

AETHLON MEDICAL INC  
Form 424B3  
August 05, 2016

**Filed Pursuant to Rule 424(b)(3)**

**Registration No. 333-201334**

**PROSPECTUS**

**Aethlon Medical, Inc.**

275,000 Shares of Common Stock

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

- 264,000 shares of common stock underlying common stock purchase warrants at an exercise price of \$5.00 per share; and
- 11,000 shares of common stock underlying common stock purchase warrants at an exercise price of \$15.00 per share.

All of the common stock covered by this prospectus is being sold by the selling stockholders for their own account. We will not receive any proceeds from the sale of these shares other than proceeds, if any, from the exercise of warrants to purchase shares of our common stock. If all of the warrants are exercised for cash, we will receive a total of \$1,485,000 in gross proceeds, which we expect to use for general corporate purposes. We cannot assure you that any warrants will be exercised for cash. The selling stockholders may offer and sell the shares covered by this prospectus at prevailing prices quoted on the Nasdaq Capital Market or at privately negotiated prices. The selling stockholders may sell the shares directly or through underwriters, brokers or dealers. The selling stockholders will bear any applicable sales commissions, transfer taxes and similar expenses. We will pay all other expenses incident to the registration of the shares. See "Plan of Distribution" on page 23 for more information on this topic.

Our common stock is traded on the Nasdaq Capital Market under the symbol "AEMD." On August 2, 2016, the last reported sale price of our common stock on the Nasdaq Capital Market was \$6.70.

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

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is August 4, 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 275,000 shares of our common stock. This prospectus does not contain all of the information included in the registration statement. The registration statement filed with the 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 60 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.

## **Corporate History**

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

## **Our Contact Information**

Our executive offices are located at 9635 Granite Ridge Drive, Suite 100, San Diego, California 92123. Our telephone number is (858) 459-7800. Our website address is [www.aethlonmedical.com](http://www.aethlonmedical.com). Our website and the information contained on our website are not incorporated by reference into this prospectus or the registration statement of which it forms a part.

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

On December 2, 2014, we completed a private placement of units, each unit being comprised of one share of common stock, \$0.001 par value per share, and a warrant to purchase 1.2 shares of our common stock at an exercise price per share of \$15.00, with a term of five years from the date of issuance. We sold a total of 220,000 units, consisting of 220,000 shares of common stock and warrants to purchase 264,000 shares of common stock for gross proceeds of \$3,300,000 and net proceeds of \$3,001,428. We are using the proceeds from the private placement for general corporate purposes. At the closing of the private placement, we issued to Roth Capital Partners, LLC, the placement agent for the transaction, a five-year warrant to purchase up to 11,000 shares of our common stock at an exercise price of \$15.00 per share. 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 20 calendar days following the closing of the private placement. We agreed to use our best efforts to keep the registration statement effective under the Securities Act until the earlier of (i) the date that is two and one-half years after the closing of the



private placement or (ii) the date on which the purchasers have sold all of the shares covered by the registration statement. We are filing this post-effective amendment to the original registration statement on Form S-1 in order to fulfill our obligation under this registration rights agreement.

On June 27, 2016, we and the purchasers in the private placement entered into Consent and Waiver and Amendment agreements, in which we agreed to change the exercise price per share of the 264,000 warrants issued to the purchasers from \$15.00 to \$5.00. In exchange, the purchasers provided their consent under certain restrictive provisions set forth in the securities purchase agreement entered into in the private placement, and waived certain rights, in order to facilitate certain offerings made by us.

On June 25, 2015, we consummated another private placement of units, each comprised of one share of common stock and 0.75 of a five-year warrant to purchase one share of common stock at an exercise price of \$6.30 per share, for gross proceeds of \$6,000,000 and net proceeds of \$5,591,988. In that private placement, we issued 952,383 shares of common stock and warrants to purchase 714,285 shares of common stock to purchasers and warrants to purchase 32,371 shares of common stock to Roth Capital Partners as placement agent in the transaction. The securities sold in the June 2015 financing are not being offered in this prospectus.

In both private placement transactions, the issuance of the shares of common stock and the warrants was exempt from registration under the Securities Act 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 Up to 275,000 shares  
stockholders

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 \$1,485,000. 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.

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 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 für Arzneimittel und Medizinprodukte, BfArM), an independent federal higher authority within the portfolio of the Federal Ministry of Health of Germany. While we believe the results of the treatment of the Ebola patient in Germany to be positive with respect to the usage of the Hemopurifier to combat Ebola, no medical organization or regulatory organization, inside or outside the U.S., has cleared the use of the device for Ebola treatment on a commercial basis.

In addition, although the FDA approved a supplement to our investigational device exemption to establish a protocol for the treatment of Ebola patients in the U.S., this approval is very limited and 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 health***