

AETHLON MEDICAL INC  
Form POS AM  
July 14, 2015

**As filed with the Securities and Exchange Commission on July 14, 2015**

**Registration No. 333-201334**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**POST-EFFECTIVE AMENDMENT NO. 1 TO FORM S-1**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

AETHLON MEDICAL, INC.  
(Exact name of registrant as specified in its charter)

Nevada  
(State or other jurisdiction of incorporation or organization)

3826  
(Primary Standard Industrial Classification Code Number)

13-3632859  
(I.R.S. Employer Identification Number)

9635 Granite Ridge Drive, Suite 100

San Diego, California 92123

(858) 459-7800  
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

James A. Joyce

9635 Granite Ridge Drive, Suite 100

San Diego, California 92123

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(858) 459-7800

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

With copies of all correspondence to:

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per unit (2)	Proposed maximum aggregate offering price	Amount of registration fee (3)
Common Stock, par value \$0.001, underlying warrants held by current stockholders subject to this offering	275,000 shares	\$15.00 (2)	\$4,125,000	\$479.33
Total	275,000 shares		\$4,125,000	\$479.33

(1) Pursuant to Rule 416 of the Securities Act of 1933, as amended, this Registration Statement also shall cover any additional shares of common stock that shall become issuable by reason of any stock dividend, stock split, recapitalization, or other similar transaction by the registrant. The number of shares remaining to be offered hereunder consists of 275,000 of common stock underlying warrants.

(2) Estimated pursuant to Rule 457(g) of the Securities Act of 1933, as amended, solely for purposes of calculating amount of the registration fee, based upon an exercise price of \$15.00 per share.

(3) Fee paid in connection with the registrant's Form S-1 filed with the Securities and Exchange Commission on December 31, 2014.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.**

## **Explanatory Note**

This Post-Effective Amendment No. 1 to Form S-1 relates solely to the sale by selling stockholders of up to 275,000 shares of common stock to be issued upon exercise of warrants issued with respect to that certain securities purchase agreement between the registrant and certain selling stockholders, which are signatories thereto, which were previously registered under the registration statement on Form S-1 (Registration No. 333-201334) of the registrant declared effective on January 28, 2015 by the Securities and Exchange Commission. The aforesaid registration statement originally registered for resale 220,000 shares of common stock and 275,000 shares of common stock underlying warrants. Of that original amount, selling stockholders sold 220,000 shares of common stock, thus leaving 275,000 shares of common stock to be issued upon exercise of the warrants available for resale under the registration statement. This Post-Effective Amendment No. 1 to Form S-1 is being filed to include the financial statements for the year ended March 31, 2015. All filing fees payable in connection with the registration of these securities were previously paid by the registrant at the time of filing the original registration statement on Form S-1.

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**Subject to completion, dated July 14, 2015**

## **PROSPECTUS**

**Aethlon Medical, Inc.**

275,000 Shares of Common Stock

This prospectus relates to the following common stock that may be sold from time to time by the selling stockholders identified in this prospectus:

275,000 shares of common stock underlying common stock purchase warrants at an exercise price of \$15.00 per share.

All of the common stock covered by this prospectus is being sold by the selling stockholders for their own account. We will not receive any proceeds from the sale of these shares other than proceeds, if any, from the exercise of warrants to purchase shares of our common stock. If all of the warrants are exercised for cash, we will receive a total of \$4,125,000 in gross proceeds, which we expect to use for general corporate purposes. We cannot assure you that any warrants will be exercised for cash. The selling stockholders may offer and sell the shares covered by this prospectus at prevailing prices quoted on the Nasdaq Capital Market or at privately negotiated prices. The selling stockholders may sell the shares directly or through underwriters, brokers or dealers. The selling stockholders will bear any applicable sales commissions, transfer taxes and similar expenses. We will pay all other expenses incident to the registration of the shares. See "Plan of Distribution" on page 30 for more information on this topic.

Our common stock is traded on the Nasdaq Capital Market under the symbol "AEMD." On July 13, 2015, the last reported sale price of our common stock on the Nasdaq Capital Market was \$8.94.

**Investing in our securities involves significant risks, including those set forth in the “Risk Factors” section of this prospectus beginning at page 4.**

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 \_\_\_\_\_, 2015.

**AETHLON MEDICAL, INC.**

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## **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission for the selling stockholders referred to in this prospectus. Under the registration statement, once effective, the selling stockholders may offer and sell from time to time up to 275,000 shares of our common stock. This prospectus does not contain all of the information included in the registration statement. The registration statement filed with the Securities and Exchange Commission includes exhibits that provide more details about the matters discussed in this prospectus.

**You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this document, regardless of the time of delivery of this prospectus or the time of issuance or sale of any securities. Our business, financial condition, results of operations and prospects may have changed since that date. You should read this prospectus in its entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the section of this prospectus entitled “Where You Can Find More Information.”**

**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.**

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

This prospectus, in particular the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing herein, contains certain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These 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 Securities and Exchange 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 important information about us and our business, this offering and selected other information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding whether to invest in our securities. You should carefully read the entire prospectus, including the information set forth in the section entitled “Risk Factors.”*

### **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 from 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 and have completed the treatment protocol on one patient. The expected duration of the study is one year.

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 \$4,871,726 for achieving 25 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 March 31, 2015, we had a cash balance of \$855,596 and working capital of \$630,420. 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 for the fiscal year ending March 31, 2016, including the cost of our current clinical trials. However, 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 beyond the fiscal year ending March 31, 2016.

## **Risks Associated with our Business**

We have experienced substantial operating losses since inception. As of March 31, 2015, we had an accumulated deficit of \$81,629,714, which included losses of approximately \$6,797,157 and \$13,357,232 for the fiscal years ended March 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 \$3,992,853 and \$3,055,928 for the fiscal years ended March 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 common stock.

## **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 executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. Exosome Sciences, Inc. maintains offices and laboratories at 11 Deer Park Drive, South Brunswick, New Jersey 08810. 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.

## **Private Placement of Common Stock and Warrants**

On December 2, 2014, we completed a private placement of units, each unit being comprised of one share of common stock, \$0.001 par value per share, and a warrant to purchase 1.2 shares of our common stock at an exercise price per share of \$15.00, with a term of five years from the date of issuance. We sold a total of 220,000 units, consisting of 220,000 shares of common stock and warrants to purchase 264,000 shares of common stock for gross proceeds of \$3,300,000 and net proceeds of \$3,001,000. We are using the proceeds from the private placement for general corporate purposes. At the closing of the private placement, we issued to Roth Capital Partners, LLC, the placement agent for the transaction, a five-year warrant to purchase up to 11,000 shares of our common stock at an exercise price of \$15.00 per share.

As part of the private placement, we entered into a registration rights agreement with the purchasers pursuant to which we agreed to file a registration statement to register for resale the shares of common stock sold in the private placement, including the shares underlying the warrants sold in the private placement, within 20 calendar days following the closing of the private placement. We agreed to use our best efforts to keep the registration statement effective under the Securities Act of 1933, as amended, until the earlier of (i) the date that is two and one-half years after the closing of the private placement or (ii) the date on which the purchasers have sold all of the shares covered by the registration statement. We are filing this post-effective amendment to the original registration statement on Form S-1 in order to fulfill our obligation under this registration rights agreement.

On June 25, 2015, we consummated another private placement of units, each comprised of one share of common stock and 0.75 of a five-year warrant to purchase one share of common stock at an exercise price of \$6.30 per share, for gross proceeds of \$6,000,000 and net proceeds of \$5,591,988. We issued 952,383 shares of common stock and warrants to purchase 714,286 shares of common stock. The securities sold in the June 2015 financing are not being offered in this prospectus.

In both private placement transactions, the issuance of the shares of common stock and the warrants was exempt from registration under the Securities Act of 1933, as amended, pursuant to the exemption for transactions by an issuer not involving a public offering under Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder.

## The Offering

Common stock  
offered by the selling Up to 275,000 shares  
stockholders

Common stock  
outstanding 7,610,344 shares as of July 10, 2015

Terms of the offering The selling stockholders will determine when and how they sell the common stock offered in this prospectus, as described in “Plan of Distribution.”

Use of proceeds We will not receive any of the proceeds from the sale of the shares of common stock being offered under this prospectus. To the extent that we receive proceeds upon the exercise of the warrants by the selling stockholders, we intend to use any such proceeds for general corporate purposes. If all of the warrants are exercised in full for cash, we would receive \$4,125,000. See “Use of Proceeds.”

Market symbol and trading Our common stock is traded on the Nasdaq Capital Market under the symbol “AEMD.” On July 7, 2015, The NASDAQ Stock Market LLC approved our application to list our common stock on the Nasdaq Capital Market under the symbol “AEMD,” and we commenced trading on the Nasdaq Capital Market on July 13, 2015.

Risk factors You should read the “Risk Factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

## 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. 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 Securities and Exchange 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 Securities Exchange Act of 1934, as amended, and are not effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, 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 controls 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.***

We recently 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 for the fiscal year ending March 31, 2016, including the cost of our current clinical trials. However, 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 beyond the fiscal year ending March 31, 2016. In addition, as we expand our activities, our overhead costs to support personnel, laboratory materials and infrastructure will increase. Should the financing we require to sustain our working capital needs be unavailable to us on reasonable terms, if at all, when we require it, 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.

*We have a limited number of shares of common stock that we may issue, or reserve for issuance, under our Articles of Incorporation; as a result we will need to increase the number of shares of authorized common stock in order to raise any significant amount of capital in the future or issue stock options, or pursue acquisitions using our common stock as consideration.*

We are currently unable to raise any significant amount of working capital through the issuance of common stock or securities, including debt securities, convertible into or exercisable for, common stock. Under our Articles of Incorporation, we are authorized to issue 10,000,000 shares of common stock. As of June 25, 2015, we have either issued, or reserved for issuance, nearly all of the 10,000,000 authorized shares. As a result, we cannot raise any significant amount of working capital through the issuance of securities, including debt securities that are convertible into, or exercisable for, common stock until we increase the number of shares of common stock available for issuance. Upon increasing our authorized common stock to a number greater than 10,000,000, we will be able to use such newly authorized shares for issuance in capital raising transactions, or in connection with acquisitions, or for the granting of incentive equity including stock options. However, we cannot assure you that we will be able to increase our authorized shares prior to the need to raise additional capital or utilize our common stock for strategic or incentive purposes, if at all. If we are unable to raise additional working capital when needed, 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. If we are unable to utilize our common stock for strategic purposes we may not be able to take advantage of acquisition opportunities when they arise. If we are unable to utilize our common stock for incentive purposes, we may not be able to retain key persons or we may be unable to attract new employees if the need should arise.

## **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 do. 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 that are either more effective than those that we may develop, alone or with our collaborators, or that are marketed before any products we develop are marketed. Our competitors include fully integrated pharmaceutical companies and biotechnology companies as well as universities and public and private research institutions. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in product development and in obtaining regulatory approvals, and greater marketing capabilities than we 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 which comply with good manufacturing practice standards and other standards prescribed by various federal, state and local regulatory agencies in the U.S. and any other country of use. We have limited experience coordinating and overseeing the manufacture of medical device products on a large scale. 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 which would render our technology obsolete. Further, our ability to achieve significant and sustained penetration of our key target markets will depend upon our success in developing or acquiring technologies developed by other companies, either independently, through joint ventures or through acquisitions. If we fail to develop or acquire, and manufacture and sell, products that satisfy our customers' demands, or we fail to respond effectively to new product announcements by our competitors by quickly introducing competitive products, then market acceptance

of our products could be reduced and our business could be adversely affected. 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 preclinical testing of the Hemopurifier. All other chemicals are fully inventoried and reported to the appropriate authorities, such as the fire department, who inspect the facility on a regular basis. We are subject to federal, state, local and foreign laws governing the use, manufacture, storage, handling and disposal of such materials. Although we believe that our safety procedures for the use, manufacture, storage, handling and disposal of such materials comply with the standards prescribed by federal, state, local and foreign regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We have had no incidents or problems involving hazardous chemicals or biological samples. In the event of such an accident, we could be held liable for significant damages 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, our Chief Science Officer, Richard H. Tullis, and our President, Rodney S. Kenley. If one or more 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 and Dr. Tullis have signed employment agreements providing for their continued service to us, these agreements will not preclude them from leaving us should we be unable to compete with offers for employment they may receive from other companies. We do not currently carry key man life insurance policies on any of our key executive officers which would assist us in recouping our costs in the event of the loss of those officers. If any of our key officers were to leave us, it could make it impossible, if not cause substantial delays and costs, to implement our long term business objectives and growth.

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

We have five full-time employees consisting of our Chief Executive Officer, our President, our Chief Science Officer, our Chief Financial Officer, and an executive assistant. Exosome has three additional full-time employees, consisting of its Chief Science Officer, its Clinical Research Director, and a research scientist. We utilize, whenever appropriate, consultants in order to conserve cash and resources.

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

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

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

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

Our Hemopurifier 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, 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:

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

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

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

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. 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 of 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, 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 other or future product candidates that we may develop and may harm our reputation.***

If we or our manufacturers or other third party contractors fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to regulatory actions, which could affect our ability to develop, market and sell our current product candidates or any future product candidates under development successfully and could harm our reputation and lead to reduced or non-acceptance of our proposed product candidates by the market. Even technical recommendations or evidence by the FDA through letters, site visits, and overall recommendations to academia or biotechnology companies may make the manufacturing of a clinical product extremely labor intensive or expensive, making the product candidate no longer viable to manufacture in a cost efficient manner. The mode of administration may make the product candidate not commercially viable. The required testing of the product candidate may make that candidate no longer commercially viable. The conduct of clinical trials may be critiqued by the FDA, or a clinical trial site's institutional review board or institutional biosafety committee, which may delay or make impossible clinical testing of a product candidate. The institutional review board for a clinical trial may stop a trial or deem a product candidate unsafe to continue testing. This 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 other or future product candidates that we may develop, and do not have the capability and resources to manufacture, market or sell our current product candidates or any future product candidates that we may develop. Our business model calls for the partial or full outsourcing of the clinical and other development and manufacturing, sales and marketing of our product candidates in order to reduce our capital and infrastr