AETHLON MEDICAL INC
Form POS AM
July 22, 2016

As filed with the Securities and Exchange Commission on July 22, 2016

Registration No. 333-205832

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Nevada
(State or other jurisdiction of incorporation or organization)

3826
(Primary Standard Industrial Classification Code Number)

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

9635 Granite Ridge Drive, Suite 100

San Diego, California 92123

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

James A. Joyce

9635 Granite Ridge Drive, Suite 100

San Diego, California 92123

(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: [X]

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 [X]

(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 (2)
Common Stock, par value $0.001	301,418 shares	$6.19 (3)	$1,865,777.42	$187.88
Common Stock, par value $0.001, underlying warrants held by current stockholders subject to this offering	746,657 shares	$6.30 (4)	$4,703,939.10	$473.69
Total	1,048,075 shares		$6,569,716.52	$661.57

(1) Pursuant to Rule 416 of the Securities Act of 1933, as amended (the "Securities Act"), this registration statement also shall cover any additional shares of common stock that shall become issuable by reason of any stock dividend, stock split, recapitalization, or other similar transaction by the registrant. The number of shares remaining to be offered hereunder consists of 301,418 shares of common stock and 746,657 shares of common stock underlying warrants.

(2) Fee paid in connection with the registrant's registration statement on Form S-1 (Registration No. 333-205832) filed with the Securities and Exchange Commission (the "Commission") on July 24, 2015.

(3) Estimated pursuant to Rule 457(c) of the Securities Act solely for purposes of calculating amount of the registration fee, based upon the average of the high and low prices reported on July 20, 2016, as reported on the Nasdaq Capital Market.

(4) Estimated pursuant to Rule 457(g) of the Securities Act 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.

Explanatory Note

This Post-Effective Amendment No. 1 to Form S-1 relates solely to the sale by selling stockholders of up to 301,418 issued and outstanding shares of common stock and 746,657 shares of common stock to be issued upon exercise of warrants issued with respect to that certain securities purchase agreement between the registrant and certain selling stockholders, which are signatories thereto, which were previously registered under the registration statement on Form S-1 (Registration No. 333-205832) of the registrant declared effective on August 4, 2016 by the Commission. The aforesaid registration statement originally registered for resale 952,383 shares of common stock and 746,657 shares of common stock underlying warrants. Of that original amount, selling stockholders sold 650,965 shares of common stock, thus leaving 301,418 shares of common stock and 746,657 shares of common stock to be issued upon exercise of the warrants available for resale under the registration statement. This Post–Effective Amendment No. 1 to Form S-1 is being filed to include the financial statements for the year ended March 31, 2016. All filing fees payable in connection with the registration of these securities were previously paid by the registrant at the time of filing the original registration statement on Form S-1.

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

Subject to completion, dated July 22, 2016

PROSPECTUS

Aethlon Medical, Inc.

1,048,075 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:

- 301,418 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 28 for more information on this topic.

Our common stock is traded on the Nasdaq Capital Market under the symbol “AEMD.” On July 18, 2016, the last reported sale price of our common stock on the Nasdaq Capital Market was $6.98.

Investing in our securities involves significant risks, including those set forth in the "Risk Factors" section of this prospectus beginning at page 5.

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 _____, 2016.

AETHLON MEDICAL, INC.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the 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 1,048,075 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 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 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements represent our expectations, beliefs, intentions or strategies concerning future events, including, but not limited to, any statements regarding our assumptions about financial performance; the continuation of historical trends; the sufficiency of our cash balances for future liquidity and capital resource needs; the expected impact of changes in accounting policies on our results of operations, financial condition or cash flows; anticipated problems and our plans for future operations; and the economy in general or the future of the medical device industry, all of which are subject to various risks and uncertainties.

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

PROSPECTUS SUMMARY

This summary highlights information included or incorporated by reference in this prospectus. This summary may not contain all of the information that may be important to you. Before making an investment decision, you should read carefully this entire prospectus, any accompanying prospectus supplement and any other offering materials, together with the additional information described under the heading "Where You Can Find More Information" on page 69 of this prospectus.

Company Overview

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

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

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

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

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

Through our majority-owned subsidiary, Exosome Sciences, Inc., or Exosome, 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, 2016, we had a cash balance of $2,123,737 and working capital of $1,877,532. 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, has financed our operations through June 30, 2016. We will require significant additional financing to complete the current and expected 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 through the fiscal year ending March 31, 2017.

Risks Associated with our Business

We have experienced substantial operating losses since inception. As of March 31, 2016, we had an accumulated deficit of $86,502,043, which included losses of approximately $4,872,329 and $6,797,157 for the fiscal years ended March 31, 2016 and 2015, 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 $5,271,406 and $4,755,270 for the fiscal years ended March 31, 2016 and 2015, respectively. We expect to 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.

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Corporate History

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

Our Contact Information

Our executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. Our website address is www.aethlonmedical.com. 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 714,285 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 until the earlier of (i) the date that is two and one-half years after the closing of the private placement or (ii) the date on which the purchasers have sold all of the shares covered by the registration statement. We are filing this post-effective amendment to the original registration statement on Form S-1 in order to fulfill our obligation under this registration rights agreement.

On 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 $3,001,428. 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 various prospectus supplements related thereto, a post-effective amendment filed on July 14, 2015 and a post-effective amendment filed on July 20, 2016, pursuant to which we are seeking to register the remaining 275,000 shares underlying the warrants, which post-effective amendment has not yet been declared effective by the 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 pursuant to the exemption for transactions by an issuer not involving a public offering under Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

The Offering

Common stock offered by the selling stockholders	Up to 1,048,075 shares
Common stock outstanding	7,627,393 shares as of July 18, 2016
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, 2016 and March 31, 2015, in the amounts of $886,572, and $762,417, 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.

We have received an explanatory paragraph from our auditors regarding our ability to continue as a going concern.

Our independent registered public accounting firm noted in their report accompanying our financial statements for our fiscal year ended March 31, 2016 that we have a significant accumulated deficit and that a significant amount of additional capital will be necessary to advance the development of our products to the point at which we may become commercially viable. Our independent registered public accounting firm stated that those conditions raised substantial doubt about our ability to continue as a going concern. Note 1 to our financial statements for the year ended March 31, 2016 describes management's plans to address these matters. We cannot assure you that our business plans will be successful in addressing these issues. This explanatory paragraph about our ability to continue as a going concern could affect our ability to obtain additional financing at favorable terms, if at all, as it may cause investors to lose faith in our long-term prospects. If we cannot successfully continue as a going concern, our shareholders may lose their

entire investment.

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

We raised $5,591,988 in net proceeds from a financing in June 2015. That amount, coupled with previously existing funds on hand and expected revenues from our government contracts, has financed our operations into the first quarter of the fiscal year ending March 31, 2017. However, we will require significant additional financing to complete the current and expected 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 through the remainder of the fiscal year ending March 31, 2017. In addition, as we expand our activities, our overhead costs to support personnel, laboratory materials and infrastructure will increase. Should the financing we require to sustain our working capital needs be unavailable to us on reasonable terms, if at all, when we require it, we may be unable to support our research and FDA clearance activities including our planned clinical trials. The failure to implement our research and clearance activities would have a material adverse effect on our ability to commercialize our products.

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

We will need to raise additional funds through debt or equity financings in order to complete our ultimate business objectives, including funding working capital to support development and regulatory clearance of our products. We also may choose to raise additional funds in debt or equity financings if they are available to us on reasonable terms to increase our working capital and to strengthen our financial position. Any sales of additional equity or convertible debt securities would result in dilution of the equity interests of our existing stockholders, which could be substantial. Also, new investors may require that we and certain of our stockholders enter into voting arrangements that give them additional voting control or representation on our Board of Directors.

Risks Related to Our Business Operations

We face intense competition in the medical device industry.

We compete with numerous U.S. and foreign companies in the medical device industry, and many of our competitors have greater financial, personnel and research and development resources than we do. Our competitors are developing vaccine candidates, which could compete with the Hemopurifier medical device candidates we are developing. Our commercial opportunities will be reduced or eliminated if our competitors develop and market products for any of the diseases we target that:

- are more effective;
- have fewer or less severe adverse side effects;
- are better tolerated;
- are more adaptable to various modes of dosing;
- are easier to administer; or
- are less expensive than the products or product candidates we are developing.

Even if we are successful in developing the Hemopurifier and other Aethlon ADAPT based-products, and obtain FDA and other regulatory approvals necessary for commercializing them, our products may not compete effectively with other successful products. Researchers are continually learning more about diseases, which may lead to new technologies for treatment. Our competitors may succeed in developing and marketing products that are either more effective than those that we may develop, alone or with our collaborators, or that are marketed before any products we develop are marketed. Our competitors include fully integrated pharmaceutical companies and biotechnology companies as well as universities and public and private research institutions. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in product development and in obtaining regulatory approvals, and greater marketing capabilities than we do. If our competitors develop more effective pharmaceutical treatments for infectious disease or cancer, or bring those treatments to market before we can commercialize the Hemopurifier for such uses, we may be unable to obtain any market traction for our products, or the diseases we seek to treat may be substantially addressed by competing treatments. If we are unable to successfully compete against larger companies in the pharmaceutical industry, we may never generate significant revenue or be profitable.

We have limited experience in identifying and working with large scale contracts with medical device manufacturers; manufacture of our devices must comply with good manufacturing practices in the U.S.

To achieve the levels of production necessary to commercialize our Hemopurifier and other future Aethlon ADAPT-based products, we will need to secure large scale manufacturing agreements with contract manufacturers which comply with good manufacturing practice standards and other standards prescribed by various federal, state and local regulatory agencies in the U.S. and any other country of use. We have limited experience coordinating and overseeing the manufacture of medical device products on a large scale. We cannot assure you that manufacturing and control problems will not arise as we attempt to commercialize our products or that such manufacturing can be completed in a timely manner or at a commercially reasonable cost. In addition, we cannot assure you that we will be able to adequately finance the manufacture and distribution of our products on terms acceptable to us, if at all. If we cannot successfully oversee and finance the manufacture of our products when they have obtained regulatory clearances, we may never generate revenue from product sales and we may never be profitable.

Our Aethlon ADAPT technology may become obsolete.

Our Aethlon ADAPT products may be made unmarketable by new scientific or technological developments where new treatment modalities are introduced that are more efficacious and/or more economical than our Aethlon ADAPT products. The homeland security industry is growing rapidly with many competitors that are trying to develop products or vaccines to protect against infectious disease. Any one of our competitors could develop a more effective product which would render our technology obsolete. Further, our ability to achieve significant and sustained penetration of our key target markets will depend upon our success in developing or acquiring technologies developed by other companies, either independently, through joint ventures or through acquisitions. If we fail to develop or acquire, and manufacture and sell, products that satisfy our customers' demands, or we fail to respond effectively to new product announcements by our competitors by quickly introducing competitive products, then market acceptance of our products could be reduced and our business could be adversely affected. We cannot assure you that our products will remain competitive with products based on new technologies.

Our use of hazardous materials, chemicals and viruses exposes us to potential liabilities for which we may not have adequate insurance.

Our research and development involves the controlled use of hazardous materials, chemicals and viruses. The primary hazardous materials include chemicals needed to construct the Hemopurifier cartridges and the infected plasma samples used in preclinical testing of the Hemopurifier. All other chemicals are fully inventoried and reported to the appropriate authorities, such as the fire department, who inspect the facility on a regular basis. We are subject to federal, state, local and foreign laws governing the use, manufacture, storage, handling and disposal of such materials. Although we believe that our safety procedures for the use, manufacture, storage, handling and disposal of such materials comply with the standards prescribed by federal, state, local and foreign regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We have had no incidents or problems involving hazardous chemicals or biological samples. In the event of such an accident, we could be held liable for significant damages or fines.

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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 limited number of key executive officers.

Our success depends to a critical extent on the continued services of our Chief Executive Officer, James A. Joyce, and our President, Rodney S. Kenley. If one or both of these key executive officers were to leave us, we would be forced to expend significant time and money in the pursuit of a replacement, which would result in both a delay in the implementation of our business plan and the diversion of limited working capital. The unique knowledge and expertise of these individuals would be difficult to replace within the biotechnology field. We can give you no assurances that we can find satisfactory replacements for these key executive officers at all, or on terms that are not unduly expensive or burdensome to us. Although Mr. Joyce has signed an employment agreement providing for his continued service to us, that agreement will not preclude him from leaving us should we be unable to compete with offers for employment he may receive from other companies. We do not currently carry key man life insurance policies on 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 Financial Officer, a research scientist and an executive assistant. We utilize, whenever appropriate, consultants in order to conserve cash and resources.

Although we believe that these employees and consultants will be able to handle most of our additional administrative, research and development and business development in the near term, we will nevertheless be required over the longer-term to hire highly skilled managerial, scientific and administrative personnel to fully implement our business plan and growth strategies, including to mitigate the material weakness in our internal control over financial reporting described above. Due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific, technical and managerial personnel. Competition for these individuals,

especially in San Diego, California, where many biotechnology companies are located, is intense and we may not be able to attract, assimilate or retain additional highly qualified personnel in the future. We cannot assure you that we will be able to engage the services of such qualified personnel at competitive prices or at all, particularly given the risks of employment attributable to our limited financial resources and lack of an established track record. Also, if we are required to attract personnel from other parts of the U.S. or abroad, we may have significant difficulty doing so due to the high cost of living in the Southern California area and due to the costs incurred with transferring personnel to the area. If we cannot attract and retain qualified staff and executives, we will be unable to develop our products and achieve regulatory clearance, and our business could fail.

We plan to grow rapidly which will strain our resources; our inability to manage our growth could delay or derail implementation of our business objectives.

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

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

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

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

Our Hemopurifier products are subject to extensive government regulations related to development, testing, manufacturing and commercialization in the U.S. and other countries. The determination of when and whether a product is ready for large-scale purchase and potential use will be made by the U.S. Government through consultation with a number of governmental agencies, including the FDA, the National Institutes of Health, the Centers for Disease Control and Prevention and the Department of Homeland Security. Our product candidates are in the pre-clinical and clinical stages of development and have not received required regulatory approval from the FDA, or any foreign regulatory agencies, to be commercially marketed and sold. The process of obtaining and complying with FDA and other governmental regulatory approvals and regulations in the U.S. and in foreign countries is costly, time consuming, uncertain and subject to unanticipated delays. Obtaining such regulatory approvals, if any, can take several years. Despite the time and expense exerted, regulatory approval is never guaranteed. We also are subject to the following risks and obligations, among others:

- the FDA may refuse to approve an application if they believe that applicable regulatory criteria are not satisfied;

- the FDA may require additional testing for safety and effectiveness;
- the FDA may interpret data from pre-clinical testing and clinical trials in different ways than we interpret them;
- if regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
- the FDA may change their approval policies and/or adopt new regulations.

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

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

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

Our business prospects will depend on our ability to complete studies, clinical trials, obtain satisfactory results, obtain required regulatory approvals and successfully commercialize our Hemopurifier product candidates. Completion of our clinical trials, announcement of results of the trials and our ability to obtain regulatory approvals could be delayed for a variety of reasons, including:

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

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

If we or our suppliers fail to comply with ongoing FDA or foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party suppliers may be required to comply with the FDA's Quality System Regulation, or QSR. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements in the U.S., this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

In addition, the FDA assesses compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

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

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

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

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In this case, 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 firm-initiated medical device corrections and removals. In addition, in December of 2012, the FDA issued a draft guidance intended to assist the FDA and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the Federal Food, Drug, and Cosmetic Act, that change would generally constitute a medical device recall and require submission of a recall report to the FDA.

We outsource almost all of our operational and development activities, and if any party to which we have outsourced certain essential functions fails to perform its obligations under agreements with us, the development and commercialization of our lead product candidate and any future product candidates that we may develop could be delayed or terminated.

We generally rely on third-party consultants or other vendors to manage and implement the day-to-day conduct of our operations, including conducting clinical trials and manufacturing our current product candidates and any future product candidates that we may develop. Accordingly, we are and will continue to be dependent on the timeliness and effectiveness of their efforts. Our dependence on third parties includes key suppliers and third party service providers supporting the development, manufacture and regulatory approval of our products as well as support for our information technology systems and other infrastructure. While our management team oversees these vendors, failure of any of these third parties to meet their contractual, regulatory and other obligations or the development of factors that materially disrupt the performance of these third parties could have a material adverse effect on our business. For example, all of the key oversight responsibilities for the development and manufacture of our lead product candidate are conducted by our management team but all activities are the responsibility of third party vendors.

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

If we or our contractors or service providers fail to comply with regulatory laws and regulations, we or they could be subject to regulatory actions, which could affect our ability to develop, market and sell our product candidates and any other or future product candidates that we may develop and may harm our reputation.

If we or our manufacturers or other third party contractors fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to regulatory actions, which could affect our ability to develop, market and sell our current product candidates or any future product candidates under development successfully and could harm our reputation and lead to reduced or non-acceptance of our proposed product candidates by the market. Even technical recommendations or evidence by the FDA through letters, site visits, and overall recommendations to academia or biotechnology companies may make the manufacturing of a clinical product extremely labor intensive or expensive, making the product candidate no longer viable to manufacture in a cost efficient manner. The mode of administration may make the product candidate not commercially viable. The required testing of the product candidate may make that candidate no longer commercially viable. The conduct of clinical trials may be critiqued by the FDA, or a clinical trial site's Institutional Review Board or Institutional Biosafety Committee, which may delay or make impossible clinical testing of a product candidate. The Institutional Review Board for a clinical trial may stop a trial or deem a product candidate unsafe to continue testing. This may have a material adverse effect on the value of the product candidate and our business prospects.

We will need to outsource and rely on third parties for the clinical development and manufacture, sales and marketing of our current product candidates or any future product candidates that we may develop, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.

We do not have the required financial and human resources to carry out on our own all the pre-clinical and clinical development for our current product candidates or any other or future product candidates that we may develop, and do not have the capability and resources to manufacture, market or sell our current product candidates or any future product candidates that we may develop. Our business model calls for the partial or full outsourcing of the clinical and other development and manufacturing, sales and marketing of our product candidates in order to reduce our capital and 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 preclinical liability risks, which could place a substantial financial burden upon us should we be sued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of medical devices. 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 to be adequate or available. We may not be able to secure product liability insurance coverage on acceptable terms or at reasonable costs when needed. Any product recall or lawsuit seeking significant monetary damages may have a material effect on our business and financial condition. Any liability for mandatory damages could exceed the amount of our coverage. Moreover, a product recall could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other future product candidates.

We have not received, and may never receive, approval from the FDA to market a medical device in the United States.

Before a new medical device can be marketed in the U.S., it must first receive either premarket approval, or a PMA, or 510(k) clearance from the FDA, unless an exemption exists. A PMA submission, which is a higher standard than a 501(k) clearance, is used to demonstrate to the FDA that a new or modified device is safe and effective. The 510(k) is used to demonstrate that a device is "substantially equivalent" to a predicate device (one that has been cleared by the FDA). We expect that any product we seek regulatory approval for will require a PMA. The FDA approval process involves, among other things, successfully completing clinical trials and filing for and obtaining a PMA. The PMA process requires us to prove the safety and effectiveness of our products to the FDA's satisfaction. This process, which includes preclinical studies and clinical trials, can take many years and requires the expenditure of substantial resources and may include post-marketing surveillance to establish the safety and efficacy of the product. Notwithstanding the effort and expense incurred, the process may never result in the FDA granting a PMA. Data obtained from preclinical studies and clinical trials are subject to varying interpretations that could delay, limit or prevent regulatory approval. Delays or rejections may also be encountered based upon changes in governmental policies for medical devices during the period of product development. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our inability to demonstrate safety or effectiveness to the FDA's satisfaction;
- insufficient data from our preclinical studies and clinical trials to support approval;
- failure of the facilities of our third-party manufacturer or suppliers to meet applicable requirements;
- inadequate compliance with preclinical, clinical or other regulations;
- our failure to meet the FDA's statistical requirements for approval; and
- changes in the FDA's approval policies, or the adoption of new regulations that require additional data or additional clinical studies.

Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much costlier and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained. Any of our products considered to be a class III device, which are considered to pose the greatest risk and the approval of which is governed by the strictest guidelines, will require the submission and approval of a PMA in order for us to market it in the U.S. We also may design new products in the future that could require the clearance of a 510(k).

Although we have received approval to proceed with clinical trials in the U.S. under the investigational device exemption, 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 PMA 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 there is no assurance 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 fur 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 the results of such protocol and potential treatments, if any, cannot be predicted. 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 be proven to be useful in the treatment of Ebola or that it will ever be approved by U.S. or foreign regulatory agencies for such use, or if approved, successfully commercialized by us 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 or may develop will be subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad. In the future we may conduct clinical trials to support approval of new products. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, 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. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Should our products be approved for commercialization, lack of third-party coverage and reimbursement for our devices could delay or limit their adoption.

In both the U.S. and international markets, the use of medical devices is dependent in part on the availability of reimbursement from third-party payors, such as government and private insurance plans. Healthcare providers that use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services. Should our products be approved for commercialization by the FDA, 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 coverage decisions of third-party payors will be significantly influenced by the assessment of our future products by health technology assessment bodies. 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, or CMS, which administers the Medicare program and works in partnership with state governments to administer Medicaid, other government programs and private insurance plans. The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive. Further, Medicare coverage is based on our ability to demonstrate 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 CMS. 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 CMS as guidelines in setting their coverage and reimbursement policies and amounts. If CMS or other agencies limit coverage or decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors.

Should our products be approved for commercialization, adverse changes in reimbursement policies and procedures by payors may impact our ability to market and sell our products.

Healthcare costs have risen significantly over the past decade, and there have been and continue to be proposals by legislators, regulators and third-party payors to decrease costs. Third-party payors are increasingly challenging the prices charged for medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services.

For example, in the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the PPACA, among other things, reduced and/or limited Medicare reimbursement to certain providers. The Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by 2 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 our product or the procedures or patient care performed using our product will be reimbursed at a cost-effective level. We face similar risks relating to adverse changes in reimbursement procedures and policies in other countries where we may market our products. Reimbursement and healthcare payment systems vary significantly among international markets. Our inability to obtain international reimbursement approval, or any adverse changes in the reimbursement policies of foreign payors, could negatively affect our ability to sell our products and have a material adverse effect on our business and financial condition.

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

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

The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law on Dec. 18, 2015, includes a two-year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2017.

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 sales, once commenced, of medical devices in the U.S. will be subject to this 2.3% excise tax following December 31, 2017.

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 the underlying patents and intellectual property be challenged or defeated, or should patents and intellectual property assigned to us be challenged or defeated, suitable replacements can be obtained or developed on terms acceptable to us, if at all. There is also the related risk that we may not be able to make the required payments under any patent license or assignment agreement, in which case we may lose the ability to use one or more of the licensed or assigned patents.

We could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from selling our commercially available products and/or reduce the margins we may realize from our products.

The medical devices industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the determination is often uncertain. There may be existing patents of which we are unaware that our products under development may inadvertently infringe. The likelihood that patent infringement claims may be brought against us increases as the number of participants in the infectious 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, litigation may be threatened or brought by a patent holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence. If we were found to infringe any patents, we could be required to pay substantial damages, including triple damages if an infringement is found to be willful. We also could be required to pay royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. We may not be able to obtain a license enabling us to sell our products on reasonable terms, or at all, 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 four issued U.S. patents and eight pending U.S. patent applications. We also have fourteen issued foreign patents and have applied for five additional foreign patents and for seven international patents. Our issued patents begin to expire in 2019, with the last of these patents expiring in 2029, although terminal disclaimers, patent term extension or patent term adjustment can shorten or lengthen the patent term. We rely on a combination of patent protection, trade secret laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these may not adequately protect our rights or permit us to gain or keep any competitive advantage.

The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office or foreign patent offices where our applications are pending. The U.S. Patent and Trademark Office or foreign offices may deny or require significant narrowing of claims in our pending patent applications. Patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the U.S. Patent and Trademark Office or foreign offices could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. The laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S., if at all. Some of our patents may expire before we receive FDA approval to market our products in the U.S. or we receive approval to market our products in a foreign country. Although we believe that certain patent applications and/or other patents issued more recently will help protect the proprietary nature of the Hemopurifier treatment technology, 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, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

In the event a competitor infringes upon any of our patents or other intellectual property rights, enforcing our rights may be difficult, time consuming and expensive, and would divert management’s attention from managing our business. We 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 rely on licenses for new technology, which may affect our continued operations with respect thereto.

As we develop our technology, we may need to license additional technologies to optimize the performance of our products. We may not be able to license these technologies on commercially reasonable terms or at all. In addition, we may fail to successfully integrate any licensed technology into our proposed products. Our inability to obtain any necessary licenses could delay our product development and testing until alternative technologies can be identified,

licensed and integrated. The inability to obtain any necessary third-party licenses could cause us to abandon a particular development path, which could seriously harm our business, financial position and results of our operations.

New technology may lead to our competitors developing superior products which would reduce demand for our products.

Research into technologies similar to ours is proceeding at a rapid pace, and many private and public companies and research institutions are actively engaged in the development of products similar to ours. These new technologies may, if successfully developed, offer significant performance or price advantages when compared with our technologies. We can provide no assurance 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 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 which 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. Time-consuming and costly litigation could be necessary to enforce and determine the scope of our rights under these agreements. In addition, we may be required to commence litigation to enforce such agreements if they are violated, and it is certainly possible that we will not have adequate remedies for breaches of our confidentiality agreements as monetary damages may not be sufficient to compensate us. 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 our products or technology will not be found to infringe upon the intellectual property or proprietary rights of others. Third parties may claim that our products or technology infringe on their patents, copyrights, trademarks or other proprietary rights and demand that we cease development or marketing of those products or technology or pay license fees. We may not be able to avoid costly patent infringement litigation, which will divert the attention of management away from the development of new products and the operation of our business. We cannot assure investors that we would prevail in any such litigation. If we are found to have infringed on a third party’s intellectual property rights, we may be liable for money damages, encounter significant delays in bringing products to market or be precluded from manufacturing particular products or using particular technology.

Other parties may challenge certain of our foreign patent applications. If 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 we are unable to meet any of the remaining DARPA contract milestones to the satisfaction of DARPA, if at all, we may not earn future 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. Upon the completion of the DARPA contract, we can provide no assurance that we will develop other sources of revenue in the short term.

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 obtaining government contracts is lengthy with the uncertainty that we will be successful in obtaining announced grants or contracts for therapeutics as a medical device technology. Accordingly, we 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.

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As a U.S. Government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and would be subject to periodic audits and reviews. As part of any such audit or review, the U.S. Government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. Government may adjust our contract-related costs and fees, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we would possibly be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. Government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. Although we have not had any government audits and reviews to date, future audits and reviews could cause adverse effects. In addition, under U.S. Government purchasing regulations, some of our costs, including most financing costs, amortization of intangible assets, portions of our research and development costs, and some marketing expenses, would possibly not be reimbursable or allowed under such contracts. Further, as a U.S. Government contractor, we would be subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities 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 specific procurement regulations and other requirements. These requirements, although customary in government contracts, impact our performance and compliance costs. In addition, current U.S. Government budgetary constraints could lead to changes in the procurement environment, including the Department of Defense’s recent initiative focused on efficiencies, affordability and cost growth and other changes to its procurement practices. If and to the extent such changes occur, they could impact our results of operations and liquidity, and could affect whether and, if so, how we pursue certain opportunities and the terms under which we are able to do so.

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

In fulfilling our U.S. Government 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, some of our suppliers or subcontractors may be impacted by the recent global financial crisis, 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 has in the past and may in the future 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, there is no assurance that we will not be sued 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 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 Commission's "penny stock" rules. If our common stock is subject to the "penny stock" rules promulgated under the Exchange Act, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected. For any transaction involving a penny stock, unless exempt, the rules require:

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

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

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

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

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

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

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

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

Trading in our common shares historically has been volatile and often has been thin, meaning that the number of persons interested in purchasing our common shares at or near trading prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. 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 them, which may result in losses to you.

The market for our common shares is characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than a seasoned issuer for the indefinite future. In fact, during the 52-week period ended March 31, 2016, the high and low closing sale prices of a share of our common stock were $14.00 and $4.34, 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-adverse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. The following factors may add to the volatility in the price of our common shares: actual or anticipated variations in our quarterly or annual operating results; acceptance of our proprietary technology as a viable method of augmenting the immune response of clearing viruses and toxins from human blood; government regulations, announcements of significant acquisitions, strategic partnerships or joint ventures; our capital commitments and additions or departures of our key personnel. Many of these factors are beyond our control and may decrease the market price of our common shares regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common shares will be at any time, including as to whether our common shares will sustain their current market prices, or as to what effect the sale of shares or the availability of common shares for sale at any time will have on the prevailing market price.

We cannot assure you that we will be able to comply with the continued listing standards of the Nasdaq Capital Market.

We cannot assure you that we will be able to comply with the listing standards that we are required to meet in order to maintain a listing of our common stock on the Nasdaq Capital Market. Our failure to meet those requirements may result in our common stock being delisted from the Nasdaq Capital Market.

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.” Because our common stock is listed on the Nasdaq Capital Market, we believe 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 our common stock is no longer listed

on the Nasdaq Capital Market, our securities would not be covered securities 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 10% 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 18, 2016, our officers and directors beneficially own or control approximately 10% 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, 2016, there are outstanding purchase options and warrants entitling the holders to purchase 2,602,639 common shares at a weighted average exercise price of $7.40 per share. This includes 26,105 warrants that are conditional upon the exercise of other warrants. As of March 31, 2016, there are 107,468 shares underlying promissory notes convertible into common stock at a weighted average exercise price of $5.60.

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

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

We are entitled under our Articles of Incorporation to issue up to 30,000,000 shares of common stock. We have reserved for issuance 2,710,107 shares of common stock for existing options, warrants and convertible notes. As of March 31, 2016, we had issued and outstanding 7,622,393 shares of common stock. As a result, as of March 31, 2016 we had 19,667,500 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.

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, 2016), we issued a total of 1,626,032 shares for debt to reduce our obligations. However, we did not issue any shares as payment for services in the fiscal year ended March 31, 2016. The average price discount of common stock issued for debt during the previous two fiscal years, 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, 2016), we issued a total of 147,001 shares as payment for services. However, we did not issue any shares as payment for services in the fiscal year ended March 31, 2016. The average price discount (premium) of common stock issued for services during the previous two fiscal years, 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.

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 which 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. The foregoing indemnification obligations could result in our company incurring substantial expenditures to cover the cost of settlement or damage awards against directors, officers and employees that we may be unable to recoup. These provisions and resultant costs may also discourage our company from bringing a lawsuit against directors, officers and employees for breaches of their fiduciary duties, and may similarly discourage the filing of derivative litigation by our stockholders against our directors, officers and employees even though such actions, if successful, might otherwise benefit our company and stockholders.

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

Provisions of Nevada anti-takeover law (NRS 78.378 *et seq.*) could have the effect of delaying or preventing a third party from acquiring us, even if the acquisition arguably could benefit our stockholders. Various provisions of our by-laws may delay, defer or prevent a tender offer or takeover attempt of us that a stockholder might consider in his or her best interest. Our 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 shall have 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 existence of the foregoing provisions and other potential anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

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

As a public company, we incur significant legal, insurance, accounting and other expenses, including costs associated with public company reporting. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management’s time and attention from product development and commercialization activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. These laws and regulations could make it more difficult and costly for us to obtain director and officer liability insurance for our directors and officers, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and qualified members of our Board of Directors, particularly to serve on our audit and compensation committees. In addition, if we are unable to continue to meet the legal, regulatory and other

requirements related to being a public company, we may not be able to maintain the listing of our common stock on the Nasdaq Capital Market or on any other senior market to which we may apply for listing, which would likely have a material adverse effect on the trading price of our common stock.

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

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

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, 764,657 shares of our common stock are issuable at an exercise price of $6.30 per share of common stock upon exercise of warrants owned by the selling stockholders and covered by this prospectus. 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 18, 2016, 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 was initially filed with the 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 was initially filed with the 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)	574,221	405,812	168,409
Empery Asset Master, Ltd. (3)	170,638	86,448	84,190
Empery Tax Efficient, LP (4)	92,042	70,341	21,701
Empery Tax Efficient II, LP (5)	239,416	81,307	158,109
Frontier Ventures LLC (6)	99,188	5,556	93,632
Lincoln Park Capital Fund, LLC (7)	18,750	18,750	0
Osher Capital Partners LLC (8)	59,183	11,905	47,278
Joshua S. Brodkin (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)	91,187	9,889	81,298
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.

(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, 59,688 shares of common stock issuable upon the exercise of warrants to purchase shares of common stock with an exercise price of $5.00 per share, subject to customary adjustments, which expire on November 6, 2019, and 108,721 shares of common stock issuable upon the conversion of a convertible promissory note with a conversion price of $5.00 per share, subject to customary adjustments. Konrad Ackermann and Dr. Nicola Feuerstein have discretionary authority to vote and dispose of the shares held by Alpha Capital Anstalt, and each may be deemed to be the beneficial owner of these shares.

(3) Includes 84,190 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $5.00 per share, subject to customary adjustments, which expires on December 2, 2019, and 86,448 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. Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd., has discretionary authority to vote and dispose of the shares held by Empery Asset Master Ltd. and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by Empery Asset Master Ltd. Empery Asset Management LP, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(4) Includes 21,701 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $5.00 per share, subject to customary adjustments, which expires on December 2, 2019, and 70,341 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. Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP, has discretionary authority to vote and dispose of the shares held by Empery Tax Efficient, LP and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by Empery Tax Efficient, LP. Empery Asset Management LP, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(5) Includes 158,109 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $5.00 per share, subject to customary adjustments, which expires on December 2, 2019, and 81,307 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. Empery Asset Management LP, the authorized agent of Empery Tax Efficient II, LP, has discretionary authority to vote and dispose of the shares held by Empery Tax Efficient II, LP and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by Empery Tax Efficient II, LP. Empery Asset Management LP, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares.

(6) Includes 2,381 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, 13,333 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $5.65 per share, subject to customary adjustments, which expires on October 15, 2019, 15,625 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.80 per share, subject to customary adjustments, which expires on February 11, 2020, and 2,252 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $8.35 per share, subject to customary adjustments, which expires on August 5, 2020. Munish Sood has discretionary authority to vote and dispose of the shares held by Frontier Ventures LLC and may be deemed to be the beneficial owner of these shares.

(7) Includes 18,750 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. Joshua Scheinfeld and Jonathan Cope have discretionary authority to vote and dispose of the shares held by Lincoln Park Capital Fund, LLC and may be deemed to be the beneficial owner of these shares.

(8) Includes 11,905 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, 17,436 shares of common stock issuable upon the exercise of warrants to purchase shares of common stock with an exercise price of $5.00 per share, subject to customary adjustments, which expire on November 6, 2019, and 29,842 shares of common stock issuable upon the conversion of a convertible promissory note with a conversion price of $5.00 per share, subject to customary adjustments. Ari Kluger has discretionary authority to vote and dispose of the shares held by Osher Capital Partners LLC and may be deemed to be the beneficial owner of these shares.

(9) Includes 3,571 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.

(10) Includes 5,952 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.

(11) Includes 5,952 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, 10,000 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $6.25 per share, subject to customary adjustments, which expires on March 29, 2019, and 3,390 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.40 per share, subject to customary adjustments, which expires on December 14, 2019.

(12) Includes 23,810 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, 3,125 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.80 per share, subject to customary adjustments, which expires on August 12, 2021, and 7,018 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.30 per share, subject to customary adjustments, which expires on August 12, 2021.

(13) Includes 8,333 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.

(14) Includes 39,286 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, 20,000 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $6.25 per share, subject to customary adjustments, which expires on April 5, 2019, 6,250 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $6.00 per share, subject to customary adjustments, which expires on August 29, 2019, 7,752 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $9.65 per share, subject to customary adjustments, which expires on June 26, 2019, 12,281 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.30 per share, subject to customary adjustments, which expires on October 17, 2021, and 13,889 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $5.40 per share, subject to customary adjustments, which expires on October 17, 2021. Also includes 45,162 shares of common stock and 11,290 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.65 per share, subject to customary adjustments, which expires on October 17, 2021, which are held by the Judith Sackstein Irrevocable Trust. Dr. Adam Sackstein has discretionary authority to vote and dispose of the shares held by the Judith Sackstein Irrevocable Trust and may be deemed to be the beneficial owner of these shares.

(15) Includes 28,822 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, 6,173 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $6.10 per share, subject to customary adjustments, which expires on July 29, 2021, 6,250 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $6.25 per share, subject to customary adjustments, which expires on October 17, 2021, 6,944 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $5.40 per share, subject to customary adjustments, which expires on October 17, 2021, 3,125 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $6.00 per share, subject to customary adjustments, which expires on October 17, 2021, and 3,509 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.30 per share, subject to customary adjustments, which expires on October 17, 2021.

(16) Includes 11,905 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.

(17) Includes 5,952 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.

(18) Includes 5,952 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, 5,000 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an

exercise price of $6.25 per share, subject to customary adjustments, which expires on April 5, 2019, 2,778 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $5.40 per share, subject to customary adjustments, which expires on June 19, 2019, 1,306 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $6.00 per share, subject to customary adjustments, which expires on August 29, 2019, 2,660 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $7.10 per share, subject to customary adjustments, which expires on August 29, 2019, 1,667 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.65 per share, subject to customary adjustments, which expires on October 20, 2021, and 2,709 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $4.80 per share, subject to customary adjustments, which expires on October 20, 2021.

(19) Includes 6,000 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.

(20) Represents 11,000 shares of common stock issuable upon the exercise of a warrant to purchase shares of common stock with an exercise price of $15.00 per share, subject to customary adjustments, which expires on December 2, 2019, and 32,371 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. Roth Capital Partners, LLC is a Financial Industry Regulatory Authority-registered broker-dealer and received the warrants as compensation for investment banking services in connection with the private placements of securities referenced herein that were consummated in December 2014 and June 2015. The individual persons who share the power to vote and/or dispose of these securities are Byron Roth and Gordon Roth.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issued pursuant to the terms of the securities purchase agreement and upon exercise of the warrants to permit the resale of these shares of common stock by the holders of such shares and warrants from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- sales pursuant to Rule 144;
-

broker-dealers may agree with the selling security holders to sell a specified number of such shares at a stipulated price per share;

- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the shares of common stock or warrants owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or any other applicable provision of the Securities Act amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed, to any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or reallowed or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

We cannot assure you that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, estimated to be approximately $54,101 in total, including, without limitation, Commission filing fees and expenses of compliance with state securities or blue sky laws; provided, however, that a selling stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreement, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the related registration rights agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

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DESCRIPTION OF BUSINESS

Overview and Corporate History

We are a leading developer of immunotherapeutic technologies to combat infectious disease and cancer. To augment the body's natural immune defenses, the Aethlon Hemopurifier® eliminates life-threatening disease targets that are often shielded from the immune system and not well addressed by traditional drug therapies. The technology captures circulating viruses, bacterial toxins and cancer promoting exosomes through affinity attachment to a unique structure that cloaks these targets from immune detection. At present, the Hemopurifier® is being advanced under an FDA approved clinical study. Aethlon is also the majority owner of Exosome Sciences, Inc., or Exosome, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. In addition, we operate under a Department of Defense contract through the Defense Advanced Research Projects Agency, or DARPA, related to the development of a sepsis treatment device. We also operate under a second Department of Defense contract as a subcontractor.

Aethlon Medical was formed on March 10, 1999. Our executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. All references to “us” or “we” are references to Aethlon Medical, Inc., combined with its majority-owned subsidiary, Exosome Sciences, Inc.

Target Market and Strategy

Our primary therapeutic business segment is divided into two areas. First, we are advancing our lead product, the Aethlon Hemopurifier, which targets the removal of circulating viruses and shed glycoproteins to treat infectious viral pathogens. In oncology indications, the Hemopurifier targets the removal of circulating exosomes, which are released to promote cancer progression and to seed the spread of metastasis.

The second focus is government contracting. We operate under two Department of Defense contracts related to a program entitled “Dialysis-Like Therapeutics.” One is a contract with DARPA, and the other is a subcontract with Battelle Memorial Institute.. Under these contracts, 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. Specific to the Hemopurifier, the program has focused on validating the capture of viral pathogens and bacterial toxins.

The third facet of our business is conducted through Exosome, which is our diagnostic business segment and is developing exosome-based products to diagnose and monitor life-threatening disease conditions.

We initially developed the Hemopurifier as a broad-spectrum countermeasure to address the many infectious viral pathogens that are not addressed with antiviral drugs. We also envision our technology serving as an adjunct therapy to improve the benefit of infectious disease and cancer therapy regimens marketed by pharmaceutical organizations. For example, a clinical trial protocol administered at the Medanta Medicity Institute in India was designed to treat Hepatitis C patients as they began their standard of care drug regimen as a means to reduce the time it normally takes for the virus to become undetectable in the patient's blood. At completion of the Medanta Medicity study, we reported that patients who received the Hemopurifier therapy protocol had higher rapid virologic response and sustained virologic response rates as compared to what would normally be expected for Hepatitis C virus infected individuals who receive standard of care interferon-ribavirin drug therapy alone.

Our Lead Device: The Aethlon Hemopurifier

The Aethlon Hemopurifier is a device that selectively targets the rapid elimination of circulating viruses and tumor-secreted exosomes that promote cancer progression. More specifically, the Hemopurifier addresses antiviral drug-resistance in Hepatitis C virus and Human Immunodeficiency Virus-infected individuals; serves as a countermeasure against viral pathogens not addressed by drug or vaccine therapies; and, we believe, represents the first therapeutic strategy to address cancer promoting exosomes. In clinical studies conducted in India, safety and efficacy observations of Hemopurifier therapy have been observed in both Hepatitis C virus and Human Immunodeficiency Virus-infected individuals. We are currently conducting the first U.S. Food and Drug Administration, or FDA, approved studies of Hemopurifier therapy in the U.S.

The Scientific Mechanism of the Hemopurifier

The Hemopurifier is an extracorporeal (situated or occurring outside the body) device designed for the single-use removal of viruses, viral toxins, and deleterious exosomes from the circulatory system of treated patients. Delivery of Hemopurifier therapy can occur through the established infrastructure of continuous renal replacement therapy and dialysis instruments routinely found in hospitals and clinics worldwide. Most extracorporeal techniques, including dialysis and plasmapheresis, are designed to solely remove circulating particles by molecule size, which results in the elimination of disease targets as well as blood components required for health.

However, the Hemopurifier is an interactive technology that incorporates a lectin affinity agent that binds to a unique high mannose signature that is abundant on the surface of tumor-derived exosomes and glycoproteins that reside on the outer membrane of infectious viruses. The Hemopurifier is designed to provide a broad-spectrum mechanism to reduce the presence of certain cancer and infectious disease related particles. To date, clinical treatment protocols have administered Hemopurifier therapy for periods lasting from three to six and one half hours in duration.

The Hemopurifier - Antiviral Drug-Resistance; Planned U.S. Clinical Trials

The Hemopurifier provides a novel methodology to target mutant viral strains that trigger antiviral drug resistance in both Human Immunodeficiency Virus and Hepatitis C virus infections. In Hepatitis C virus care, we believe the Hemopurifier is positioned to address drug resistance associated with emerging all-antiviral therapies and also to accelerate Hepatitis C virus depletion at the outset of peginterferon+ribavirin therapy.

Based on previous studies we conducted in India, safety and efficacy observations of Hemopurifier therapy have been observed in both disease conditions. As a result of these outcomes, we have initiated the first FDA-approved feasibility study of Hemopurifier therapy in the U.S. The feasibility study is being conducted on Hepatitis C virus-infected patients at DaVita MedCenter Dialysis in Houston, Texas. The principal investigator for the study is Dr. Ronald Ralph, who replaced Dr. Stephen Z. Fadem as principal investigator in late 2015.

Successful completion of this study will permit us to initiate further stage studies that are required for market clearance to treat Hepatitis C virus and other viral pathogens in the U.S. Our feasibility study protocol calls for the enrollment of ten Hepatitis C virus-infected end stage renal disease patients who have not received any pharmaceutical therapy for their Hepatitis C virus infection for at least 30 days. The protocol will consist of a control phase of three consecutive standard dialysis treatments during week one followed by the inclusion of our Hemopurifier during a total of six dialysis sessions conducted during weeks two and three. The rate of adverse events observed during the Hemopurifier therapy phase will be compared to the rate experienced during the control phase. Per-treatment changes of viral load will be observed through quantitative polymerase chain reaction analysis. Additionally, we plan to measure the number of viral copies of Hepatitis C virus captured within the Hemopurifier during each treatment session.

On February 14, 2014, we entered into an agreement with Total Renal Research, Inc. (dba DaVita Clinical Research). Pursuant to the agreement, Da Vita Clinical Research is conducting site management administrative services for a study. The agreement with DaVita Clinical Research requires us to pay certain expenses related to the study protocol projected to be less than $200,000, including certain start-up and close-out costs, patient compensation and project management fees. Additional activities and completion of this clinical trial will require us to pay additional costs estimated to be $650,000. We will also be responsible for the fees for any third-party consulting physicians, including Dr. Ralph, utilized in connection with the study and other pass-through expenses if incurred. The work order under

this agreement was effective as of May 16, 2014 and will continue in effect until completion of the services being provided by DaVita Clinical Research.

The Hemopurifier - Antiviral Studies in India

Previously, we conducted Hepatitis C virus treatment studies at the Apollo Hospital, Fortis Hospital, and most recently the Medanta Medicity Institute in India.

In the Medanta Medicity Institute study, twelve Hepatitis C virus-infected individuals were enrolled to receive three six-hour Hemopurifier treatments during the first three days of a 48-week peginterferon+ribavirin treatment regimen. The study was conducted under the leadership of Dr. Vijay Kher at the Medanta Medicity Institute, a multi-specialty medical institute established to be a premier center for medical tourism in India. Dr. Kher's staff reported that Hemopurifier therapy was well tolerated and without device-related adverse events in the twelve treated patients.

Of these twelve patients, ten completed the Hemopurifier-peginterferon+ribavirin treatment protocol, including eight genotype-1 patients and two genotype-3 patients. Eight of the ten patients achieved a sustained virologic response, which is the clinical definition of treatment cure and is defined as undetectable Hepatitis C virus in the blood 24 weeks after the completion of the 48-week peginterferon+ribavirin drug regimen. Both genotype-3 patients achieved a sustained virologic response, while six of the eight genotype-1 patients achieved a sustained virologic response.

Of the ten patients who completed the full treatment protocol, five also achieved a rapid virologic response, defined as undetectable Hepatitis C virus in the blood at day 30 of therapy. Rapid virologic response represents the clinical endpoint that best predicts sustained virologic response cure rates resulting from peginterferon+ribavirin therapy. As a point of reference, the landmark Individualized Dosing Efficacy vs Flat Dosing to Assess Optimal Pegylated Interferon Therapy study of 3,070 Hepatitis C virus genotype-1 patients documented that 10.35% (n=318/3070) of peginterferon+ribavirin-treated patients achieved a rapid virologic response. Patients who achieved a rapid virologic response had sustained virologic response rates of 86.2% (n=274/318) versus sustained virologic response rates of 32.5% (n=897/2752) in non-rapid virologic response patients. Two of the genotype-1 patients who achieved a rapid virologic response also achieved an immediate virologic response, defined as undetectable Hepatitis C virus in the blood seven days after initiation of Hemopurifier-peginterferon+ribavirin treatment protocol. The earliest measured report of undetectable Hepatitis C virus in blood in the Individualized Dosing Efficacy vs Flat Dosing to Assess Optimal Pegylated Interferon Therapy study was on day 14 of the study.

Data from two patients was not included in the reported Hemopurifier-peginterferon+ribavirin dataset. One of these patients was a genotype-5 patient who discontinued peginterferon+ribavirin therapy at day 180, yet still achieved a sustained virologic response. The second patient was a genotype-3 patient who also achieved a sustained virologic response, yet was unable to tolerate peginterferon+ribavirin therapy and discontinued therapy at day 90. Overall, ten of the twelve patients who enrolled in the study achieved a sustained virologic response and seven of the twelve patients achieved a rapid virologic response.

Hemopurifier - Human Immunodeficiency Virus; Single Proof Study

In addition to treating Hepatitis C virus-infected individuals, we have conducted a single proof-of-principle treatment study related to the treatment of Human Immunodeficiency Virus. In the study, Hemopurifier therapy reduced viral load by 93% in a Human Immunodeficiency Virus-Acquired Immunodeficiency Syndrome-infected individual without the administration of antiviral drug therapy. The study protocol provided for 12 Hemopurifier treatments, each four hours in duration, which were administered over the course of one month.

Researchers at the Morehouse School of Medicine have since discovered that the Hemopurifier is able to capture exosomes that transport negative regulatory factor protein, which is reported to suppress the immune response in Human Immunodeficiency Virus-infected individuals.

The Hemopurifier - Viral Pathogens Not Addressed by Drug Therapies

The protocol design of our forthcoming FDA-approved study was originally designed as a human safety challenge and model for addressing drug and vaccine resistant bioterror and emerging pandemic threats. *In vitro* studies conducted by leading government and non-government researchers have demonstrated that the Hemopurifier is able to capture a broad spectrum of some of the world's deadliest viral pathogens. These include: Dengue hemorrhagic fever, Ebola hemorrhagic fever, Lassa hemorrhagic fever, H5N1 avian influenza, H1N1 swine flu virus, the reconstructed 1918 influenza virus, West Nile virus and Vaccinia and Monkeypox, which serve as models for human smallpox infection. Human efficacy studies are not permissible against high-threat bioterror and pandemic threats.

The following table lists some of the key viral pathogens captured during *in vitro* studies and the name of the research institute that ran the study.

Virus Type	**Collaborator**

Ebola Virus	United States Army Medical Research Institute of Infectious Diseases/Centers for Disease Control
Dengue Fever	National Institute of Virology/World Health Organization
Lassa Hemorrhagic Fever	Southwest Foundation for Biomedical Research
West Nile Virus	Battelle
H5N1 Avian Flu	Battelle
1918-r Spanish Flu	Battelle
2009 H1N1 Swine Flu	Battelle

The Hemopurifier - Candidate to Treat Cancer

In “Extracellular Vesicles: Emerging Targets for Cancer Therapy,” a review article sponsored by the National Cancer Institute and published in the July 2014 issue of *Trends in Molecular Medicine*, we were the sole organization referenced to have a therapeutic candidate to address tumor-secreted exosomes, which have been discovered to suppress the immune system of cancer patients, seed the creation and spread of metastasis, promote angiogenesis, trigger resistance to chemotherapy, and transport primary cancer therapeutic targets of the biopharmaceutical industry. To date, we have received an issued patent that protects the use of our Hemopurifier to remove immunosuppressive extracellular vesicles or exosomes from the blood of cancer patients. Through internal research and external research collaborations, we have demonstrated that the affinity lectin immobilized in our Hemopurifier is able to bind exosomes underlying a broad spectrum of disease indications including cancer.

We believe that Hemopurifier therapy could play a role in the emerging immuno-oncology industry as an adjunct that can combine with established and emerging cancer therapies without adding drug toxicity. More specifically, we believe that a mechanism to inhibit exosome immune suppression should be clinically tested in combination with drugs designed to stimulate the immune response.

On April 9, 2015, we entered into an investigator-initiated clinical trial agreement with the University of California, Irvine, or UCI, pursuant to which UCI will conduct a five-year clinical study protocol entitled “Plasma Exosome Concentration in Cancer Patients Undergoing Treatment.” The protocol will seek to enroll five individuals in each of nine defined tumor types for a total study population of up to 45 subjects. The tumor types include the following forms of cancer: breast adenocarcinoma, colorectal, gastric and gastroesophageal, pancreatic, cholangiocarcinoma, lung, head and neck, melanoma and ovarian adenocarcinoma. The principal investigator of the study is Edward Nelson, M.D. The budget for the protocol provides for (i) $19,032 in startup charges; (ii) $8,039 in protocol-related variable pass-through charges; and (iii) visit charges of $3,359 per subject, for a total subject visit charge of $151,155 for 45 subjects. We will bear these costs. UCI may disseminate the results of the clinical trial through presentation and publication but may not disclose any of our confidential information.

Exosome Sciences, Inc. - Diagnostic Candidates

Through our majority-owned subsidiary Exosome, which is our diagnostic product-oriented business segment, we are developing exosome-based product candidates to diagnose and monitor neurological disorders and cancer. Since it began operations in 2013, Exosome researchers have disclosed that they have isolated brain-specific biomarkers associated with Alzheimer's Disease and Chronic Traumatic Encephalopathy. Specific to Chronic Traumatic Encephalopathy, Exosome is participating in a research collaboration with The Boston University CTE Center to study the correlation of a biomarker known as tausome with Chronic Traumatic Encephalopathy. The initial results from that research collaboration were published in an article entitled “Preliminary Study of Plasma Exosomal Tau as a Potential Biomarker for Chronic Traumatic Encephalopathy” in the *Journal of Alzheimer's Disease* on April 12, 2016.

Exosome researchers have demonstrated the ability to identify, quantify, and characterize circulating Glioblastoma multiforme exosomes, which hold promise as a disease biomarker to identify the early detection of this aggressive form of cancer and monitor response to therapy. We believe that the discovery of circulating glioblastoma multiforme exosomes may offer a potential new paradigm in glioblastoma multiforme exosomes clinical management through a platform technology to predict tumor regression or progression.

U.S. Government Contract with the Defense Advanced Research Projects Agency

On September 30, 2011, we entered into a $6.8 million multi-year contract with DARPA, part of the Department of Defense, resulting from our response to a program entitled “Dialysis-Like Therapeutics.” 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.

The initial award from DARPA was a fixed-price contract with potential total payments to us of $6,794,389 over the course of five years. As noted below, such contract was subsequently reduced by $858,469. Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each year of the contract. Under the terms of the contract, we are required to perform certain incremental work towards the achievement of specific milestones against which we will invoice the government for fixed payment amounts.

Originally, only the base year (year one of the contract) was effective for the parties, however, DARPA subsequently exercised the option on the remaining four years of the contract. The milestones are comprised of planning, engineering and clinical targets, the achievement of which in some cases will require the participation and contribution of third party participants under the contract. We cannot assure you that we alone, or with third party participants, will meet such milestones to the satisfaction of the government and in compliance with the terms of the contract or that we will be paid the full amount of the contract revenues during any year of the remaining contract term. We commenced work under the contract in October 2011.

In February 2014, DARPA reduced the scope of our contract in years three through five of the contract. The reduction in scope focused our research on exosomes, viruses and blood processing instrumentation. This scope reduction will reduce the possible payments under the contract by $858,469 over years three through five.

The DARPA contract requires us to perform certain scientific research and development activities geared toward the achievement of specific milestones set forth in the contract. During the fiscal years ended March 31, 2016 and March 31, 2015, we recognized revenue of $863,011 and $630,887, respectively, under the DARPA contract. Based on the DARPA contract, as now in force, we may achieve up to an additional $387,438 in revenue under the DARPA contract during the fiscal year ending March 31, 2017.

Subcontract with Battelle Memorial Institute

We entered into a subcontract agreement with Battelle in March 2013. Battelle was chosen by DARPA to be the prime contractor on the systems integration portion of the DARPA contract, and we are one of several subcontractors on that systems integration project. We began generating revenues under the subcontract in the three months ended September 30, 2013. During the fiscal years ended March 31, 2016 and March 31, 2015, we recognized revenue of $23,561 and $131,530, respectively, under the Battelle subcontract. Our expected future revenue from the subcontract will be at the discretion of Battelle. The Battelle subcontract is our first cost-reimbursable contract.

Our revenue under this contract is a function of cost reimbursement plus an overhead mark-up for hours devoted to the project by specific employees (with specific hourly rates for those employees), for travel expenses related to the project, for any equipment purchased for the project and for the cost of any consultants hired by us to perform work on the project. Each payment will require approval by the program manager at Battelle.

Research and Development Costs

A substantial portion of our operating budget is used for research and development activities. The cost of research and development, all of which has been charged to operations, amounted to approximately $782,000 and $1,028,000 in the fiscal years ended March 31, 2016 and 2015, respectively.

Intellectual Property

We currently own or have license rights to a number of U.S. and foreign patents and patent applications and endeavor to continually improve our intellectual property position. We consider the protection of our technology, whether owned or licensed, to the exclusion of use by others, to be vital to our business. While we intend to focus primarily on patented or patentable technology, we may also rely on trade secrets, unpatented property, know-how, regulatory exclusivity, patent extensions and continuing technological innovation to develop our competitive position. We also own certain trademarks.

Patents

We have been exclusively assigned all rights and title to and interest in an invention and related worldwide patent rights for a method to treat cancer under an assignment agreement with the London Health Science Center Research, Inc. The invention provides for the "Depression of anticancer immunity through extracorporeal removal of microvesicular particles" (including exosomes) for which the U.S. Patent and Trademark Office issued a patent in 2012 (patent #8,288,172) and for which we have filed additional patent applications domestically and abroad (patent applications #US13/623662, #US14/180093, #US14/185033, #EP7,752,778.6, #HK9,104,740.6, #IN8139/DELNP/2008 and #CA2644855). Please see the tables below for more information regarding these patents and patent applications.

The agreement provides for an upfront payment of 800 shares of unregistered common stock and a 2% royalty on any future net sales. We are also responsible for paying certain patent application and filing costs. Under the assignment agreement, the London Health Science Center Research, Inc. sold and assigned all of its rights, title and interest in the worldwide patents to us.

The following table lists all of our issued patents and patent applications, including their ownership status:

Patents Issued in the United States

PATENT #	PATENT NAME	ISSUANCE DATE	OWNED OR LICENSED	EXPIRATION DATE
9,364,601	Extracorporeal removal of microvesicular particles	6/14/16	Owned	10/2/29
8,288,172	Extracorporeal removal of microvesicular particles (exosomes) (method patent)	10/16/12	Owned	3/30/29
7,226,429	Method for removal of viruses from blood by lectin affinity hemodialysis	6/5/07	Owned	1/20/25
6,528,057	Method for removal of HIV and other viruses from blood	3/4/03	Licensed	8/30/19

Patent Applications in the United States

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
14/490,418	Method for removal of viruses from blood by lectin affinity hemodialysis	9/18/14	Owned
14/856361	Device and method for purifying virally infected blood	9/16/15	Owned
14/790684	Affinity capture of circulating biomarkers	7/02/15	Owned
13/808561	Methods and compositions for quantifying exosomes	8/14/13	Owned
14/180093	Extracorporeal removal of microvesicular particles	2/13/14	Owned
14/185033	Extracorporeal removal of microvesicular particles	2/20/14	Owned
62/258340	Plasma exosomal tau as a biomarker for chronic traumatic encephalopathy	11/20/15	Owned
62/352358	Exosomal Tau as a Biomarker for Brain Disorders	6/20/16	Owned

Foreign Patents

PATENT #	PATENT NAME	ISSUANCE DATE	OWNED OR LICENSED	EXPIRATION DATE
2,353,399	Method for removal of viruses from blood by lectin affinity hemodialysis (Russia)	4/27/09	Owned	1/20/24
770,344		6/3/04	Licensed	8/30/19

	Method for removal of HIV and other viruses from blood (Australia)			
DE69929986	Method for removal of HIV and other viruses from blood (Germany)	2/22/06	Licensed	8/30/19
1,109,564	Method for removal of HIV and other viruses from blood (France)	2/22/06	Licensed	8/30/19
1,109,564	Method for removal of HIV and other viruses from blood (Great Britain)	2/22/06	Licensed	8/30/19
1,109,564	Method for removal of HIV and other viruses from blood (Italy)	2/22/06	Licensed	8/30/19
2342203	Method for removal of HIV and other viruses from blood (Canada)	3/1/11	Licensed	8/30/19
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Belgium)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Ireland)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Italy)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Great Britain)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (France)	7/17/13	Owned	1/20/24
1624785	Method for removal of viruses from blood by lectin affinity hemodialysis (Germany)	7/17/13	Owned	1/20/24
2,516,403	Method for removal of viruses from blood by lectin affinity hemodialysis (Canada)	8/12/14	Owned	1/20/24

Foreign Patent Applications

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
EP20070752778	Extracorporeal removal of microvesicular particles (exosomes) (Europe)	3/9/07	Owned
9,104,740.6	Extracorporeal removal of microvesicular particles (exosomes) (Hong Kong)	3/9/07	Owned
8139/DELNP/2008	Extracorporeal removal of microvesicular particles (exosomes) (India)	3/9/07	Owned
2644855	Extracorporeal removal of microvesicular particles (Canada)	3/9/07	Owned
EP20110804372	Methods and compositions for quantifying exosomes (Europe)	7/7/11	Owned

International Patent Applications

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
PCT/US2016/	Methods for delivering regional citrate anticoagulation during extracorporeal blood treatments	4/20/16	Owned

028482 PCT/US2015/ 017800	Brain specific exosome based diagnostics and extracorporeal therapies	2/26/15	Owned

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We expect that our ability to enforce our patents and proprietary rights in many countries will be adversely impacted due to possible changes in law, our lack of familiarity with foreign law, or our lack of professional resources in jurisdictions outside the U.S. We cannot guarantee that any patents issued or licensed to us, including within the U.S., will provide us with competitive advantages or will not be challenged by others, or will not expire prior to our successful commercialization of our products. Furthermore, we cannot be certain that others will not independently develop similar products or will not design around patents issued or licensed to us. We cannot guarantee that patents that are issued will not be challenged, invalidated or infringed upon or designed around by others, or that the claims contained in such patents will not infringe the patent claims of others, or provide us with significant protection against competitive products, or otherwise be commercially valuable. We may need to acquire licenses under patents belonging to others for technology potentially useful or necessary to us. If any such licenses are required, we cannot be certain that they will be available on terms acceptable to us, if at all. To the extent that we are unable to obtain patent protection for our products or technology, our business may be materially adversely affected by competitors who develop substantially equivalent technology.

Trademarks

We have obtained trademark registrations in the U.S. for Hemopurifier, Aethlon Medical, Inc., and the Exosome Sciences Logo and obtained a trademark registration in India for Hemopurifier. Exosome Sciences, Inc. has applied for the Tausome trademark in the U.S., which application is currently pending. We also have common law trademark rights in Aethlon ADAPT™ and ELLSA™.

Licensing and Assignment Agreements

Effective January 1, 2000, we entered into an agreement with a related party under which an invention and related patent rights for a method of removing Human Immunodeficiency and other viruses from the blood using the Hemopurifier were assigned to us by the inventors in exchange for an 8.75% royalty to be paid on future net sales of the patented product or process and shares of our common stock. On March 4, 2003, the related patent (patent #6,528,057) was issued and we issued 3,922 shares of unregistered common stock to that related party. The license runs for the life of the patent, which expires in August 2019.

On November 7, 2006, we entered into an exclusive assignment agreement with the London Health Science Center Research, Inc. under which an invention and related patent rights for a method to treat cancer were assigned to us. The invention provides for the "Extracorporeal removal of microvesicular particles" for which the U.S. Patent and Trademark Office allowed a patent (patent #8,288,172) in the U.S. as of October 2012. The agreement provides for an upfront payment of 800 shares of unregistered common stock and a 2% royalty on any future net sales. We are also responsible for paying certain patent application and filing costs. Under the assignment agreement, we own the patents outright for the life of the patent, which expires in March 2029. Under certain circumstances, ownership of the patents

may revert back to the London Health Science Center Research, Inc. if there is an uncured substantial breach of the assignment agreement.

Industry

The industry for treating infectious disease and cancer is extremely competitive, and companies developing new treatment procedures face significant capital and regulatory challenges. Additionally, as the Hemopurifier is a new device, we have the additional challenge of establishing medical industry support, which will be driven by treatment data resulting from clinical studies of each disease condition that we pursue. The industry includes pharmaceutical companies and medical device companies competing to treat illnesses on a worldwide basis.

Competition

We are advancing our Hemopurifier as a treatment strategy to enhance and prolong current drug therapies by removing the viral strains that cause drug resistance. We are also advancing the Hemopurifier as a tool for cancer treatment in conjunction with existing, and to be developed, cancer therapies. The Hemopurifier also may prolong life for infected patients who have become drug resistant or have been infected with a viral pathogen for which there is no drug or vaccine therapy. We believe our Hemopurifier augments the benefit of drug therapies and should not be considered a competitor to such treatments. However, if the industry considered the Hemopurifier to be a potential replacement for drug therapy, or a device that limited the need or volume of existing drug therapies, then the marketplace for the Hemopurifier would be extremely competitive. We believe our Hemopurifier is the sole therapeutic device able to selectively remove viruses and immunosuppressive proteins from circulation. However, we are aware that Asahi Kasei Kurary Medical based in Japan has created a double filtration plasmapheresis system that indiscriminately removes particles from blood in a certain molecule range that includes Hepatitis C virus. Asahi Kasei Kurary Medical is now marketing this device in Japan as an adjunct therapy for Hepatitis C virus. We may also face competition from producers of antiviral drugs and vaccines.

Government Regulation of Medical Devices

The Hemopurifier is subject to regulation by numerous regulatory bodies, primarily the FDA, and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing, storage, distribution, advertising and promotion, and post-marketing surveillance reporting of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation program be conducted before a device receives approval for commercial distribution. Failure to obtain approval or clearance to market our product and products under development and to meet the ongoing requirements of these regulatory authorities could prevent us from commercializing the Hemopurifier and future products in the U.S. and elsewhere.

Hemopurifier Investigational Device Exemption and Supplement

In 2013, the FDA approved our investigational device exemption to initiate human clinical studies in the U.S. as a feasibility study. We were required to reach agreement with the internal review board of DaVita MedCenter Dialysis prior to beginning our U.S. clinical trial. We are also required to obtain patients' informed consent that complies with both FDA requirements and state and federal privacy regulations. We, the FDA or the internal review board at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval of the product. The investigational device exemption is part of the FDA’s clearance process. This process is discussed in detail in the “Pre-Marketing Regulations in the U.S.” section below.

In December 2014, the FDA approved our request for a supplement to our investigational device exemption to establish a protocol to clinically investigate the use of the Hemopurifier for the treatment of Ebola-infected patients in the U.S. Under the supplement, we may treat up to 20 Ebola-infected persons, at no more than 10 institutions in the U.S., using the supplement protocol; however, this is not a clinical trial. We must clearly distinguish data collected in the supplement protocol from data collected in our chronic Hepatitis C virus clinical trial (discussed above). Prior to treating Ebola-infected patients, we must comply with specified patient protection procedures established by the applicable institution including its institutional review board. Also, we must report any unanticipated adverse events resulting from the supplement protocol to the FDA within 10 working days. Even if the protocol is established, and patients are treated, the results of such treatments may not demonstrate the safety and efficacy of the device. In addition, we cannot assure you that any Ebola-infected individuals will be treated under this protocol.

Pre-Marketing Regulations in the U.S.

Unless an exemption applies, each medical device distributed commercially in the U.S. requires either prior 510(k) clearance or premarket approval, or PMA, from the FDA. The FDA classifies medical devices into one of three classes. Class I devices are subject to only general controls, such as establishment registration and device listing, labeling, medical device reporting, and prohibitions against adulteration and misbranding. Class II medical devices generally require prior 510(k) clearance before they may be commercially marketed in the U.S. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, are placed in Class III, generally requiring submission of a PMA supported by clinical trial data. Our Hemopurifier is a Class III product, and we believe that products utilizing our Aethlon ADAPT™ system will be considered to be Class III products and thus will require submission and approval of a PMA. In the future, we may develop new products that are considered to be Class II and require the clearance of a 510(k).

510(k) Clearance Pathway

To obtain 510(k) clearance, a premarket notification must be submitted to FDA demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications. FDA’s 510(k) clearance pathway usually takes from three to twelve months, but it can take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, require premarket approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), or a premarket approval, but the FDA can review any such decision and can disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires a 510(k) holder to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, the 510(k) holder also may be required to cease marketing or recall the modified device until this clearance or approval is obtained.

Premarket Approval Pathway

A PMA must be supported by extensive data, including but not limited to data obtained from technical, preclinical and clinical studies and relating to manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA submission is sufficiently complete, the FDA will accept the application and begin an in-depth review, which generally takes between one and three years, but may take significantly longer. During this review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, or QSR. New PMA applications or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials

Clinical trials are almost always required to support a PMA. To perform a clinical trial in the U.S. for a significant risk device, the FDA requires the device sponsor to file an Investigational Device Exemption, or IDE, application with the FDA and obtain IDE approval prior to commencing the human clinical trial. An IDE amendment or supplement must also be submitted before initiating a significant change to the clinical protocol or device under an existing IDE. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, and any available data on human clinical experience, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound.

The IDE must be approved in advance by the FDA for a specific number of patients. Clinical trials conducted in the U.S. for significant risk devices may begin once the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, overseeing the welfare of the research subjects and responsible for that particular clinical trial. Under its regulations, the FDA responds to an IDE or an IDE amendment within 30 days. The FDA may approve the IDE or amendment, grant an approval with certain conditions, or identify deficiencies and request additional information. It is common for the FDA to require additional information before approving an IDE or amendment for a new trial, and thus final FDA approval on a submission may require more than the initial 30 days. The FDA may also require that a small-scale feasibility study be conducted before a pivotal trial may commence. In a

feasibility trial, the FDA limits the number of patients, sites and investigators that may participate. Feasibility trials are typically structured to obtain information on safety and to help determine how large a pivotal trial should be to obtain statistically significant results.

Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S.

Post-Marketing Regulations in the U.S.

Should our Hemopurifier device be cleared for market use in the U.S. by the FDA, numerous regulatory requirements continue to apply. These include:

- the FDA's Quality System Regulation which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for un-cleared, unapproved or off-label uses;
- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The regulations also require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury.

We will also be required to register with the FDA as a medical device manufacturer within 30 days of commercial distribution of our products and must obtain all necessary state permits or licenses to operate our business. As a manufacturer, we are subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;

- customer notifications for 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 premarket approval of new products or modified products;
- operating restrictions;
- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Compliance with U.S. Health Care Laws

Should our Hemopurifier device be cleared for market use in the U.S. by the FDA, we must comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback regulations, as well as other healthcare laws in connection with the commercialization of our products. Fraud and abuse laws are interpreted broadly and enforced aggressively by various state and federal agencies, including the U.S. Department of Justice, the U.S. Office of Inspector General for the Department of Health and Human Services and various state agencies.

The U.S. federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, as amended, prohibits persons, including a medical device manufacturer (or a party acting on its behalf), from knowingly or willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for a service or product or the purchasing, ordering, arranging for, or recommending the ordering of, any service or product for which payment may be made by Medicare, Medicaid or any other federal healthcare program. This statute has been interpreted to apply to arrangements between medical device manufacturers on one hand and healthcare providers on the other. The term “remuneration” is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, such as cash payments, gifts or gift certificates, discounts, waiver of payments, credit arrangements, ownership interests, the furnishing of services, supplies or equipment, and the provision of anything at less than its fair market value. Courts have broadly interpreted the scope of the law, holding that it may be violated if merely one purpose of an arrangement is to induce referrals, irrespective of the existence of other legitimate purposes. The Anti-Kickback Statute prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the recently enacted Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the Affordable Care Act or ACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. In addition to the federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions, safe harbors or sanctions. In some states, these anti-kickback laws apply not only to payments made by government healthcare programs but also to payments made by other third-party payors, including commercial insurance companies.

We may also be subject to various federal and state marketing laws, such as the federal Physician Payments Sunshine Act, which generally require certain types of expenditures in the U.S. and the particular states to be tracked and reported. The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical and medical device manufacturers to engage in extensive tracking of payments or transfers of value to physicians and teaching hospitals, maintenance of a payments database, and public reporting of the payment data. Device manufacturers with products for which payment is available under Medicare, Medicaid or the State Children’s Health Insurance Program are required to track and report such payments. Moreover, several states have enacted legislation requiring pharmaceutical and medical device companies to establish marketing compliance programs or even prohibit providing meals to prescribers or other marketing related activities. Compliance with such requirements may require investment in infrastructure to ensure that tracking and reporting is performed properly. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated.

International Regulation

International development and sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. For example, the primary regulatory authority with respect to medical devices in Europe is that of the European Union. The unification of these countries into a common market has resulted in the unification of laws, standards and procedures across these countries, which may expedite the introduction of medical devices like those we are offering and developing.

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of relevant directives will be entitled to bear CE Conformity Marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the European Union. Actual implementation of these directives, however, may vary on a country-by-country basis.

To date, we have not begun any process to obtain the CE Mark and have no immediate plans to test or commercialize the Hemopurifier in any European Union countries.

Manufacturing

Manufacturing of our Hemopurifier occurs in collaboration with a contract manufacturer based in San Diego, California that is compliant with the Good Manufacturing Practice regulations promulgated by the FDA. Our contract manufacturer is registered with the FDA. We also have received an export license from the FDA that allows the export our Hemopurifier for commercial purposes to India. To date, our manufacture of the Hemopurifier has been limited to quantities necessary to support our clinical studies.

Sources and Suppliers

We are not dependent on any specific vendors for the materials used in our Hemopurifier. The key raw materials in the Hemopurifier include the affinity lectin Galanthus nivalis agglutinin, pharmaceutical grade diatomaceous earth, plasmapheresis cartridges and certain chemical binding agents. The affinity lectin is available from several life science supply companies in the U.S. Diatomaceous earth is available from several life science supply companies in the U.S. To date, we have purchased plasmapheresis cartridges from one vendor in Europe however similar cartridges are commercially available from vendors on a worldwide basis should that European vendor cease to be available for any reason, including prohibitive pricing. The chemical binding agents are available from a number of life science supply companies on a worldwide basis. We typically purchase our raw materials on purchase order basis. Therefore, we remain subject to risks of supply shortages and price increases that potentially could materially adversely affect our financial condition and operating results if and when we begin large scale manufacture of the Hemopurifier.

The key raw materials used by Exosome in its research are blood samples supplied by research partners and a number of chemical and lab products commercially available from vendors on a worldwide basis. Exosome is not dependent on any specific vendors for the materials used in its research activities.

Sales and Marketing

We do not currently have any sales and marketing capability. With respect to commercialization efforts in the future, we intend to build or contract for distribution, sales and marketing capabilities for any product candidate that is approved. From time to time, we have had and are having strategic discussions with potential collaboration partners for our product candidates, although no assurance can be given that we will be able to enter into one or more collaboration agreements for our product candidates on acceptable terms, if at all.

Product Liability

The risk of product liability claims, product recalls and associated adverse publicity is inherent in the testing, manufacturing, marketing and sale of medical products. We have limited clinical trial liability insurance coverage. We cannot assure you that future 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 liability for mandatory damages could exceed the amount of our coverage. A successful product liability claim against us could require us to pay a substantial monetary award. Moreover, a product recall could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other future product candidates.

Employees

We have five full-time employees consisting of our Chief Executive Officer, our President, our Chief Financial Officer, a research scientist and an executive assistant. We utilize, whenever appropriate, consultants in order to conserve cash and resources.

We believe our employee relations are good. None of our employees are represented by a labor union or are subject to collective-bargaining agreements.

DESCRIPTION OF PROPERTIES

We currently lease approximately 2,576 square feet of executive office space at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123 under a 39-month gross plus utilities lease that commenced on December 1, 2014 with an initial rental rate of $6,054 per month. Such lease expires in March 2018. We believe this leased facility will be satisfactory for our office needs over the term of the lease.

We also lease approximately 1,700 square feet of laboratory space at 11585 Sorrento Valley Road, Suite 109, San Diego, California 92121 at the rate of $4,168 per month on a one-year lease that expires in November 2016. We believe this leased facility will be satisfactory for our laboratory needs over the term of the lease.

Our Exosome subsidiary previously rented approximately 2,055 square feet of office and laboratory space at 11 Deer Park Drive, South Brunswick, New Jersey at the rate of $3,917 per month on a one-year lease that expired in October 2015. In October 2015, Exosome relocated to a different suite at the same office complex. Exosome leased that suite, comprised of approximately 541 square feet of office and laboratory space located at 9 Deer Park Drive, South Brunswick, New Jersey, at the rate of $1,352 per month on a month-to-month lease basis. In January 2016, we exercised our 30-day notice to terminate the Exosome lease in New Jersey prior to consolidating our laboratory operations in San Diego.

LEGAL PROCEEDINGS

We may be involved from time to time in various claims, lawsuits, and/or disputes with third parties or breach of contract actions incidental to the normal course of our business operations. We are currently not involved in any litigation or any pending legal proceedings.

MARKET PRICE FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the Nasdaq Capital Market under the trading symbol "AEMD." Trading in our common stock historically has been volatile and often has been thin. On July 7, 2015, The NASDAQ Stock Market LLC approved our application for listing our common stock on the Nasdaq Capital Market under the symbol “AEMD,” and we commenced trading on the Nasdaq Capital Market on July 13, 2015. Previously, our common stock was quoted on the OTCQB Marketplace under the trading symbol “AEMD.”

The following table sets forth for the calendar periods indicated the quarterly high and low closing or bid, as applicable, prices for our common stock as reported by the Nasdaq Capital Market and/or the OTCQB Marketplace. The prices represent quotations between dealers, without adjustment for retail markup, mark down or commission, and do not necessarily represent actual transactions.

	CLOSING/BID PRICE	
PERIOD	HIGH	LOW
Calendar 2016:		
First Quarter	$7.01	$4.34
Calendar 2015:		
Fourth Quarter	8.20	6.17
Third Quarter	11.38	6.58
Second Quarter	14.00	6.51
First Quarter	19.50	8.50
Calendar 2014:		
Fourth Quarter	28.50	6.00
Third Quarter	9.00	5.00
Second Quarter	11.00	7.50
First Quarter	13.00	8.00

There were approximately 89 record holders of our common stock at July 18, 2016. The number of registered stockholders includes any beneficial owners of common shares held in street name.

The transfer agent and registrar for our common stock is Computershare Investor Services, located at 350 Indiana Street, Suite 800, Golden, Colorado 80401.

We have not paid any dividends on our common stock to date and do not anticipate that we will pay dividends in the foreseeable future. Any payment of cash dividends on our common stock in the future will be dependent upon the amount of funds legally available, our earnings, if any, our financial condition, our anticipated capital requirements and other factors that the board of directors may think are relevant. However, we currently intend for the foreseeable future to follow a policy of retaining all of our earnings, if any, to finance the development and expansion of our business and, therefore, do not expect to pay any dividends on our common stock in the foreseeable future.

EQUITY COMPENSATION PLANS

SUMMARY EQUITY COMPENSATION PLAN DATA

Equity Compensation Plans

Summary equity compensation plan data

The following table sets forth information, as of March 31, 2016, about our equity compensation plans (including the potential effect of debt instruments convertible into common stock) in effect as of that date:

Plan category	(a) Number of securities to be issued upon exercise of outstanding options,	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation

	warrants and rights (1)(2)			plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders (3)	–	$	–	3,038,645
Equity compensation plans not approved by security holders (1)	438,547	$	10.94	0
Totals	438,547	$	10.94	3,038,645

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(1) The description of the material terms of non-plan issuances of equity instruments is discussed in Note 5 to the accompanying consolidated financial statements.

(2) Net of equity instruments forfeited, exercised or expired.

(3) On March 31, 2016 we had 3,028,845 shares available under our 2010 Stock Incentive Plan.

2000 Stock Option Plan

Our 2000 Stock Option Plan provides for the grant of incentive stock options to our full-time employees (who may also be directors) and nonstatutory stock options to non-employee directors, consultants, customers, vendors or providers of significant services. The exercise price of any incentive stock option may not be less than the fair market value of the common stock on the date of grant or, in the case of an optionee who owns more than 10% of the total combined voting power of all classes of our outstanding stock, not be less than 110% of the fair market value on the date of grant. The exercise price, in the case of any nonstatutory stock option, must not be less than 75% of the fair market value of the common stock on the date of grant. The amount reserved under the 2000 Stock Option Plan is 10,000 options.

At March 31, 2016, all of the grants previously made under the 2000 Stock Option Plan had expired and 200 common shares had been issued under the plan, with 9,800 available for future issuance.

2010 Stock Incentive Plan

In August 2010, we adopted the 2010 Stock Incentive Plan, which provides incentives to attract, retain and motivate employees and directors whose present and potential contributions are important to our success by offering them an opportunity to participate in our future performance through awards of options, the right to purchase common stock, stock bonuses and stock appreciation rights and other awards. We initially reserved a total of 70,000 common shares for issuance under the 2010 Stock Incentive Plan.

In August 2010, we filed a registration statement on Form S-8 for the purpose of registering 70,000 common shares issuable under this plan under the Securities Act, and in July 2012, we filed a registration statement on Form S-8 for the purpose of registering 100,000 common shares issuable under this plan under the Securities Act.

On January 26, 2016, our Board of Directors approved an amendment to the 2010 Stock Incentive Plan to increase the total number of shares of common stock reserved for issuance under the plan to 3,170,000 shares, subject to amendment of our Articles of Incorporation to increase our authorized common stock. On March 29, 2016, we held an annual stockholders meeting, at which our stockholders approved the Amended 2010 Stock Incentive Plan and an amendment of our Articles of Incorporation to increase our authorized common stock to 30,000,000 shares. On March 31, 2016, we filed a Certificate of Amendment to our Articles of Incorporation to effect the increase in our authorized common stock. As a result of such amendment, the Amended 2010 Stock Incentive Plan became effective on March 31, 2016.

At March 31, 2016, we had 3,028,845 shares available under this plan.

2012 Directors Compensation Program

In July 2012, our Board of Directors approved a board compensation program that modifies and supersedes the 2005 Directors Compensation Program, which was previously in effect. Under the 2012 program, in which only non-employee directors may participate, an eligible director will receive a grant of $35,000 worth of ten-year options to acquire shares of common stock, with such grant being valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. In addition, under this program, eligible directors will receive cash compensation equal to $500 for each committee meeting attended and $1,000 for each formal board meeting attended.

In the fiscal year ended March 31, 2013, our Board of Directors granted ten-year options to acquire an aggregate of 33,342 shares of our common stock, all with an exercise price of $3.80 per share, to our four outside directors under the 2012 program.

In the fiscal year ended March 31, 2014, our Board of Directors granted ten-year options to acquire an aggregate of 31,911 shares of our common stock, all with an exercise price of $4.10 per share, to our five outside directors under the 2012 program.

In the fiscal year ended March 31, 2015, our Board of Directors granted ten-year options to acquire an aggregate of 11,053 shares of our common stock, all with an exercise price of $9.50 per share, to our three outside directors under the 2012 program. No stock option grants were issued to directors during the fiscal year ended March 31, 2016.

At March 31, 2016 we had issued 26,757 options under the old 2005 program to outside directors and 79,309 options to employee-directors, 21,756 outside directors' options had been forfeited, 5,000 outside directors' options had been exercised, 79,309 employee-directors' options had been forfeited and no options under the old 2005 program remained outstanding.

On June 6, 2014, our Board of Directors approved certain changes to the 2012 program. Under this modified program, a new eligible director will receive an initial grant of $50,000 worth of options to acquire shares of common stock, with such grant being valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. These options will have a term of ten years and will vest 1/3 upon grant and 1/3 upon each of the first two anniversaries of the date of grant. In addition, at the beginning of each fiscal year, each existing director eligible to participate in the modified 2012 program also will receive a grant of $35,000 worth of options valued at the exercise price based on the average of the closing bid prices of the common stock for the five trading days preceding the first day of the fiscal year. Such options will vest on the first anniversary of the date of grant. In lieu of per meeting fees, eligible directors will receive an annual board retainer fee of $30,000. The modified 2012 program also provides for the following annual retainer fees: Audit Committee Chair - $5,000, Compensation Committee chair - $5,000, Audit Committee member - $4,000, Compensation Committee member - $4,000 and lead independent director - $15,000.

Stand-alone grants

From time to time our Board of Directors grants common stock or common share purchase options or warrants to selected directors, officers, employees and consultants as equity compensation to such persons on a stand-alone basis outside of any of our formal stock plans. The terms of these grants are individually negotiated. There were no stock option grants to either employees or directors during the fiscal year ended March 31, 2016.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Overview

We are a medical device company focused on creating innovative devices that address unmet medical needs in cancer, infectious disease and other life-threatening conditions. At the core of our developments is the Aethlon ADAPT system, a medical device platform that converges single or multiple affinity drug agents with advanced plasma membrane technology to create therapeutic filtration devices that selectively remove harmful particles from the entire circulatory system without loss of essential blood components.

In June 2013, the U.S. Food and Drug Administration, or FDA, approved our investigational device exemption application to initiate a ten-patient human clinical trial in one location in the U.S. to treat dialysis patients who are infected with the Hepatitis C virus. Successful outcomes of that human trial as well as at least one follow-on human trial will be required by the FDA in order to commercialize our products in the U.S. The regulatory agencies of certain foreign countries where we intend to sell this device will also require one or more human clinical trials.

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. However, we believe that certain patent applications and/or other patents issued more recently will help protect the proprietary nature of the Hemopurifier treatment technology.

Through our majority-owned subsidiary, Exosome Sciences, Inc., or Exosome, we are also studying potential diagnostic techniques for identifying and monitoring neurological conditions and cancer. We consolidate Exosome’s activities in our consolidated financial statements.

Fiscal Years Ended March 31, 2016 and 2015

Results of Operations

Revenues

We recorded government contract revenue in the fiscal years ended March 31, 2016 and 2015. This revenue arose from work performed under our government contract with the Defense Advanced Research Projects Agency, or DARPA, and our subcontract with Battelle Memorial Institute, or Battelle, as follows:

	Fiscal Year Ended 3/31/16	Fiscal year Ended 3/31/15	Change in Dollars
DARPA contract	$863,011	$630,887	$232,124
Battelle subcontract	23,561	131,530	(107,969)
Total government contract revenue	$886,572	$762,417	$124,155

DARPA Contract

We entered into a contract with DARPA on September 30, 2011. Under the DARPA award, we have been engaged to develop a therapeutic device to reduce the incidence of sepsis, a fatal bloodstream infection that often results in the death of combat-injured soldiers. The award from DARPA was a fixed-price contract with potential total payments to us of $6,794,389 over the course of five years. Fixed price contracts require the achievement of multiple, incremental milestones to receive the full award during each year of the contract. Under the terms of the contract, we will perform certain incremental work towards the achievement of specific milestones against which we will invoice the government for fixed payment amounts.

Originally, only the base year (year one of the contract) was effective for the parties; however, DARPA subsequently exercised the option on the second, third, fourth and fifth years of the contract. The milestones are comprised of planning, engineering and clinical targets, the achievement of which in some cases will require the participation and contribution of third party participants under the contract. We cannot assure you that we alone, or with third party participants, will meet such milestones to the satisfaction of the government and in compliance with the terms of the contract or that we will be paid the full amount of the contract revenues during any year of the contract term. We commenced work under the contract in October 2011.

In February 2014, DARPA reduced the scope of our contract in years three through five of the contract. The reduction in scope focused our research on exosomes, viruses and blood processing instrumentation. This scope reduction reduced the possible payments under the contract by $858,469 over years three through five.

In the fiscal year ended March 31, 2016, we reported $863,011 in contract revenue for that fiscal year and in the fiscal year ended March 31, 2015, we reported $630,887 in contract revenue for that fiscal year.

As of March 31, 2016, we had invoiced DARPA for contract payments totaling $5,548,573 over the course of the contract.

Battelle Subcontract

We entered into a subcontract agreement with Battelle in March 2013. Battelle was chosen by DARPA to be the prime contractor on the systems integration portion of the original DARPA contract, and we are one of several subcontractors on that systems integration project. The Battelle subcontract is under a time and materials basis and we began generating revenues under the subcontract in the three months ended September 30, 2013. Our expected future revenue from the subcontract will be at the discretion of Battelle. The Battelle subcontract is our first cost-reimbursable contract.

Our revenue under this contract is a function of cost reimbursement plus an overhead mark-up for hours devoted to the project by specific employees (with specific hourly rates for those employees), for travel expenses related to the project, for any equipment purchased for the project and for the cost of any consultants hired by us to perform work on the project. Each payment will require approval by the program manager at Battelle.

Operating Expenses

Consolidated operating expenses were $5,271,406 for the fiscal year ended March 31, 2016 compared to $4,755,270 in the fiscal year ended March 31, 2015, an increase of $516,136. The net increase of $516,136 was due to increases in professional fees of $686,900 and to an increase in general and administrative expense of $21,898, which were partially offset by a decrease in payroll and related expenses of $192,662.

The $686,900 increase in our professional fees arose from a $815,125 increase in non-DARPA-related professional fees, which was partially offset by a decrease in DARPA-related professional fees of $36,446 and a decrease in Exosome's professional fees of $91,779.

The $815,125 increase in our non-DARPA-related professional fees was primarily due to $424,264 of credits and write-offs on accrued professional fees taken in the fiscal year ended March 31, 2015 as part of a negotiation of payoffs of those accrued fees. There was no comparable activity in the 2016 period. Without those write-offs in the 2015 period, our non-DARPA-related professional fees in the 2016 period were $390,861 over the pre write-off amount of non-DARPA-related professional fees in the 2015 period. That increase was due to a combination of an increase in our US clinical trial expenses of $84,212, an increase of scientific consulting expenses of $138,471, an increase in business development expense of $71,579 and an increase in our legal fees of $125,525, which largely related to work on financings and related registration statement filings.

The $21,898 increase in general and administrative expenses primarily arose from a $183,819 increase in our general and administrative expenses, which was partially offset by a $130,233 decrease in general and administrative expenses at Exosome and a $31,690 decrease in our DARPA-related general and administrative expenses. The $183,819 increase arose from a combination of $100,000 in Nasdaq listing fees and an increase of $70,161 in conference and trade show expenses.

The $192,662 decrease in payroll and related expenses was principally driven by a $258,240 decrease in the payroll and related expenses of Exosome due to headcount reductions and a $213,637 reduction in our stock-based compensation, which were partially offset by a $279,215 increase in payroll and related expenses of Aethlon Medical due primarily to salary increases and bonus payments.

Other Expense (Income)

In the fiscal year ended March 31, 2016, we recognized other expenses of $573,782 compared to $2,986,641 of other expense in the fiscal year ended March 31, 2015. The following table breaks out the various components of our other expense over the fiscal years ended March 31, 2016 and 2015:

	Components of Other Expense in Fiscal Year Ended March 31, 2016	March 31, 2015	Change
Loss on debt conversion	$–	$2,753,989	$(2,753,989)
Interest and other debt expenses	573,782	452,276	121,506
Other (income)	–	(219,624)	219,624
Total other expense	$573,782	$2,986,641	$(2,412,859)

We recorded a loss on debt conversion of $2,753,989 in the fiscal year ended March 31, 2015, which arose from the conversion to equity of principal and accrued interest on certain notes payable. There was no comparable loss on debt conversion in the fiscal year ended March 31, 2016.

Other income for the fiscal year ended March 31, 2015 included a gain of $362,800 related to a reduction in our accrued damages due to various debt settlements over the fiscal year and a charge of $143,176 for the change in fair value related to the extension of the warrants of a note holder in exchange for a postponement in the agreed payment date of his notes.

Our interest and other debt expense increased by $121,506 from the fiscal year ended March 31, 2015 to the fiscal year ended March 31, 2016. The following table breaks out the various components of our interest expense over the fiscal years ended March 31, 2016 and 2015:

	Components of Interest Expense and Other Debt Expenses in Fiscal Year Ended March 31, 2016	March 31, 2015	Change

Interest expense	$56,549	$166,899	$(110,350)
Amortization of deferred financing costs	144,683	118,147	26,536
Amortization of note discounts	372,550	155,230	217,320
Note restructuring expense	–	12,000	(12,000)
Total interest and other debt expenses	$573,782	$452,276	$121,506

As noted in the above table, the primary factor in the $121,506 overall increase in interest and other debt expenses was a $217,320 increase in the amortization of note discounts. That increase was due to a full year of amortization in the fiscal year ended March 31, 2016 compared to a partial year of amortization in the previous fiscal year since the related convertible notes that were assigned the note discount were funded in November 2014.

As a result of the above factors, our net loss before noncontrolling interests decreased from $6,979,494 for the fiscal year ended March 31, 2015 to $4,958,616 for the fiscal year ended March 31, 2016.

Liquidity and Capital Resources

At March 31, 2016, we had a cash balance of $2,123,737 and working capital of $1,877,532. This compares to a cash balance of $855,596 and working capital of $630,420 at March 31, 2015. Between April 1, 2016 and June 28, 2016, we billed $4,635 and collected $204,106 under our government contracts. Significant additional financing must be obtained in order to provide a sufficient source of operating capital and to allow us to continue to operate as a going concern. In addition, we will need to raise capital to complete the approved human clinical trial in the U.S. We anticipate the primary source of this additional financing will be from proceeds of the Company's at-the-market offering program.

We raised $5,591,988 in net proceeds from a financing in June 2015. That amount, coupled with previously existing funds on hand and expected revenues from our government contracts, has financed our operations into the first quarter of the fiscal year ending March 31, 2017. However, we will require significant additional financing to complete the current and expected 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 through the remainder of the fiscal year ending March 31, 2017. In addition, as we expand our activities, our overhead costs to support personnel, laboratory materials and infrastructure will increase. Should the financing we require to sustain our working capital needs be unavailable to us on reasonable terms, if at all, when we require it, we may be unable to support our research and U.S. Food and Drug Administration, or 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.

Future capital requirements will depend upon many factors, including progress with pre-clinical testing and clinical trials, the number and breadth of our clinical programs, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the time and costs involved in obtaining regulatory approvals, competing technological and market developments, as well as our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We expect to continue to incur increasing negative cash flows and net losses for the foreseeable future.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the ordinary course of business. We have incurred continuing losses from operations and at March 31, 2016 had an accumulated deficit of approximately $86,502,000. These factors, among other matters, raise substantial doubt about our ability to continue as a going concern. A significant amount of additional capital will be necessary to advance the development of our products to the point at which they may become commercially viable. We intend to fund operations, working

capital and other cash requirements for the fiscal year ending March 31, 2017 through debt and/or equity financing arrangements as well as through revenues and related cash receipts under our government contracts.

We are currently addressing our liquidity issue by seeking additional investment capital through issuances of common stock under our existing registration statement on Form S-3 (Registration No. 333-211151), originally filed on May 5, 2016, and by applying for additional grants issued by government agencies in the United States. We believe that our cash on hand and funds expected to be received from additional debt and equity financing arrangements will be sufficient to meet our liquidity needs for fiscal 2017. However, no assurance can be given that we will receive any funds in addition to the funds we have received to date.

The successful outcome of future activities cannot be determined at this time and there is no assurance that, if achieved, we will have sufficient funds to execute our intended business plan or generate positive operating results.

The consolidated financial statements do not include any adjustments related to this uncertainty and as to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

Cash Flows

Cash flows from operating, investing and financing activities, as reflected in the accompanying Consolidated Statements of Cash Flows, are summarized as follows (in thousands):

	(In thousands) For the year ended March 31, 2016	March 31, 2015
Cash (used in) provided by:		
Operating activities	$(4,329)	$(5,049)
Investing activities	(9)	–
Financing activities	5,607	4,655
Net increase (decrease) in cash	$1,269	$(394)

Net Cash from Operating Activities.

We used cash in our operating activities due to our losses from operations. Net cash used in operating activities was approximately $4,329,000 in fiscal 2016 compared to net cash used in operating activities of approximately $5,049,000 in fiscal 2015, a decrease of approximately $720,000. The $720,000 decrease was primarily due to the combination of the use of approximately $1,802,000 in fiscal 2015 to pay down accounts payable, related party payables and other current liabilities and an increase in fiscal 2016 in the cash used in operations before changes in operating assets and liabilities of approximately $1,017,000.

Net Cash from Investing Activities.

During the fiscal year ended March 31, 2016, we purchased approximately $9,000 of equipment while in the fiscal year ended March 31, 2015 we did not use any cash for purchases of equipment.

Net Cash from Financing Activities.

Net cash generated from financing activities increased from approximately $4,655,000 in the fiscal year ended March 31, 2015 to approximately $5,607,000 in the fiscal year ended March 31, 2016. The net cash provided by financing activities in fiscal 2016 was all from the issuance of common stock, while the net cash provided by financing activities in fiscal 2015 arose from approximately $4,763,000 from the issuance of common stock and $415,000 from the issuance of notes payable, which was partially offset by approximately $523,000 in repayments of notes payable in cash.

At the date of this filing, we plan to invest significantly into purchases of our raw materials and into our contract manufacturing arrangement.

Current Events

Common Stock Sales Agreement with H.C. Wainwright

On June 28, 2016, we entered into a Common Stock Sales Agreement (the "Agreement") with H.C. Wainwright & Co., LLC ("H.C. Wainwright") which establishes an at-the-market equity program pursuant to which we may offer and sell shares of our common stock from time to time as set forth in the Agreement. The Agreement provides for the sale of shares of our common stock having an aggregate offering price of up to $12,500,000 (the "Shares").

Subject to the terms and conditions set forth in the Agreement, H.C. Wainwright will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell the Shares from time to time, based upon our instructions. We have provided H.C. Wainwright with customary indemnification rights, and H.C. Wainwright will be entitled to a commission at a fixed rate equal to three percent (3.0%) of the gross proceeds per Share sold. In addition, we have agreed to pay certain expenses incurred by H.C. Wainwright in connection with the Agreement, including up to $50,000 of the fees and disbursements of their counsel. The Agreement will terminate upon the sale of all of the Shares under the Agreement unless terminated earlier by either party as permitted under the Agreement.

Sales of the Shares, if any, under the Agreement shall be made in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act, including sales made by means of ordinary brokers' transactions, including on the Nasdaq Capital Market, at market prices or as otherwise agreed with H.C. Wainwright. We have no obligation to sell any of the Shares, and, at any time, we may suspend offers under the Agreement or terminate the Agreement.

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Amendment of November 2014 Investment Documents

On June 27, 2016, we and certain investors (the "Investors") entered into Amendments (the "Amendments") to our November 2014 convertible notes in the original principal amount of $527,780 (the "Notes") and Class A Common Stock Purchase Warrants to purchase an aggregate of 47,125 shares of common stock (the "Existing Warrants") issued and sold by us to the Investors under a Subscription Agreement dated November 6, 2014. The Amendments provide that the Maturity Date (as defined in the Notes) is extended from June 1, 2016 to July 1, 2017 and that the Conversion Price (as defined in the Notes) is reduced from $5.60 per share of common stock to $5.00 per share of common stock. In addition, we reduced the purchase price (as defined in the Existing Warrants) from $8.40 per share to $5.00 per share. In connection with these modifications, each of the Investors signed a Consent and Waiver providing its consent under certain restrictive provisions, and waiving certain rights, including a right to participate in certain offerings made by us, under a Securities Purchase Agreement dated June 23, 2015, (the "2015 SPA") to which we, the Investors and certain other investors are parties, in order to facilitate the at-the-market equity program described above.

The Amendments also increase the principal amount of the Notes to $692,811.23 (in the aggregate) to (i) include accrued and unpaid interest through June 15, 2016, and (ii) increase the principal amount by $80,000 (in the aggregate) as an extension fee for the extended maturity date of the Notes set forth above. With respect to each Note, we entered into an Allonge to Convertible Promissory Note (each, an "Allonge") reflecting the changes in the principal amount, Maturity Date and Conversion Price of the Note.

We also issued to the Investors new warrants (the "New Warrants") to purchase an aggregate of 30,000 shares of common stock with a Purchase Price (as defined in the New Warrants) of $5.00 per share of common stock. We issued the New Warrants in substantially the same form as the Existing Warrants, and the New Warrants will expire on November 6, 2019, the same date on which the Existing Warrants will expire.

Amendment of December 2014 Warrants

On June 27, 2016, we and certain investors (the "Unit Investors") entered into Consent and Waiver and Amendment agreements (the "CWAs"), relating to an aggregate of 264,000 Warrants to Purchase Common Stock (the "Unit Warrants") we had issued to the Unit Investors on December 2, 2014 pursuant to a Securities Purchase Agreement dated November 26, 2014 (the "2014 SPA"). In the CWAs, each of the Unit Investors provided its consent under certain restrictive provisions, and waived certain rights, including a right to participate in certain offerings made by us, under the 2014 SPA in order to facilitate the at-the-market equity program described above. Pursuant to the CWAs, we reduced the Exercise Price (as defined in the Unit Warrants) from $15.00 per share of common stock to $5.00 per share of common stock. At any time that the shares of common stock underlying the Unit Warrants are covered by an effective registration statement that permits the public resale of the shares, if the Unit Investors exercise the Unit

Warrants, they must do so in a cash exercise, which could yield up to $1,320,000 in proceeds to us.

On June 27, 2016, each of the Unit Investors also entered into a Consent and Waiver providing its consent under certain provisions, and waiving certain rights, including a right to participate in certain offerings made by us, under the 2015 SPA in order to facilitate the at-the market equity program described above.

Critical Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make a number of estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. Such estimates and assumptions affect the reported amounts of expenses during the reporting period. On an ongoing basis, we evaluate estimates and assumptions based upon historical experience and various other factors and circumstances. We believe our estimates and assumptions are reasonable in the circumstances; however, actual results may differ from these estimates under different future conditions. We believe that the estimates and assumptions that are most important to the portrayal of our financial condition and results of operations, in that they require the most difficult, subjective or complex judgments, form the basis for the accounting policies deemed to be most critical to us. These critical accounting estimates relate to revenue recognition, stock purchase warrants issued with notes payable, beneficial conversion feature of convertible notes payable, impairment of intangible assets and long lived assets, stock compensation, deferred tax asset valuation allowance, and contingencies.

Fair Value Measurements

We measure the fair value of applicable financial and non-financial instruments based on the following fair value hierarchy:

- Level 1: Quoted market prices in active markets for identical assets or liabilities.
- Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.
- Level 3: Unobservable inputs that are not corroborated by market data.

The hierarchy noted above requires us to minimize the use of unobservable inputs and to use observable market data, if available, when determining fair value.

The fair value of derivative liabilities was determined based on unobservable inputs that are not corroborated by market data, which is a Level 3 classification. We recorded derivative liabilities on our balance sheet at fair value with changes in fair value recorded in our consolidated statements of operations. At March 31, 2016, we had no derivative liabilities.

Revenue Recognition

With respect to revenue recognition, we entered into a government contract with DARPA and have recognized revenue during the fiscal years ended March 31, 2016 and 2015 of $863,011 and $630,887, respectively, under such contract. We adopted the Milestone method of revenue recognition for the DARPA contract under Financial Accounting Standards Board's Accounting Standards Codification ("ASC") 605-28 "Revenue Recognition – Milestone Method" and we believe we meet the requirements under ASC 605-28 for reporting contract revenue under the Milestone Method for the fiscal years ended March 31, 2016 and 2015.

We also recognize revenue for a secondary smaller contract under a time and materials non-fixed price basis where we recognize revenue as the services