHOULD REVIEW CAREFULLY THE RISKS AND UNCERTAINTIES DESCRIBED UNDER THE HEADING "RISK FACTORS" ON PAGE S-5 OF THIS PROSPECTUS SUPPLEMENT AND UNDER SIMILAR HEADINGS IN THE OTHER DOCUMENTS THAT ARE INCORPORATED BY REFERENCE INTO THIS PROSPECTUS SUPPLEMENT.**

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

**H.C. Wainwright & Co.**

Prospectus Supplement dated March 21, 2017.



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You should rely only on the information contained in or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not, and the sales agent has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the sales agent is not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information in this prospectus supplement, the accompanying prospectus, and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying

prospectus, and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus in their entirety before making an investment decision. You also should read and consider the information in the documents to which we have referred you in the section of this prospectus supplement entitled “Information Incorporated by Reference” and the sections of the accompanying prospectus entitled “Information Incorporated by Reference” and “Where You Can Find More Information.”

## **ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement and the accompanying prospectus form a part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission (the “Commission”) utilizing a “shelf” registration process. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer only to the “prospectus,” we are referring to both parts combined. This prospectus supplement may add to, update or change information contained in the accompanying prospectus. To the extent that any statement we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference herein or therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference herein and therein.

**For investors outside the United States, we have not done anything that would permit this offering or possession or distribution of this prospectus supplement in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus supplement outside of the United States.**

As permitted by the rules and regulations of the Commission, the registration statement, of which this prospectus supplement and the accompanying prospectus form a part, includes additional information not contained in this prospectus supplement or the accompanying prospectus. You may read the registration statement and the other reports we file with the Commission at the Commission's web site or at the Commission's offices described below under the heading “Where You Can Find Additional Information.”

Unless the context requires otherwise or unless otherwise noted, all references to “Aethlon” are to Aethlon Medical, Inc., a Nevada corporation, and all references to “we,” “us” or “our” are to Aethlon Medical, Inc. and its subsidiaries.

Trademarks, service marks or trade names of any other companies appearing in this prospectus supplement are the property of their respective owners. Use or display by us of trademarks, service marks or trade names owned by others is not intended to and does not imply a relationship between us and, or endorsement or sponsorship by, the owners of the trademarks, service marks or trade names.

### **Cautionary Note Regarding Forward-Looking Information**

This prospectus supplement and the documents incorporated herein by reference, in particular the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” incorporated herein by reference, contain certain “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These forward-looking statements represent our expectations, beliefs, intentions or strategies concerning future events, including, but not limited to, any statements regarding our assumptions about financial performance; the continuation of historical trends; the sufficiency of our cash balances for future liquidity and capital resource needs; the expected impact of changes in accounting policies on our results of operations, financial condition or cash flows; anticipated problems and our plans for future operations; and the economy in general or the future of the medical device industry, all of which are subject to various risks and uncertainties.

When we use in this prospectus supplement as well as in reports, statements, and information we have filed with the Commission, in our press releases, in presentations to securities analysts or investors, or in oral statements made by or with the approval of an executive officer, the words or phrases “believes,” “may,” “will,” “expects,” “should,” “continue,” “anticipates,” “intends,” “will likely result,” “estimates,” “projects” or similar expressions and variations thereof, we intend to identify forward-looking statements. However, any statements contained in this prospectus supplement that are not statements of historical fact may be deemed to be forward-looking statements. We caution that these statements by their nature involve risks and uncertainties, certain of which are beyond our control, and actual results may differ materially depending on a variety of important factors.

## PROSPECTUS SUPPLEMENT SUMMARY

*The following summary highlights some of the information contained elsewhere in this prospectus supplement or the accompanying prospectus or incorporated by reference herein or therein. Because this is only a summary, however, it does not contain all of the information that may be important to you. You should carefully read this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference, which are described under “Information Incorporated by Reference” in this prospectus supplement and under “Information Incorporated by Reference” and “Where You Can Find More Information” in the accompanying prospectus. You also should carefully consider the matters discussed in the section entitled “Risk Factors” in the accompanying prospectus and in other periodic reports incorporated herein by reference.*

### Company Overview

Our mission is to create innovative medical devices that address unmet medical needs in cancer, infectious disease, and other life-threatening conditions. Our Aethlon ADAPT™ system provides a platform to develop medical devices that target the selective removal of disease-promoting particles from the circulatory system. At present, the Aethlon ADAPT product pipeline includes the Aethlon Hemopurifier® to address infectious disease and cancer, and a medical device being developed under a five-year contract with the Defense Advanced Research Projects Agency, or DARPA, to reduce the incidence of sepsis in combat-injured soldiers.

In June 2013, the U.S. Food and Drug Administration, or FDA, approved an investigational device exemption that allows us to initiate human feasibility studies of the Aethlon Hemopurifier in the U.S. Under our approved feasibility study protocol, we will study ten end-stage renal disease patients who are infected with the Hepatitis C virus to demonstrate the safety of Hemopurifier therapy. Assuming successful completion of this study, we will be able to initiate further stage studies required for market clearance to treat Hepatitis C and other viral pathogens.

On September 30, 2011, we entered into a \$6.8 million multi-year contract with DARPA, which will terminate on September 30, 2016 unless further extended by DARPA. Under this contract, our tasks include the development of a dialysis-like device to prevent sepsis, a fatal bloodstream infection that is often the cause of death in combat-injured soldiers. To date, we have billed and collected \$5,548,573 for achieving 27 milestones under this contract.

Through our majority-owned subsidiary, Exosome Sciences, Inc., we are also developing exosome-based products to diagnose and monitor neurological disorders and cancer. To date, we are still in the product development stage.



Since inception, we have primarily financed our operations through net proceeds obtained from the private placement of our debt and equity securities. At December 31, 2015, we had a cash balance of \$3,250,897 and working capital of \$2,551,395. In June 2015, we raised \$5,591,988 in net proceeds from a financing, which, coupled with previously existing funds on hand and expected revenues from our government contracts, should finance our operations through June 30, 2016. We will require significant additional financing to complete additional future clinical trials in the U.S., as well as fund all of our continued research and development activities for the Hemopurifier and products on the Aethlon ADAPT platform.

### **Risks Associated with our Business**

We have experienced substantial operating losses since inception. As of December 31, 2015, we had an accumulated deficit of \$82,254,522, which included losses of approximately \$3,624,808 and \$5,910,444 for the nine-month periods ended December 31, 2015 and 2014, respectively. Historically, our losses have resulted principally from costs incurred in the research and development of our medical devices, and general and administrative expenses, which together were approximately \$3,980,367 and \$3,423,985 for the nine-month periods ended December 31, 2015 and 2014, respectively. We may continue to incur losses in the future.

Although we have made substantial progress in the development and testing of our devices, and have begun to generate revenue under our contract with DARPA as we meet billable milestones under such contract, we are not yet able to commercialize our devices and may never obtain the approvals necessary to commercialize our products or technologies in the U.S. or elsewhere. Our contract with DARPA is time limited. DARPA may determine to terminate our contract, and we cannot assure you that we will enter into any new government contracts with the Department of Defense or otherwise. We compete with U.S. and foreign companies that have greater scientific and organizational resources, market presence and financial backing than we have. We may be unable to obtain FDA or international clearance of the Hemopurifier. Even if we do achieve such regulatory clearances, we may be unable to successfully manufacture, market and sell our devices in the U.S. or elsewhere. These risks and others are discussed more fully in the section of the accompanying prospectus entitled "Risk Factors" immediately following the prospectus summary. You should read these risks before you invest in our securities.

### **Corporate History**

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. Upon completion of the transaction, Bishop Equities, Inc. was renamed Aethlon Medical, Inc. In 2009, we formed Exosome, which today is a majority-owned subsidiary focused on identifying and monitoring neurological conditions and cancer.

### **Our Contact Information**

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](http://www.aethlonmedical.com). Our website and the information contained on our website are not incorporated by reference into this prospectus supplement, the accompanying prospectus or the registration statement of which it forms a part.



## THE OFFERING

Common stock offered by us	In our prospectus supplement, shares having an aggregate offering price of up to \$12,500,000 reduced by us to \$9,532,294.
Manner of offering	“At the market offering” in which sales may be made from time to time at prevailing market prices through our sales agent, H.C. Wainwright & Co., LLC. See “Plan of Distribution” beginning on page S-7 of this prospectus supplement.
Common stock to be outstanding after this offering	Originally up to 2,035,830 shares, assuming a sales price of \$6.14 per share, which was the closing price on the Nasdaq Capital Market on June 23, 2016. Actual number of shares issued and outstanding will vary depending on the sales price under this offering.
Use of proceeds	We intend to use the net proceeds from this offering for general corporate purposes. See “Use of Proceeds” on page S-6 of this prospectus supplement.
Nasdaq Capital Market symbol	“AEMD”
Risk factors	This investment involves a high degree of risk. See the information set forth in “Risk Factors” beginning on page S-5 of this prospectus supplement and in the underlying prospectus and the documents incorporated by reference into this prospectus supplement and the underlying prospectus.

The number of shares of common stock to be outstanding immediately after this offering is based on 7,622,393 shares outstanding on December 31, 2015 and excludes as of that date:

· 445,557 shares of common stock issuable upon exercise of outstanding stock options under our stock incentive plans at a weighted average exercise price of \$10.89 per share;

· 2,164,093 shares of common stock reserved for issuance under outstanding warrants with a weighted average exercise price of \$6.68 per share;

· 105,112 shares of common stock reserved for issuance under outstanding convertible notes, including accrued interest through December 31, 2015, with a fixed conversion price of \$5.60 per share;

· 28,845 additional shares of common stock reserved for future issuance under our stock incentive plans.

On June 27, 2016, we modified the terms of certain outstanding notes and warrants, and issued new warrants to acquire 30,000 shares of our common stock. Giving effect to those modifications, the second and third bullet points immediately above would instead read as follows:

2,194,093 shares of common stock reserved for issuance under outstanding warrants with a weighted average exercise price of \$5.38 per share;

139,139 shares of common stock reserved for issuance under outstanding convertible notes, including accrued interest through June 27, 2016, with a fixed conversion price of \$5.00 per share.

Except as otherwise noted, all information in this prospectus supplement reflects the public offering price of \$6.14 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on June 23, 2016.

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## **RISK FACTORS**

*An investment in our securities involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below and discussed in the section titled “Risk Factors” in our most recent Annual Report on Form 10-K, as well as the risks, uncertainties and additional information set forth in our Commission reports on Forms 10-K, 10-Q and 8-K and in other documents incorporated by reference in this prospectus supplement. The risks described in such documents are not intended to be an all-inclusive list of the potential risks relating to an investment in our securities. Any of such risk factors 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 Related to This Offering**

*Our independent registered public accounting firm may conclude that there is substantial doubt regarding our ability to continue as a going concern.*

Regardless of the amount of the net proceeds that we receive from this offering, if any, our independent registered public accounting firm may conclude, in connection with the audit of our consolidated financial statements for the year ended March 31, 2016, or any other subsequent period, that there is substantial doubt regarding our ability to continue as a going concern. If our independent registered public accounting firm issues a “going concern” opinion, it could impair our ability to finance our operations through the sale of equity, incurring debt, or other financing alternatives. If we fail to raise sufficient additional capital, we will not be able to completely execute our business plan. As a result, our business would be jeopardized and we may not be able to continue. If we ceased operations, it is likely that purchasers of our common stock would lose their entire investment.

*Management will have broad discretion as to the use of the proceeds from this offering and may not use the proceeds effectively.*

Because we have not designated the amount of net proceeds from this offering to be used for any particular purpose, our management will have broad discretion as to the application of the net proceeds from this offering, as described below in “Use of Proceeds,” and could use them for purposes other than those contemplated at the time of the offering. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value of our common stock.

***Future sales of substantial amounts of our common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.***

We may issue up to \$100 in aggregate offering price of shares of common stock from time to time in this offering. The issuance from time to time of shares in this offering, as well as our ability to issue such shares in this offering, could have the effect of depressing the market price or increasing the market price volatility of our common stock.

***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 December 31, 2015, there were outstanding purchase options and warrants entitling the holders to purchase 2,659,782 common shares at a weighted average exercise price of \$7.46 per share. This includes 26,105 warrants that are conditional upon the exercise of other warrants. As of December 31, 2015, there were 105,112 shares underlying promissory notes convertible into common stock at a weighted average exercise price of \$5.60.

As of June 27, 2016, there were outstanding purchase options and warrants entitling the holders to purchase 2,632,639 common shares at a weighted average exercise price of \$6.31 per share. This includes 26,105 warrants that are conditional upon the exercise of other warrants. As of June 27, 2016, there were 139,139 shares underlying promissory notes convertible into common stock at a weighted average exercise price of \$5.00.

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. If holders exercise or convert 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.

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## USE OF PROCEEDS

We estimate that the net proceeds that we will receive from this offering will be approximately \$12,025,000, after commissions and estimated expenses payable by us, assuming the sale of an aggregate of \$12,500,000 of our common stock pursuant to this offering, which is the maximum dollar amount of gross proceeds for which we may offer our common stock under this prospectus supplement.

We currently intend to use the net proceeds from this offering for general corporate purposes, including for research and development, sales and marketing initiatives and general administrative expenses, working capital and capital expenditures. In addition, our use of proceeds may include the repayment of debt or refinancing of indebtedness or the acquisition of complementary products or companies.

We have not determined the amount of net proceeds from this offering that we will use specifically for the foregoing purposes. Pending use of the net proceeds, we intend to invest the proceeds in a variety of capital preservation instruments, including short-term, investment-grade, interest-bearing instruments.

## DILUTION

If you purchase shares of our common stock in this offering, you will experience dilution to the extent of the difference between the price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value as of December 31, 2015 was approximately \$2,612,522, or approximately \$0.34 per share. Net tangible book value per share represents our total tangible assets less total tangible liabilities, divided by the number of shares of common stock outstanding as of December 31, 2015.

After giving effect to the assumed sale by us of \$12,500,000 of our common stock in this offering at an assumed public offering price of \$6.14 per share of our common stock (the last reported sale price of our common stock on the Nasdaq Capital Market on June 23, 2016), and after deducting the estimated fees and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2015 would have been approximately \$14,637,522 or approximately \$1.52 per share of common stock. This represents an immediate increase in net tangible book value of approximately \$1.18 per share to existing shareholders and an immediate dilution of approximately \$4.62 per share to new investors. The following table illustrates this per share dilution:

Assumed public offering price per share	\$6.14
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Net tangible book value per share as of December 31, 2015	\$0.34
Increase in net tangible book value per share attributable to new investors	\$1.18
As adjusted net tangible book value per share as of December 31, 2015, after giving effect to this offering	\$1.52
Dilution per share to new investors in the offering	\$4.62

The table above assumes for illustrative purposes that an aggregate of 2,035,830 shares of our common stock are sold at a price of \$6.14 per share, the last reported sale price of our common stock on the Nasdaq Capital Market on June 23, 2016, for aggregate gross proceeds of \$12,500,000. The shares, if any, sold in this offering will be sold from time to time at various prices. An increase of \$1.00 per share in the price at which the shares are sold from the assumed offering price of \$6.14 per share shown in the table above, assuming all of our common stock in the aggregate amount of \$12,500,000 is sold at that price, would increase our adjusted net tangible book value per share after this offering to \$1.56 per share and would increase the dilution in net tangible book value per share to new investors in this offering to \$5.58 per share, after deducting commissions and estimated aggregate offering expenses payable by us. A decrease of \$1.00 per share in the price at which the shares are sold from the assumed offering price of \$6.14 per share shown in the table above, assuming all of our common stock in the aggregate amount of \$12,500,000 is sold at that price, would decrease our adjusted net tangible book value per share after this offering to \$1.46 per share and would decrease the dilution in net tangible book value per share to new investors in this offering to \$3.68 per share, after deducting commissions and estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

The above discussion and table are based on 7,622,393 shares of our common stock outstanding as of December 31, 2015 and exclude the following, as of that date:

· 445,557 shares of common stock issuable upon exercise of outstanding stock options under our stock incentive plans at a weighted average exercise price of \$10.89 per share;

· 2,164,093 shares of common stock reserved for issuance under outstanding warrants with a weighted average exercise price of \$6.68 per share;

· 105,112 shares of common stock reserved for issuance under outstanding convertible notes, including accrued interest through December 31, 2015, with a fixed conversion price of \$5.60 per share;

· 28,845 additional shares of common stock reserved for future issuance under our stock incentive plans.

On June 27, 2016, we modified the terms of certain outstanding notes and warrants, and issued new warrants to acquire 30,000 shares of our common stock. Giving effect to those modifications, the second and third bullet points immediately above would instead read as follows:

· 2,194,093 shares of common stock reserved for issuance under outstanding warrants with a weighted average exercise price of \$5.38 per share;

· 139,139 shares of common stock reserved for issuance under outstanding convertible notes, including accrued interest through June 27, 2016, with a fixed conversion price of \$5.00 per share.

## **PLAN OF DISTRIBUTION**

We have entered into a sales agreement with H.C. Wainwright, under which we may issue and sell from time to time up to \$12,500,000 (now at \$9,532,294, as amended) of our common stock through H.C. Wainwright as our sales agent. Upon our delivery of a placement notice to H.C. Wainwright pursuant to the sales agreement and subject to the terms of the sales agreement, H.C. Wainwright may sell our common stock by any method in sales deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Securities Act, including sales made from time to time directly on or through the Nasdaq Capital Market, on any other existing trading market for our common stock, to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or in any other method permitted by law.

H.C. Wainwright will offer our common stock at prevailing market prices subject to the terms and conditions of the sales agreement as agreed upon by us and H.C. Wainwright. We will designate the number of shares which we desire to sell, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in one day and any minimum price below which sales may not be made. Subject to the terms and conditions of the sales agreement, H.C. Wainwright will use its commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us. Either H.C. Wainwright or we may suspend the offering of our common stock being made under the sales agreement upon proper notice to the other party.

Under the terms of the sales agreement, we may also sell our common stock to H.C. Wainwright, as principals for their own accounts, at a price negotiated at the time of sale.

We will pay commissions to H.C. Wainwright for their services in acting as agent in the sale of our common stock at a commission rate equal to 3.0% of the gross sale price per share sold. We estimate that the total expenses for this offering, excluding commissions payable under the sales agreement, will be approximately \$100,000. We have agreed to reimburse H.C. Wainwright their reasonable out-of-pocket expenses, including attorneys' fees in an amount not to exceed \$50,000 in the aggregate, which amount is included in the estimated total expenses for this offering.

Settlement for sales of common stock will occur on the third business day following the date on which any sales are made, or on another date that is agreed upon by us and H.C. Wainwright in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sale of the common stock on our behalf, H.C. Wainwright may be deemed to be underwriters within the meaning of the Securities Act, and the compensation may be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to H.C. Wainwright against certain civil liabilities, including liabilities under the Securities Act.

This offering will terminate upon the earlier of (1) the issuance and sale of all shares of our common stock covered by this prospectus supplement and (2) the termination of the sales agreement as permitted therein.

H.C. Wainwright and each of its affiliates may in the future provide various investment banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, H.C. Wainwright will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus supplement. This summary of the material provisions of the sales agreement does not purport to be a complete statement of its terms and conditions. We will file a copy of the sales agreement with the Commission on a Current Report on Form 8-K.

## **EXPERTS**

The consolidated financial statements of Aethlon Medical, Inc. as of March 31, 2015 and 2014 and for each of the years in the two-year period ended March 31, 2015 have been audited by Squar Milner LLP (formerly Squar, Milner, Peterson, Miranda & Williamson, LLP), an independent registered public accounting firm, as stated in their report thereon and incorporated by reference in this prospectus supplement, the accompanying prospectus and the registration statement in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

## **LEGAL MATTERS**

Raines Feldman LLP has passed upon the validity of the securities offered by this prospectus supplement. Jennifer A. Post, Esq., a partner of the firm, owns approximately 16,000 shares of our common stock. Duane Morris LLP, Newark, New Jersey, is counsel for H.C. Wainwright in connection with this offering.

## **INFORMATION INCORPORATED BY REFERENCE**

This prospectus supplement is part of a registration statement on Form S-3. The Commission allows this filing to "incorporate by reference" information that we previously have filed with the Commission. This means we can disclose important information to you by referring you to other documents that we have filed with the Commission. The information that is incorporated by reference is considered part of this prospectus supplement, and information that we file later will automatically update and may supersede this information. For further information about our company and the securities being offered, you should refer to the registration statement and the following documents that are incorporated by reference:

Our Annual Report on Form 10-K for the fiscal year ended March 31, 2015, filed with the Commission on June 26, 2015, as amended on July 13, 2015 and our Annual Report on Form 10-K for the fiscal year ended March 31, 2016, filed with the Commission on June 29, 2016.

Our Quarterly Reports on Form 10-Q for the quarter ended June 30, 2015, filed with the Commission on August 13, 2015, for the quarter ended September 30, 2015, filed with the Commission on November 16, 2015, and for the quarter ended December 31, 2015, filed with the Commission on February 4, 2016, respectively and our Quarterly Reports on Form 10-Q for the quarter ended June 30, 2016, filed with the Commission on August 11, 2016, for the quarter ended September 30, 2016, filed with the Commission on November 10, 2016 and for the quarter ended December 31, 2016, filed with the Commission on February 10, 2017.

Our Current Reports on Form 8-K filed with the Commission on April 7, 2015, April 9, 2015, April 14, 2015, April 15, 2015, June 9, 2015, June 15, 2015, June 16, 2015, June 18, 2015, June 24, 2015, June 26, 2015, July 8, 2015, September 10, 2015, September 28, 2015, October 22, 2015, October 29, 2015, November 12, 2015, February 16, 2016, March 30, 2016, June 3, 2016, June 7, 2016, August 10, 2016, December 30, 2016, January 17, 2017, February 7, 2017, March 14, 2017, and March 21, 2017 respectively.

Our Definitive Proxy Statements on Schedule 14A filed with the Commission on February 23, 2016 and February 13, 2017.

All other reports filed by us pursuant to Section 13(a) or 15(d) of the Exchange Act since the end of the fiscal year covered by the annual report referred to above; and

The description of our common stock contained in our registration statement on Form 8-A filed with the Commission on July 8, 2015, including any amendments or reports filed for the purpose of updating such description.

All documents filed by us subsequent to those listed above with the Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act following the date of filing of the registration statement of which this prospectus supplement is a part and prior to the termination of the offering, shall be deemed to be incorporated by reference into this prospectus supplement and to be a part hereof from the date of filing of such documents. The information relating to our company contained in this prospectus supplement does not purport to be comprehensive and should be read together with the information contained in the incorporated documents. Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

You may request a copy of all documents that are incorporated by reference in this prospectus supplement by writing or telephoning us at the following address and number: Aethlon Medical, Inc., 9635 Granite Ridge Drive, Suite 100 San Diego, California 92123, (858) 459-7800. We will provide copies of all documents requested (not including exhibits to those documents, unless the exhibits are specifically incorporated by reference into those documents or this prospectus supplement) without charge.

**You should rely only on the information provided in and incorporated by reference into this prospectus supplement or the accompanying prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date on the front cover of these documents.**

**PROSPECTUS**

**Aethlon Medical, Inc.**

**\$12,500,000**

**Common Stock  
Debt Securities  
Warrants  
Units**

From time to time, we may offer up to \$12,500,000 of any combination of the securities described in this prospectus, either individually or in units.

This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as any documents incorporated by reference herein and therein, before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

Our common stock is listed on the Nasdaq Capital Market under the symbol "AEMD." On May 2, 2016, the last reported sale price for our common stock was \$5.16 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing on the Nasdaq Capital Market or any securities market or other exchange of the securities, if any, covered by the prospectus supplement.

The closing sale price of our common stock on April 4, 2016 was \$5.89 per share. As of April 4, 2016, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was approximately \$38,164,378 based upon 6,479,521 shares of our outstanding stock held by non-affiliates at the per share price of \$5.89. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our common stock in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75,000,000. We have not offered any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on and includes the date of this prospectus. One-third of



our public float, calculated in accordance with General Instruction I.B.6 of Form S-3, is equal to approximately \$12,721,459.

**INVESTING IN OUR SECURITIES INVOLVES RISKS. YOU SHOULD REVIEW CAREFULLY THE RISKS AND UNCERTAINTIES DESCRIBED UNDER THE HEADING "RISK FACTORS" ON PAGE 5 AND CONTAINED IN THE APPLICABLE PROSPECTUS SUPPLEMENT AND ANY RELATED FREE WRITING PROSPECTUS AND UNDER SIMILAR HEADINGS IN THE OTHER DOCUMENTS THAT ARE INCORPORATED BY REFERENCE INTO THIS PROSPECTUS.**

We will sell these securities directly to investors, through agents designated from time to time or to or through underwriters or dealers. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution" in this prospectus. If any underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

**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 May 12, 2016.**

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**No dealer, salesperson, or other person has been authorized to give any information or to make any representation not contained in this prospectus, and, if given or made, such information and representation should not be relied upon as having been authorized by us. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any of the securities offered by this prospectus in any jurisdiction or to any person to whom it is unlawful to make such offer or solicitation. Neither the delivery of this prospectus nor any sale made hereunder shall under any circumstances create an implication that there has been no change in the facts set forth in this prospectus or in our affairs since the date hereof.**

## ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement that we filed with the Securities and Exchange Commission (the "Commission") utilizing a "shelf" registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$12,500,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in any documents that we have incorporated by reference into this prospectus. You should read this prospectus, any applicable prospectus supplement and any related free writing prospectus, together with the information incorporated herein by reference as described under the heading "Where You Can Find More Information."

You should rely only on the information that we have provided or incorporated by reference in this prospectus, any applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you. We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus, any applicable prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. This prospectus and the accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus, any applicable prospectus supplement or any related free writing prospectus is delivered or securities sold on a later date.

**For investors outside the United States, we have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus outside of the United States.**

As permitted by the rules and regulations of the Commission, the registration statement, of which this prospectus forms a part, includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the Commission at the Commission's web site or at the Commission's offices described below under the heading "Where You Can Find Additional Information."

You should assume that the information contained or incorporated by reference in this prospectus, any prospectus supplement or other offering materials is accurate only as of the dates of those documents or documents incorporated by reference, as applicable. Our business, financial condition, results of operations and prospects may have changed since those dates.

Unless the context requires otherwise or unless otherwise noted, all references to "Aethlon" are to Aethlon Medical, Inc., a Nevada corporation, and all references to "we," "us" or "our" are to Aethlon Medical, Inc. and its subsidiaries.

Trademarks, service marks or trade names of any other companies appearing in this prospectus are the property of their respective owners. Use or display by us of trademarks, service marks or trade names owned by others is not intended to and does not imply a relationship between us and, or endorsement or sponsorship by, the owners of the trademarks, service marks or trade names.

### **Cautionary Note Regarding Forward-Looking Information**

This prospectus, in particular the "Management's Discussion and Analysis of Financial Condition and Results of Operations" incorporated herein by reference, contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements represent our expectations, beliefs, intentions or strategies concerning future events, including, but not limited to, any statements regarding our assumptions about financial performance; the continuation of historical trends; the sufficiency of our cash balances for future liquidity and capital resource needs; the expected impact of changes in accounting policies on our results of operations, financial condition or cash flows; anticipated problems and our plans for future operations; and the economy in general or the future of the medical device industry, all of which are subject to various risks and uncertainties.

When used in this prospectus as well as in reports, statements, and information we have filed with the Commission, in our press releases, in presentations to securities analysts or investors, or in oral statements made by or with the approval of an executive officer, the words or phrases "believes," "may," "will," "expects," "should," "continue," "anticipates," "intends," "will likely result," "estimates," "projects" or similar expressions and variations thereof are intended to identify such forward-looking statements. However, any statements contained in this prospectus that are not statements of historical fact may be deemed to be forward-looking statements. We caution that these statements by their nature involve risks and uncertainties, certain of which are beyond our control, and actual results may differ materially depending on a variety of important factors.



## PROSPECTUS SUMMARY

*This summary highlights information included or incorporated by reference in this prospectus. This summary may not contain all of the information that may be important to you. Before making an investment decision, you should read carefully this entire prospectus, any accompanying prospectus supplement and any other offering materials, together with the additional information described under the heading "Where You Can Find More Information" on page 37 of this prospectus.*

### Company Overview

Our mission is to create innovative medical devices that address unmet medical needs in cancer, infectious disease, and other life-threatening conditions. Our Aethlon ADAPT™ system provides a platform to develop medical devices that target the selective removal of disease-promoting particles from the circulatory system. At present, the Aethlon ADAPT product pipeline includes the Aethlon Hemopurifier® to address infectious disease and cancer, and a medical device being developed under a five-year contract with the Defense Advanced Research Projects Agency, or DARPA, to reduce the incidence of sepsis in combat-injured soldiers.

In the treatment of infectious diseases, the Hemopurifier is designed for the single-use removal of viruses and shed glycoproteins from circulation. In cancer-related therapy situations, we are exploring the potential use of the Hemopurifier to remove tumor-secreted exosomes, which promote cancer progression. *In vitro* studies have demonstrated that our Hemopurifier can capture exosomes underlying a broad-spectrum of cancer indications. To support our endeavors, we applied for and have received patent protection for the capture of tumor-secreted exosomes.

In June 2013, the U.S. Food and Drug Administration, or FDA, approved an investigational device exemption that allows us to initiate human feasibility studies of the Aethlon Hemopurifier in the U.S. Under our approved feasibility study protocol, we will study ten end-stage renal disease patients who are infected with the Hepatitis C virus to demonstrate the safety of Hemopurifier therapy. Assuming successful completion of this study, we will be able to initiate further stage studies required for market clearance to treat Hepatitis C and other viral pathogens.

We began enrolling patients for the study at the DaVita Dialysis Medical Center in Houston, Texas in February 2015. We expect to complete the study by the end of 2016. However, we cannot assure you that the clinical trial will be completed by then.

On September 30, 2011, we entered into a \$6.8 million multi-year contract with DARPA, which will terminate on September 30, 2016 unless further extended by DARPA. Under this contract, our tasks include the development of a dialysis-like device to prevent sepsis, a fatal bloodstream infection that is often the cause of death in combat-injured soldiers. To date, we have billed and collected \$5,548,573 for achieving 27 milestones under this contract.

Through our majority-owned subsidiary, Exosome Sciences, Inc., we are also developing exosome-based products to diagnose and monitor neurological disorders and cancer. To date, we are still in the product development stage.

Since inception, we have primarily financed our operations through net proceeds obtained from the private placement of our debt and equity securities. At December 31, 2015, we had a cash balance of \$3,250,897 and working capital of \$2,551,395. In June 2015, we raised \$5,591,988 in net proceeds from a financing, which, coupled with previously existing funds on hand and expected revenues from our government contracts, should finance our operations through June 30, 2016. We will require significant additional financing to complete additional future clinical trials in the U.S., as well as fund all of our continued research and development activities for the Hemopurifier and products on the Aethlon ADAPT platform.

### **Risks Associated with our Business**

We have experienced substantial operating losses since inception. As of December 31, 2015, we had an accumulated deficit of \$82,254,522, which included losses of approximately \$3,624,808 and \$5,910,444 for the nine-month periods ended December 31, 2015 and 2014, respectively. Historically, our losses have resulted principally from costs incurred in the research and development of our medical devices, and general and administrative expenses, which together were approximately \$3,980,367 and \$3,423,985 for the nine-month periods ended December 31, 2015 and 2014, respectively. We may continue to incur losses in the future.



Although we have made substantial progress in the development and testing of our devices, and have begun to generate revenue under our contract with DARPA as we meet billable milestones under such contract, we are not yet able to commercialize our devices and may never obtain the approvals necessary to commercialize our products or technologies in the U.S. or elsewhere. Our contract with DARPA is time limited. DARPA may determine to terminate our contract, and we cannot assure you that we will enter into any new government contracts with the Department of Defense or otherwise. We compete with U.S. and foreign companies that have greater scientific and organizational resources, market presence and financial backing than we have. We may be unable to obtain FDA or international clearance of the Hemopurifier. Even if we do achieve such regulatory clearances, we may be unable to successfully manufacture, market and sell our devices in the U.S. or elsewhere. These risks and others are discussed more fully in the section of this prospectus entitled “Risk Factors” immediately following this prospectus summary. You should read these risks before you invest in our securities.

## **Corporate History**

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, 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 Contact Information**

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](http://www.aethlonmedical.com). Our website and the information contained on our website are not incorporated by reference into this prospectus or the registration statement of which it forms a part.

## **Securities We May Offer**

With this prospectus, together with any applicable prospectus supplement and related free writing prospectus, we may offer common stock, debt securities and warrants, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities. The aggregate initial offering price of all securities we sell in the primary offering under this prospectus will not exceed \$12,500,000. If we issue debt securities at a discount from their

original stated principal amount, then, for purposes of calculating the total dollar amount of all securities issued under this prospectus, we will treat the initial offering price of the debt securities as the total original principal amount of the debt securities. Each time we offer securities with this prospectus, we will provide offerees with a prospectus supplement that will contain the specific terms of the securities being offered. The following is a summary of the securities we may offer with this prospectus.

We may sell the securities to or through underwriters, dealers or agents or directly to purchasers. We, as well as any agents acting on our behalf, reserve the sole right to accept and to reject in whole or in part any proposed purchase of securities. Each prospectus supplement will set forth the names of any underwriters, dealers or agents involved in the sale of securities described in that prospectus supplement and any applicable fee, commission or discount arrangements with them.

### ***Common Stock***

We may offer shares of our common stock, par value \$0.001 per share, either alone or underlying other registered securities convertible into or exercisable for our common stock. Holders of our common stock are entitled to such dividends as our Board of Directors may declare from time to time out of legally available funds. Currently, we do not pay any dividends. Each holder of our common stock is entitled to one vote per share. In this prospectus, we provide a general description of, among other things, our dividend policy and the rights and restrictions that apply to holders of our common stock.

### ***Debt Securities***

We may offer general debt obligations, which may be secured or unsecured, senior or subordinated and convertible into shares of our common stock. In this prospectus, we refer to the senior debt securities and the subordinated debt securities together as the "debt securities." We may issue debt securities under a note purchase agreement or under an indenture to be entered between us and a trustee. If we issue debt securities under an indenture, a form of the indenture will be filed as an exhibit to the registration statement of which this prospectus is a part, or will be incorporated by reference from a current report on Form 8-K that we file with the Commission. The senior debt securities will have the same rank as all of our other indebtedness that is not subordinated. The subordinated debt securities will be subordinated to our senior debt on terms set forth in the applicable prospectus supplement. In addition, the subordinated debt securities will be effectively subordinated to creditors of our subsidiaries. Our Board of Directors will determine the terms of each series of debt securities being offered.

This prospectus contains only general terms and provisions of the debt securities. The applicable prospectus supplement will describe the particular terms of the debt securities offered thereby. We urge you to read the prospectus supplements and any free writing prospectus that we may authorize to be provided to you related to the debt securities being offered, as well as the complete indentures that contain the terms of the debt securities. Although the forms of indentures may be filed as exhibits to the registration statement to which this prospectus is a part, supplemental indentures and forms of debt securities containing the terms of debt securities being offered will be incorporated by reference into the registration statement of which this prospectus is a part in reports we file with the Commission.

### *Warrants*

We may offer warrants for the purchase of debt securities or shares of common stock. We may issue the warrants by themselves or together with debt securities or common stock, and the warrants may be attached to or separate from any offered securities. Each series of securities warrants will be issued under a separate warrant agreement to be entered into between us and the investors or a warrant agent. Our Board of Directors will determine the terms of the warrants. This prospectus contains only general terms and provisions of the warrants. The applicable prospectus supplement will describe the particular terms of the warrants being offered thereby. We urge you to read the prospectus supplements and any free writing prospectus that we may authorize to be provided to you related to the warrants being offered, as well as the complete warrant agreements and warrant certificates that contain the terms of the warrants.

### *Units*

We may offer units consisting of common stock, debt securities and/or warrants to purchase any of such securities in one or more series. In this prospectus, we have summarized certain general features of the units under "Description of Units." We urge you, however, to read the prospectus supplements and any free writing prospectus that we may authorize to be provided to you related to the series of units being offered, as well as the unit agreements that contain the terms of the units. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from a current report on Form 8-K that we file with the Commission, the form of unit agreement and any supplemental agreements that describe the terms of the series of units we are offering before the issuance of the related series of units.

We will evidence each series of units by unit certificates that we will issue under a separate agreement. We will enter into the unit agreements with a unit agent. Each unit agent will be a bank or trust company that we select. We will indicate the name and address of the unit agent in the applicable prospectus supplement relating to a particular series of units.

## **RISK FACTORS**

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

### **Risks Relating to Our Financial Position and Need for Additional Capital**

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

We have never been profitable. We have generated revenues during the fiscal years ended March 31, 2015 and March 31, 2014, in the amounts of \$762,417, and \$1,623,769, respectively, primarily from our contract with DARPA. During the nine-month periods ended December 31, 2015 and December 31, 2014, we generated revenues in the amounts of \$681,907 and \$563,805, respectively, primarily from our contract with DARPA.

However, our revenues continue to be insufficient to cover our cost of operations. Future profitability, if any, will require the successful commercialization of our Hemopurifier technology, other products that may emerge from our Aethlon ADAPT platform or from additional government contract or grant income. We cannot assure you when or if we will be able to successfully commercialize one or more of our products, or if commercialization is successful, whether we will ever be profitable.

***Our internal control over financial reporting does not currently meet the standards required by Section 404 of the Sarbanes-Oxley Act of 2002, as amended, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could result in material misstatements of our annual or interim financial statements and have a material adverse effect on our business and share price.***

We are not currently required to make a formal assessment of the effectiveness of our internal control over financial reporting for purposes of compliance with the Commission's rules that implement Section 404 of the Sarbanes-Oxley Act of 2002. We are, however, required to comply with certain of these rules, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting. This assessment must include the disclosure of any material weaknesses or significant deficiencies in our internal control over financial reporting identified by our management or our independent registered public accounting firm. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with our audits for the years ended March 31, 2015 and 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of such periods, due to the material weaknesses in our internal controls over financial reporting identified in our Annual Report on Form 10-K for the year ended March 31, 2015, our disclosure controls and procedures are not effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act and are not effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management identified material weaknesses related to a lack of segregation of duties and a lack of sufficient staffing in our accounting department.

We are in the process of developing and implementing remediation plans to address these material weaknesses. We cannot assure you that our plans will sufficiently address these issues, nor can we assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. A failure to remediate these issues may lead to significant year-end audit adjustments to our consolidated financial statements and related disclosures or to material misstatement of our annual or interim financial statements. Additionally, in the event that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, we may be unable to raise capital and the trading price of our common stock could decline.

***We will require additional financing to sustain our operations, and without it, we will not be able to continue operations.***

In June 2015, we raised \$5,591,988 in net proceeds from a financing. That amount, coupled with previously existing funds on hand and expected revenues from our government contracts, should finance our operations through June 30, 2016. We will require significant additional financing to complete additional future clinical trials in the U.S., as well as fund all of our continued research and development activities for the Hemopurifier and products on our Aethlon ADAPT platform. In addition, as we expand our activities, our overhead costs to support personnel, laboratory materials and infrastructure will increase. The financing we require to sustain our working capital needs may not be available to us on reasonable terms, if at all, when we require it. In addition, raising funds at a price below \$6.30 per share of common stock will require us to obtain the consent of certain of our investors, which they may or may not be willing to provide. Therefore, 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.

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

We will need to raise additional funds through debt or equity financings in order to complete our ultimate business objectives, including funding working capital to support development and regulatory clearance of our products. We also may choose to raise additional funds in debt or equity financings if they are available to us on reasonable terms to increase our working capital and to strengthen our financial position. Any sales of additional equity or convertible debt securities would 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 and research and development resources than we have. Our competitors are developing vaccine candidates, which could compete with the Hemopurifier medical device candidates 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;
- are better tolerated;
- are more adaptable to various modes of dosing;
- are easier to administer; or
- are less expensive than the products or product candidates we are developing.

Even if we are successful in developing the Hemopurifier and other Aethlon ADAPT-based 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 either that are 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 have. 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 Aethlon ADAPT-based products, we will need to secure large-scale manufacturing agreements with contract manufacturers that 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. We cannot assure you that manufacturing and control problems will not arise as we attempt to commercialize our products or that such manufacturing can be completed in a timely manner or at a commercially reasonable cost. In addition, we cannot assure you that we will 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 when they have obtained regulatory clearances, we may never generate revenue from product sales and we may never be profitable.

***Our Aethlon ADAPT technology may become obsolete.***

Our Aethlon ADAPT products may be made unmarketable by new scientific or technological developments where new treatment modalities are introduced that are more efficacious and/or more economical than our Aethlon ADAPT 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 that 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. We cannot assure you that our products will remain competitive with products based on new technologies.



***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 pre-clinical testing of the Hemopurifier. All other chemicals are fully inventoried and reported to the appropriate authorities, such as the fire department, who inspect our facilities 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 and/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 success is dependent in part on a few key executive officers.***

Our success depends to a critical extent on the continued services of our Chief Executive Officer, James A. Joyce, and our President, Rodney S. Kenley. 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 can give you no assurances that we can find satisfactory replacements for these key executive officers at all, or on terms that are not unduly expensive or burdensome to us. Although Mr. Joyce has signed an employment agreement providing for his continued service to us, this agreement will not preclude him from leaving us should we be unable to compete with offers for employment he may receive from other companies. We do not currently carry key man life insurance policies on either 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 five full-time employees consisting of our Chief Executive Officer, our President, our Chief Financial Officer, a research scientist and an executive assistant and one consultant acting in the capacity of Chief Science Officer. We utilize consultants, whenever appropriate, 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 cannot assure you that we will be able to engage the services of such 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 also will 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 that 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 to 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 that 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 products are 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 it believes that applicable regulatory criteria are not satisfied;
  - the FDA may require additional testing for safety and effectiveness;
- the FDA may interpret data from pre-clinical testing and clinical trials in different ways than we interpret them; if regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
  - the FDA may change its approval policies and/or adopt new regulations.

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

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

***Delays in successfully completing our planned clinical trials could jeopardize our ability to obtain regulatory approval.***

Our business prospects will depend on our ability to complete studies and clinical trials, obtain satisfactory results, obtain required regulatory approvals and successfully commercialize our Hemopurifier product candidates. 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:

- 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 other 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. 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 Quality System Regulation 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 Quality System Regulation 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:

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

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

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

***In the future, our products may 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. In the case of the FDA, the authority to require a recall must be based on an FDA 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 the recalls when they occurred.

We are also required to follow detailed recordkeeping requirements for all company-initiated medical device corrections and removals. In addition, in December 2012, the FDA issued a draft guidance intended to assist the FDA

and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 301 et seq., that change would generally constitute a medical device recall and require submission of a recall report to the FDA.

***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 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 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 acceptance 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 may 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 future product candidates that we may develop, and we 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 such 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 pre-clinical liability risks, which could place a substantial financial burden upon us should we be sued.***

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

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

Our Hemopurifier products 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. We cannot give assurances that our insurance coverage will 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 adverse 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 510(k) clearance from the FDA, unless an exemption exists. A premarket approval 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. A 510(k) submission is used to demonstrate that a device is “substantially equivalent” to a predicate device (one that has been cleared by the FDA). A 510(k) submission is cleared when the FDA issues an order finding the device to be substantially equivalent to the predicate device and stating that the device can be marketed in the U.S. We expect that any product we seek regulatory approval for will require a premarket approval. The FDA approval process involves, among other things, successfully completing clinical trials and filing for and obtaining a premarket approval. The premarket approval process requires us to prove the safety and effectiveness of our products to the FDA’s satisfaction. This process, which includes pre-clinical 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 premarket approval. Data obtained from pre-clinical 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 premarket approval application for many reasons, including:

- our inability to demonstrate safety or effectiveness to the FDA’s satisfaction;
- insufficient data from our pre-clinical 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 pre-clinical, 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 premarket approval 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 premarket approval is much more costly and 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 premarket approval in order for us to market them 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, we cannot assure you that the current approval from the FDA to proceed will not be revoked, that the study will be successful, or that the FDA premarket approval will eventually be obtained and not 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 we cannot be certain any products we develop for such uses would 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 we cannot be certain that the FDA will approve any of our product candidates.

***The Hemopurifier was used to treat one patient suffering from Ebola, and we have received a supplement to our investigational device exemption to establish protocols to treat Ebola patients in the U.S.; however, you should not construe these events as demonstrating that the device is effective in treating Ebola.***

In October 2014, physicians at the Frankfurt University Hospital in Frankfurt, Germany administered Hemopurifier therapy in a 6.5-hour treatment session to a patient infected with Ebola. This treatment was made on an emergency basis. The patient was administered Hemopurifier therapy through special approval from The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), an independent federal higher authority within the portfolio of the Federal Ministry of Health of Germany. While we believe the results of the treatment of the Ebola patient in Germany to be positive with respect to the usage of the Hemopurifier to combat Ebola, no medical organization or regulatory organization, inside or outside the U.S., has cleared the use of the device for Ebola treatment on a commercial basis.

In addition, although the FDA approved a supplement to our investigational device exemption to establish a protocol for the treatment of Ebola patients in the U.S., this approval is very limited and we cannot predict the results of such protocol and potential treatments, if any. The usefulness of the Hemopurifier in treating Ebola is still unproven in any clinical or regulatory process in the U.S. or elsewhere. Even if we enroll patients in the Ebola protocol, the results of such treatments may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval of the Hemopurifier for any uses associated with Ebola. In addition, the approval of the supplement to our investigational device exemption does not in any way ensure clearance or approval of the Hemopurifier device for any purpose. In April 2015, we submitted a Humanitarian Use Device submission to the FDA to support market clearance of the Hemopurifier as a treatment for Ebola virus. If the application is designated by the FDA, we then may submit a Humanitarian Device Exemption marketing application to the Center for Devices and Radiological Health for marketing review. We cannot assure you that the Hemopurifier will prove to be useful in the treatment of Ebola, that U.S. or foreign regulatory agencies will ever approve it for such use, or if approved, that we will successfully commercialize it for such use. We may never commercialize the Hemopurifier specifically for use in treating Ebola.

***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. We must conduct clinical studies in compliance with FDA regulations, or the FDA may take enforcement action. Ultimately, we may use the data collected from these clinical studies to support market clearance for these products. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will 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. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. We cannot 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.

***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 the FDA approve our products for commercialization, we cannot assure you that our future products will be considered cost-effective, that reimbursement will be available in other sites or in other countries, including the U.S., if approved, or that reimbursement will be sufficient to allow sales of our future products on a profitable basis. The assessment of our future products by health technology assessment bodies will significantly influence coverage decisions of third-party payors. Such assessments are outside our control, and we cannot assure you that such evaluations will be conducted or that they will 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, 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 the Centers for Medicare & Medicaid Services is lengthy and expensive. Further, Medicare coverage is based on our ability to demonstrate the treatment is “reasonable and necessary” for Medicare beneficiaries. Even if products utilizing our Aethlon ADAPT system receive FDA and other regulatory clearance or approval, they may not be granted coverage and reimbursement by any payor, including by the Centers for Medicare & Medicaid Services. For some governmental programs, such as Medicaid, coverage and 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 Aethlon ADAPT system, or any payment at all. Moreover, many private payors use coverage decisions and payment amounts determined by the Centers for Medicare & Medicaid Services as guidelines in setting their coverage and reimbursement policies and amounts. If the Centers for Medicare & Medicaid Services 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.

***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, as amended, 42 U.S.C. § 18001 et seq., among other things, reduced and/or limited Medicare reimbursement to certain providers. The Budget Control Act of 2011, Pub. L. 112-25, as amended by subsequent legislation, further reduces Medicare's payments to providers by two percent through fiscal year 2024. 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, we cannot be certain that payors will reimburse our product or the procedures or patient care performed using our product 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.***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, as amended, 42 U.S.C. §18001 et seq., 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. Once we market products, 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 future sales of medical devices in the U.S. will be subject to this 2.3% excise tax.



## **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 should be challenged or defeated by third parties, our research efforts could be materially and adversely affected. We cannot assure you that any of our licenses or patents assigned to us will continue in force for as long as we require for our research, development and testing of cancer treatments. We cannot assure you that, should our licenses terminate, should third parties challenge or defeat the underlying patents and intellectual property, or should third parties challenge or defeat patents and intellectual property assigned to us, we can obtain suitable replacements or develop suitable replacements 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 our 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. We may be unaware of existing third-party patents 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 disease 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, a patent holding company or other adverse patent owner that has no relevant product revenues and against which our patents may provide little or no deterrence may threaten or bring litigation. If a court were to find that we infringed any of these patents, it could require us to pay substantial damages, including triple damages if it were to find a willful infringement. A court could require us to pay royalties and could prevent us 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, and we cannot assure you that we would be able to redesign our products in a way that would not infringe those patents. If we fail to obtain any required licenses or make any necessary changes to our technologies or the products that incorporate them, 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 three issued U.S. patents and eight pending U.S. patent applications. We also have fourteen issued foreign patents, have applied for five additional foreign patents and have two pending international patent applications. 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. Third parties can challenge the scope, validity or enforceability of our issued patents 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, we cannot assure you that this protection will 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, we may not be able to enforce these agreements, or they 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 cannot assure you that we will 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 need to rely on licenses for new technology, and any inability to obtain licenses or integrate those licenses could have a material adverse effect on our continued operations.***

As we develop our technology, we may need to license additional technologies to optimize the performance of our products and/or to develop new 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. We cannot provide assurances that our existing patents or our pending and proposed patent applications will offer meaningful protection if a competitor develops a novel product based on a new technology. If our

competitors develop new technology that is competitive with our products, the demand for our products could decline and adversely affect the results of our operations.

***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. We cannot assure you that our patents will prevent other companies from developing similar products or products that produce benefits substantially the same as our products, or that other companies will not 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. Additionally, we cannot assure investors that any of our products or technology will be patentable or that any future patents we obtain will give us an exclusive position in the subject matter claimed by those patents. Furthermore, we cannot assure investors that our pending patent applications will result in issued patents, that patent protection will be secured for any particular technology, or that our issued patents will be valid or enforceable or provide us with meaningful protection.

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

Although we have entered into invention assignment agreements with our employees and with certain advisors, and we routinely enter into confidentiality agreements with our contract partners, if those employees, advisors or contract partners develop inventions or processes independently that may relate to products or technology under development by us, disputes may arise about the ownership of those inventions or processes. We may be required to engage in time-consuming and costly litigation 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. In addition, we may be unable to fund the costs of 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, we cannot assure you that a court will not find our products or technology 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 cannot assure investors that we would prevail in any such litigation. If a court finds us 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 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**

***Our revenues are almost entirely derived from one U.S. Government contract.***

We have derived and expect for the near future to continue to derive substantially all of our revenue under our DARPA contract. If DARPA chooses not to continue our contract in year five (commencing October 1, 2015 through September 30, 2016) of the contract, our revenues could be substantially reduced. In addition, if we are unable to meet any of the DARPA contract milestones to the satisfaction of DARPA, if at all, we may not earn payments under the contract. Any reduction in our revenues, or the termination of the DARPA contract for any reason, could have a material and adverse effect on our business and operations. In addition, DARPA has the right to unilaterally cancel the contract at any time.

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

We can give no assurances that we will be successful in obtaining additional government grants or contracts. The process of applying for government contracts is lengthy, and we cannot be certain that we will be successful in obtaining announced grants or contracts for therapeutics as a medical device technology. Accordingly, we cannot be certain that we will 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 ADAPT system is likely 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 anyone were to make allegations of impropriety 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 to which purely private sector companies are not.

***Our DARPA contract is a fixed price contract, which may not adequately cover our costs in performance should those costs increase.***

Our contract with DARPA is on a firm fixed price basis, which means that we are required to deliver our products at a fixed price regardless of the actual costs we incur and to absorb any costs in excess of the fixed price. If we have not accurately estimated the costs of expenses to perform the contract, we may not have positive revenue and we may incur losses to cover our costs. We expect that our future contracts, if any, with the U.S. Government also may be fixed price contracts. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss, which could in turn harm our operating results.

***As a U.S. Government contractor, we are subject to a number of procurement rules and regulations.***

Government contractors must comply with numerous procurement regulations. These regulations, 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 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 could also lead to suspension or debarment, for cause, from government contracting or subcontracting for a period of time. Among the causes for debarment are violations of various statutes, including those related to procurement integrity, export control, government security regulations, employment practices, protection of the environment, accuracy of records and the recording of costs, and foreign corruption. The termination of our government contract as a result of any of these acts could have a negative impact on our results of operations and financial condition and could have a negative impact on our reputation and ability to procure other government contracts in the future.

*In fulfilling our DARPA contract, we depend on a predictable supply of raw materials and components.*

We are dependent upon the delivery by suppliers of materials and the assembly by subcontractors of major components and subsystems used in our products in a timely and satisfactory manner and in full compliance with applicable terms and conditions. Some products require relatively scarce raw materials. We are generally subject to specific procurement requirements, which may, in effect, limit th