

AETHLON MEDICAL INC
Form S-1
July 24, 2015

As filed with the Securities and Exchange Commission on July 24, 2015

Registration No. 333-_____

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

(858) 459-7800
(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies of all correspondence to:

Jennifer A. Post, Esq.

Raines Feldman LLP

9720 Wilshire Boulevard, Fifth Floor

Beverly Hills, California 90212

(310) 440-4100

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	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, par value \$0.001	952,383 shares	\$9.53 (2)	\$9,076,209.99	\$1,054.66
Common Stock, par value \$0.001, underlying warrants held by current stockholders subject to this offering	746,657 shares	\$6.30 (3)	\$4,703,939.10	\$546.60
Total	1,699,040 shares		\$13,780,149.09	\$1,601.26

(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.

(2) Estimated pursuant to Rule 457(c) of the Securities Act of 1933, as amended, solely for purposes of calculating amount of the registration fee, based upon the average of the high and low prices reported on July 20, 2015, as reported on the Nasdaq Capital Market.

(3) 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 \$6.30 per share.

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.

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 24, 2015

PROSPECTUS

Aethlon Medical, Inc.

1,699,040 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:

- 952,383 shares of common stock; and
- 746,657 shares of common stock underlying common stock purchase warrants at an exercise price of \$6.30 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 \$4,703,939 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 26 for more information on this topic.

Our common stock is traded on the Nasdaq Capital Market under the symbol “AEMD.” On July 23, 2015, the last reported sale price of our common stock on the Nasdaq Capital Market was \$11.10.

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.

TABLE OF CONTENTS

	Page
About this Prospectus	1
Cautionary Note Regarding Forward-Looking Statements	1
Prospectus Summary	1
Risk Factors	4
Use of Proceeds	23
Selling Stockholders	23
Plan of Distribution	26
Description of Business	28
Description of Properties	39
Legal Proceedings	39
Market Price for Common Equity and Related Stockholder Matters	40
Management's Discussion and Analysis of Financial Condition and Results of Operations	44
Directors and Executive Officers	55
Executive Compensation	59
Security Ownership of Certain Beneficial Owners and Management	63
Certain Relationships and Related Transactions and Director Independence	64
Description of Securities	65
Legal Matters	66
Experts	66
Where You Can Find More Information	66
Index to Consolidated Financial Statements	F-1

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 1,699,040 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 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 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 maintains offices and laboratories at 11 Deer Park Drive, South Brunswick, New Jersey 08810. Our website address is 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 June 25, 2015, 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 0.75 shares of our common stock at an exercise price per share of \$6.30, with a term of five years from the date of issuance. We sold a total of 952,383 units, consisting of 952,383 shares of common stock and warrants to purchase 714,286 shares of common stock for gross proceeds of \$6,000,000 and net proceeds of \$5,591,988. 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 32,371 shares of our common stock at an exercise price of \$6.30 per share. The common stock sold in the private placement, the shares underlying the warrants sold in the private placement and the shares underlying the warrants issued to Roth Capital Partners are the shares covered by this registration statement.

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 30 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 registration statement in order to fulfill our obligation under this registration rights agreement.

On December 2, 2014, we consummated a prior private placement of units, each comprised of one share of common stock and 1.2 of a five-year warrant to purchase one share of common stock at an exercise price of \$15.00 per share, for gross proceeds of \$3,300,000 and net proceeds of \$3,001,000. In that private placement, we issued 220,000 shares of common stock and warrants to purchase 264,000 shares of common stock to purchasers and warrants to purchase 11,000 shares of common stock to Roth Capital Partners as placement agent in the transaction. The securities sold in the December 2014 financing have been registered for resale on a Registration Statement on Form S-1 (File No. 333-201334) originally filed on December 31, 2014, as amended by prospectus supplements filed on February 10, 2015, March 16, 2015, April 7, 2015, April 10, 2015, April 14, 2015 and April 15, 2015, and a post-effective amendment thereto filed on July 14, 2015, pursuant to which we are seeking to register the remaining 275,000 shares underlying the warrants, which has not yet been declared effective by the Securities and Exchange Commission. The securities sold in the December 2014 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 stockholders Up to 1,699,040 shares

Common stock outstanding 7,610,344 shares as of July 23, 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 \$4,703,939. See “Use of Proceeds.”

Market symbol and trading Our common stock is traded on the Nasdaq Capital Market under the symbol “AEMD.”

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 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.

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. 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; 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.

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 July 23, 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 common stock or 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 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, 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 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:

- 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 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 nine pending U.S. patent applications. We also have fourteen issued foreign patents and have applied for five additional foreign patents. Our issued patents begin to expire in 2019, with the last of these patents expiring in 2029, although terminal disclaimers, patent term extension or patent term adjustment can shorten or lengthen the patent term. We rely on a combination of patent protection, trade secret laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these may not adequately protect our rights or permit us to gain or keep any competitive advantage.

The issuance of a patent is not conclusive as to its scope, validity or enforceability. 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 the suppliers and subcontractors we may utilize. In some instances, we are dependent on sole-source suppliers. If any of these suppliers or subcontractors fails to meet our needs, we may not have readily available alternatives. In addition, the recent global financial crisis may impact some of our suppliers or subcontractors, which could impair their ability to meet their obligations to us. If we experience a material supplier or subcontractor problem, our ability to satisfactorily and timely complete our clinical trial or delivery obligations could be negatively impacted which could result in reduced sales, termination of contracts and damage to our reputation and relationships with clinical trial providers and if applicable, the U.S. Government. We could also incur additional costs in addressing such a problem. Any of these events could have a negative impact on our results of operations and financial condition.

Risks Relating to Our Common Stock, This Offering and Our Corporate Governance

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

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

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

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

- revenue or results of operations in any quarter failing to meet the expectations, published or otherwise, of the investment community;
- reduced investor confidence in equity markets, due in part to corporate collapses in recent years;
- speculation in the press or analyst community;

- wide fluctuations in stock prices, particularly with respect to the stock prices for other medical device companies;
- announcements of technological innovations by us or our competitors;
- new products or the acquisition of significant customers by us or our competitors;
- changes in interest rates;
- changes in investors' beliefs as to the appropriate price-earnings ratios for us and our competitors;
- changes in recommendations or financial estimates by securities analysts who track our common stock or the stock of other medical device companies;
- changes in management;
- sales of common stock by directors and executive officers;
- rumors or dissemination of false or misleading information, particularly through Internet chat rooms, instant messaging, and other rapid-dissemination methods;
- conditions and trends in the medical device industry generally;
- the announcement of acquisitions or other significant transactions by us or our competitors;
- adoption of new accounting standards affecting our industry;
- general market conditions;
- domestic or international terrorism and other factors; and
- the other factors described in this section.

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

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

If at any time our common stock is not listed on a national securities exchange or we have net tangible assets of \$5,000,000 or less and our common stock has a market price per share of less than \$5.00, transactions in our common stock will be subject to the Securities and Exchange Commission's "penny stock" rules. If our common stock is subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, as amended, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person's account for transactions in penny stocks; and
- that the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

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

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

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Securities and Exchange Commission relating to the penny stock market, which, in highlight form sets forth:

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

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

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

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

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

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

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than a seasoned issuer for the indefinite future. In fact, during the 52-week period ended March 31, 2015, the high and low closing sale prices of a share of our common stock were \$36.00 and \$5.00, respectively. The volatility in our share price is attributable to a number of factors. First, as noted above, trading in our common shares often has been thin. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline precipitously in the event that a large number of our common shares are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without adverse impact on its share price. Secondly, we are a speculative investment due to our limited operating history, limited amount of revenue, lack of profit to date, and the uncertainty of future market acceptance for our potential products. As a consequence of this enhanced risk, more risk-averse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. The following factors may add to the volatility in the price of our common shares: actual or anticipated variations in our quarterly or annual operating results; acceptance of our proprietary technology as a viable method of augmenting the immune response of clearing viruses and toxins from human blood; government regulations; announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments; and additions or departures of our key personnel. Many of these factors are beyond our control and may decrease the market price of our common shares regardless of our operating performance. We cannot predict or project the prevailing market price for our common shares at any time, including whether our common shares will sustain their current market prices, or what effect the sale of shares or the availability of common shares for sale at any time will have on the prevailing market price.

Although our common stock trades on the Nasdaq Capital Market, we cannot assure you that we will be able to comply with the continued listing standards of the Nasdaq Capital Market.

Although our common stock trades on the Nasdaq Capital Market, we cannot assure you that we will be able to comply with the continued listing standards that we are required to meet in order to maintain that listing. Our failure to meet the listing maintenance requirements may result in our common stock being delisted from the Nasdaq Capital Market. If the Nasdaq Capital Market were to delist our common stock, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as “covered securities.” While our common stock is listed on the Nasdaq Capital Market, such securities will be covered securities. Although the states would be preempted from regulating the sale of our securities, in that event, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if the Nasdaq Capital Market were to delist our common stock, our common stock would not be a covered security and we would be subject to regulation in each state in which we offer our securities.

The Depository Trust Company imposed restrictions upon electronic trading of our common stock, which negatively affected liquidity of the stock and our ability to raise capital.

In September 2011, The Depository Trust Company placed a "chill" on the electronic clearing of trades in our shares, which led to some brokerage firms being unwilling to accept certificates and/or electronic deposits of our stock. We have since been successful in lifting the restrictions and our shares now clear electronically, making more brokers willing to trade in our common stock. We cannot assure you that The Depository Trust Company will not again place a chill on our common stock. A chill, if placed on our common stock, would affect the liquidity of our shares, which may make it difficult to purchase or sell shares in the open market. It may also have an adverse effect on our ability to raise capital since investors may be unable to resell shares into the market. Our inability to raise capital on terms acceptable to us, if at all, could have a material and adverse effect on our business and operations.

Our directors and officers own or control approximately 7% of our outstanding common shares, which may limit your ability to propose new management or influence the overall direction of the business. This concentration of control may also discourage potential takeovers that could otherwise provide a premium to you.

As of July 23, 2015, our officers and directors beneficially own or control approximately 7% of our outstanding common shares (assuming the exercise of all outstanding options and warrants held by our officers and directors). These persons will have the ability to substantially influence all matters submitted to our stockholders for approval and to control our management and affairs, including extraordinary transactions such as mergers and other changes of corporate control, and going private transactions.

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

As of March 31, 2015, there are outstanding purchase options and warrants entitling the holders to purchase 1,932,405 common shares at a weighted average exercise price of \$7.92 per share. This includes 26,105 warrants that are conditional upon the exercise of other warrants. As of March 31, 2015, there are 98,043 shares underlying promissory notes convertible into common stock at a weighted average exercise price of \$5.60.

As a result of our June 2015 financing, and as of July 23, 2015, there are outstanding purchase options and warrants entitling the holders to purchase 2,771,127 common shares at a weighted average exercise price of \$7.44 per share. This includes 26,105 warrants that are conditional upon the exercise of other warrants and includes the 402,318 purchase options and warrants that were suspended by certain of our officers and directors in June 2015.

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.

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

We are entitled under our Articles of Incorporation to issue up to 10,000,000 shares of common stock. We have reserved for issuance 2,030,448 shares of common stock for existing options, warrants and convertible notes. As of March 31, 2015, we had issued and outstanding 6,657,046 shares of common stock. As a result, as of March 31, 2015, we had 1,312,506 common shares available for issuance to new investors or for use to satisfy indebtedness or pay service providers.

Our Board of Directors may generally issue shares of common stock, or options or warrants to purchase those shares, without further approval by our stockholders based upon such factors as our Board of Directors may deem relevant at that time. It is likely that we will be required to issue a large amount of additional securities to raise capital to further our development. It is also likely that we will be required to issue a large amount of additional securities to directors, officers, employees and consultants as compensatory grants in connection with their services, both in the form of stand-alone grants or under our stock plans. We cannot give you any assurance that we will not issue additional shares of common stock, or options or warrants to purchase those shares, under circumstances we may deem appropriate at the time.

However, as of July 23, 2015, and as a result of our June 2015 financing, substantially all 10,000,000 shares of common stock are either issued or reserved for issuance upon the conversion or exercise of outstanding securities including options, warrants and convertible notes, and we cannot issue any meaningful amount of shares of common stock, or options or warrants, or convertible notes until we increase the number of authorized shares to a number above 10,000,000, or unless outstanding warrants, options or convertible notes expire or are surrendered back to us before they are exercised or converted.

Our issuance of additional shares of common stock in satisfaction of services, or to repay indebtedness, would be dilutive to your holdings.

Our Board of Directors may generally issue shares of common stock to pay for debt or services, without further approval by our stockholders based upon such factors that our Board of Directors may deem relevant at that time. For the past four fiscal years (ending March 31, 2015), we issued a total of 2,602,909 shares for debt to reduce our obligations. The average price discount of common stock issued for debt in this period, weighted by the number of shares issued for debt in such period, was 76% and 43% for the years ended March 31, 2015 and 2014, respectively.

For the past four fiscal years (ending March 31, 2015), we issued a total of 216,032 shares as payment for services. The average price discount (premium) of common stock issued for services during this period, weighted by the number of shares issued, was (6.6)% and 16.0% for the years ended March 31, 2015 and 2014, respectively. It is likely that we will issue additional securities to pay for services and reduce debt in the future, after we increase our authorized shares. We cannot give you any assurance that we will not issue additional shares of common stock at various discounts under circumstances we may deem appropriate at the time. However, as of July 23, 2015, and as a result of our June 2015 financing, substantially all 10,000,000 shares of common stock are either issued or reserved for issuance upon the conversion or exercise of outstanding securities including options, warrants and convertible notes, and we cannot issue any meaningful amount of shares of common stock, or options or warrants, or convertible notes until we increase the number of authorized shares to a number above 10,000,000, or unless outstanding warrants, options or convertible notes expire or are surrendered back to us before they are exercised or converted.

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

Our Articles of Incorporation contain provisions that eliminate the liability of our directors for monetary damages to our company and stockholders. Our by-laws also require us to indemnify our officers and directors. We may also have contractual indemnification obligations under our agreements with our directors, officers and employees. As a result of these obligations, we could incur substantial expenditures to cover settlement or damage awards against directors, officers and employees that we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against directors, officers and employees for breaches of their fiduciary duties, and may similarly discourage stockholders from filing derivative litigation against our directors, officers and employees even though such actions, if successful, might otherwise benefit our company and stockholders.

Our by-laws and Nevada law may discourage, delay or prevent a change of control of our company or changes in our management, which may depress the trading price of our common stock.

Provisions of Nevada anti-takeover law (NRS 78.378 *et seq.*) could delay or prevent a third party from acquiring us, even if the acquisition arguably could benefit our stockholders. Our by-laws may be adopted, amended or repealed by the affirmative vote of the holders of at least a majority of our outstanding shares of capital stock entitled to vote for the election of directors, and except as provided by Nevada law, our Board of Directors has the power to adopt, amend or repeal the by-laws by a vote of not less than a majority of our directors. The interests of these stockholders and directors may not be consistent with your interests, and they may make changes to the by-laws that are not in line with your concerns.

Our authorized but unissued shares of common stock are available for our Board or Directors to issue without stockholder approval. We may use these additional shares for a variety of corporate purposes; however, faced with an attempt to obtain control of us by means of a proxy contest, tender offer, merger or other transaction, our Board of

Directors acting alone and without approval of our stockholders can issue large amounts of capital stock as part of a defense to a take-over challenge.

The foregoing provisions and other potential anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

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

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

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

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

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholders identified in this prospectus. We will not receive any of the proceeds resulting from the sale of the shares held by the selling stockholders, including shares obtained by the selling stockholders upon exercise of the warrants. If any of the selling stockholders were to exercise warrants to acquire the common stock to be sold pursuant to this prospectus, we would receive the cash exercise price, if any. As of the date of this prospectus, 746,657 shares of our common stock are issuable upon exercise of warrants owned by the selling stockholders and covered by this prospectus at an exercise price of \$6.30 per share of common stock. Accordingly, we would receive up to \$4,703,939 in gross proceeds if all of the warrants were exercised for cash. We expect to use the proceeds received from the cash exercise of warrants, if any, for general working capital purposes. However, the selling stockholders may not exercise the warrants at all, or for cash. If the selling stockholders exercise the warrants on a cashless basis, we will not receive any proceeds from such exercise.

SELLING STOCKHOLDERS

The shares of common stock being offered by the selling stockholders include those issued to the selling stockholders pursuant to the securities purchase agreement we entered into with certain of the selling stockholders and shares of common stock issuable upon exercise of the warrants purchased pursuant to the securities purchase agreement. The shares of common stock being offered by the selling stockholders also include common stock underlying warrants issued to the placement agent in connection with the securities purchase agreement. For additional information regarding the issuance of the common stock and warrants, see "Private Placement of Common Stock and Warrants" above. We are registering the shares of common stock in order to permit the selling stockholders to offer the shares for resale from time to time. Except for the ownership of shares of common stock, warrants and convertible promissory notes by certain of the selling stockholders acquired in various transactions, and Roth Capital Partners, LLC having acted as placement agent in connection with the private placement of securities effected pursuant to the securities purchase agreement and in connection with the December 2014 financing, the selling stockholders have not had any material relationship with us within the past three years.

The table below lists the selling stockholders and other information regarding the beneficial ownership of shares of our common stock by each of the selling stockholders. The second column lists the number of shares of common stock beneficially owned by each selling stockholder, based on its ownership of our common stock and warrants, as of July 10, 2015, assuming exercise of all warrants held by the selling stockholders on that date, without regard to any limitations on exercise.

The third column lists the shares of common stock being offered by this prospectus by the selling stockholders.

In accordance with the terms of a registration rights agreement with the selling stockholders, this prospectus generally covers the resale of at least the sum of (i) the number of shares of common stock issued pursuant to the securities purchase agreement as of the trading day immediately preceding the date the registration statement is initially filed with the Securities and Exchange Commission, and (ii) the maximum number of shares of common stock issued and issuable upon exercise of the warrants as of the trading day immediately preceding the date the registration statement is initially filed with the Securities and Exchange Commission.

Under the terms of the warrants, a selling stockholder may not exercise the warrants to the extent such exercise would cause such selling stockholder, together with its affiliates, to beneficially own a number of shares of common stock which would exceed 4.99% of the then-outstanding shares of our common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon exercise of the warrants which have not been exercised. The number of shares in the second column does not reflect this limitation. The selling stockholders may sell in this offering all, some or none of the shares they acquired, or may acquire upon exercise of warrants acquired, pursuant to the securities purchase agreement. See "Plan of Distribution."

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Number of Shares of Common Stock Owned After Offering (1)
Alpha Capital Anstalt (2)	806,008	694,444	111,564
Empery Asset Master, Ltd. (3)	285,902	201,712	84,190
Empery Tax Efficient, LP (4)	185,829	164,128	21,701
Empery Tax Efficient II, LP (5)	347,825	189,716	158,109
Frontier Ventures LLC (6)	99,188	5,556	93,632
Lincoln Park Capital Fund, LLC (7)	43,750	43,750	0
Osher Capital Partners LLC (8)	57,585	27,778	29,807
Joshua S. Brodtkin (9)	9,465	8,333	1,132
Rajendra P. Gupta (10)	13,889	13,889	0
Gary Karlin and Jane Zamost (11)	54,058	13,889	40,169
Kevin L. Kunkle (12)	96,128	55,556	40,572
Jay K. Patel (13)	41,894	19,444	22,450
Adam Sackstein (14)	367,086	91,667	275,419
Chirag S. Shah (15)	222,773	67,251	155,522
Nirav K. Shah (16)	27,778	27,778	0
Sydney Tyson (17)	17,889	13,889	4,000
Christopher Wetzel (18)	87,187	13,889	73,298
Marshall Wolf (19)	17,501	14,000	3,501
Roth Capital Partners, LLC (20)	43,371	32,371	11,000

(1) Represents the number of shares of common stock that will be beneficially owned by the selling stockholder after completion of this offering based on the assumptions that (i) all of the shares of common stock registered for resale by the registration statement of which this prospectus is a part will be sold and (ii) no other shares of common stock will be acquired or sold by the selling stockholder before completion of this offering. However, the selling stockholder may sell all, part or none of its shares of common stock offered pursuant to this prospectus and may sell all, part or none of its common stock pursuant to one or more exemptions from the registration provisions of the Securities Act of 1933, as amended.

(2) Includes 297,619 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of \$6.30 per share, subject to customary adjustments, which expires on June 25, 2020, 37,188 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of \$8.40 per share, subject to customary adjustments, which expires on November 6, 2019, and 74,376 shares of common stock issuable upon the conversion of a convertible promissory note with a conversion price of \$5.60 per share, subject to customary adjustments. Konrad Ackermann and