

AETHLON MEDICAL INC
Form S-8
August 02, 2010

As filed with the Securities and Exchange Commission on August 2, 2010

Registration No. 333-_____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-8

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)

13-3632859
(I.R.S. Employer Identification No.)

8910 University Center Lane, Suite 660
San Diego, California
(Address of principal executive offices)

92122
(Zip Code)

AETHLON MEDICAL, INC.
2010 STOCK INCENTIVE PLAN

INDIVIDUAL RESTRICTED STOCK AWARD
(Full titles of the plans)

James A. Joyce
8910 University Center Lane, Suite 660
San Diego, California 92122
(Name and address of agent for service)

(858) 458-7800
(Telephone number, including area code, of agent for service)

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

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

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Title of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Common Stock, par value \$0.001	3,500,000 shares (3)	\$ 0.2585	\$ 904,750	\$ 64.51
Common Stock, par value \$0.001	4,000,000 shares (4)	\$ 0.2585	\$ 1,034,000	\$ 73.72
Total	7,500,000 shares	\$ 0.2585	\$ 1,938,750	\$ 138.23

(1) Pursuant to Rule 416 of 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.

(2) Estimated pursuant to Rule 457(h) 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 30, 2010, as reported on the OTC Electronic Bulletin Board.

(3) Represents shares issuable under the registrant's 2010 Stock Incentive Plan.

(4) Represents shares issued or to be issued pursuant to a grant by the registrant to its Chief Executive Officer, James A. Joyce.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Information required in Part I of Form S-8 to be contained in a prospectus meeting the requirements of Section 10(a) of the Securities Act is not required to be filed with the Commission and is omitted from this Registration Statement in accordance with the explanatory note to Part I of Form S-8 and Rule 428(b)(1) under the Securities Act.

REOFFER PROSPECTUS

Aethlon Medical, Inc.

7,500,000 Shares of Common Stock

This reoffer prospectus relates to up to 7,500,000 shares of our common stock that may be offered and resold from time to time by the selling stockholders to be identified herein for their own account. We anticipate that the selling stockholders will be current or former directors, officers, employees, consultants or advisers of our company. We will not receive any proceeds from the sale of shares made by selling stockholders. We anticipate that selling stockholders will sell at prevailing prices quoted on the OTC Bulletin Board or at privately negotiated prices. 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.

Our common stock currently is quoted on the OTC Bulletin Board under the symbol "AEMD."

An investment in our common stock involves a high degree of risk. You should purchase our securities only if you can afford a complete loss of your investment. See "Risk Factors" beginning at page 1.

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 reoffer prospectus is August 2, 2010.

AETHLON MEDICAL, INC.

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OUR COMPANY

Aethlon Medical, Inc. (the “Company,” “we” or “us”) is a developmental stage company focused on creating medical devices that address infectious disease and cancer. Our devices are designed to be novel platform solutions that fill significant therapeutic voids or aid in disease diagnosis and monitoring. We believe that our Hemopurifier(R) is the first medical device to selectively target the removal of infectious viruses and immunosuppressive proteins from the entire circulatory system. We have also discovered that our Hemopurifier(R) captures tumor-secreted exosomes, known to kill off the immune cells of those afflicted with cancer. Currently, a therapeutic strategy to directly inhibit or reverse the immunosuppressive destruction caused by exosomes does not exist in cancer care but we believe the Hemopurifier(R) can be developed for that use. By eliminating this mechanism deployed by all cancers to survive, we believe our Hemopurifier(R) could fill an unmet clinical need that offers the potential benefit of an immune-based therapy without adding drug toxicity or interaction risks to established and emerging treatment strategies. Through in vitro studies we have demonstrated that our Hemopurifier(R) captures exosomes underlying ovarian cancer and have since initiated collaborations with universities and research institutes to determine if the Hemopurifier(R) has broad-spectrum capability to address exosomes underlying other types of cancers. Upon the completion of in vitro studies, we also hope to initiate human pilot studies to demonstrate the clinical effect of removing exosomes from cancer patients.

Our website address is www.aethlonmedical.com. Our website and the information contained on our website are not incorporated into this prospectus or the Registration Statement of which it forms a part.

Our principal executive offices are located at 8910 University Center Lane, Suite 660, San Diego, California 92122.

RISK FACTORS

An investment in our common shares involves a high degree of risk and is subject to many uncertainties. These risks and uncertainties may adversely affect our business, operating results and financial condition. In such an event, the trading price for our common shares could decline substantially, and you could lose all or part of your investment. In order to attain an appreciation for these risks and uncertainties, you should read this prospectus in its entirety and consider all of the information and advisements contained in this prospectus, including the following risk factors and uncertainties.

RISKS RELATING TO OUR BUSINESS

WE HAVE INCURRED SIGNIFICANT LOSSES AND EXPECT LOSSES TO CONTINUE FOR THE FORESEEABLE FUTURE.

We have yet to establish any history of profitable operations. We have incurred annual operating losses of \$2,848,892 and \$2,923,254, for the fiscal years ended March 31, 2010 and 2009, respectively. At March 31, 2010 and 2009, we had an accumulated deficit of \$42,760,510 and \$38,311,414, respectively. We have incurred net losses of \$4,573,315 and \$6,084,158 for the fiscal years ended March 31, 2010 and 2009. We have not had significant revenues to date. We expect that our revenues, if any, will not be sufficient to sustain our operations for the foreseeable future. Our profitability will require the successful commercialization of our Hemopurifier(R) technology. No assurances can be given when or if this will occur or that we will ever generate revenues or 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 in our Annual Report on Form 10-K for our fiscal year ended March 31, 2010 that we had a significant deficit accumulated during the development stage, had a working capital 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 and 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, 2010 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 in our common shares.

WE WILL REQUIRE ADDITIONAL FINANCING TO SUSTAIN OUR OPERATIONS AND WITHOUT IT WE WILL NOT BE ABLE TO CONTINUE OPERATIONS.

Should the financing we require to sustain our working capital needs be unavailable to us on reasonable terms when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects. If we cannot raise operating capital, we may be forced to cease operations.

WE ARE RELIANT UPON LICENSES OF PATENTS AND TECHNOLOGIES FROM THIRD PARTIES FOR THE DEVELOPMENT OF CERTAIN APPLICATIONS AND USES OF OUR DEVICES; THE TERMINATION OF ANY SUCH LICENSE, OR A CHALLENGE TO THE PATENT AND INTELLECTUAL PROPERTY UNDERLYING SUCH LICENSE COULD HAVE A MATERIAL AND ADVERSE EFFECT UPON OUR ABILITY TO CONTINUE THE DEVELOPMENT OF OUR DEVICES IN CERTAIN FIELDS OF USE, WHICH WOULD ADVERSELY AFFECT OUR BUSINESS PROSPECTS AND THE VALUE OF YOUR INVESTMENT IN OUR SECURITIES.

We rely upon third party licenses for the development of specific uses for our Hemopurifier® devices, including in the area of cancer treatment. Specifically, we are researching, developing and testing cancer-related applications for our devices under a license with Boston University and with the London Health Science Center Research, Inc. and Mr. Thomas Ichim. Should either of these licenses be prematurely terminated for any reason, or should the patents and intellectual property owned by such entities that we have licensed be challenged or defeated by third parties, our research efforts could be materially and adversely affected. There can be no assurances that these licenses will continue in force for as long as we require for our research, development and testing of cancer treatments. There can be no assurances that should these licenses terminate, or should the underlying patents and intellectual property be challenged or defeated, that suitable replacements can be obtained or developed on terms acceptable to the Company, if at all.

WE WILL FACE INTENSE COMPETITION FROM COMPANIES THAT HAVE GREATER FINANCIAL, PERSONNEL AND RESEARCH AND DEVELOPMENT RESOURCES THAN OURS. THESE COMPETITIVE FORCES MAY IMPACT OUR PROJECTED GROWTH AND ABILITY TO GENERATE REVENUES AND PROFITS, WHICH WOULD HAVE A NEGATIVE IMPACT ON OUR BUSINESS AND THE VALUE OF YOUR INVESTMENT.

Our competitors are developing vaccine candidates, which could compete with the Hemopurifier(R) 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;

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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 effective Hemopurifier(R) 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.

The Congress' passage of the Project BioShield Bill, a comprehensive effort to develop and make available modern, effective drugs and vaccines to protect against attack by biological and chemical weapons or other dangerous pathogens, may encourage competitors to develop their own product candidates. We cannot predict the decisions that will be made in the future by the various government agencies as a result of such legislation.

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.

The market for medical devices is intensely competitive. Many of our potential competitors have longer operating histories, greater name recognition, more employees, and significantly greater financial, technical, marketing, public relations, and distribution resources than we have. This intense competitive environment may require us to make changes in our products, pricing, licensing, services or marketing to develop, maintain and extend our current technology. Price concessions or the emergence of other pricing or distribution strategies of competitors may diminish our revenues (if any), adversely impact our margins or lead to a reduction in our market share (if any), any of which may harm our business.

WE HAVE LIMITED MANUFACTURING EXPERIENCE.

To achieve the levels of production necessary to commercialize our Hemopurifier(R) products, we will need to secure 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 manufacturing products for testing purposes and no experience manufacturing products for large scale commercial purposes. We will likely outsource the manufacture of our Hemopurifier(R) products to third parties operating FDA-certified facilities. To date, we have manufactured devices on a small scale for testing purposes and have begun to utilize the services of a contract manufacturer. There can be no assurance 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. Any failure to address such problems could delay or prevent commercialization of our products and would have a material adverse effect on us.

OUR HEMOPURIFIER(R) TECHNOLOGY MAY BECOME OBSOLETE.

Our Hemopurifier(R) 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 Hemopurifier(R) products. The Homeland Security industry is growing rapidly with many competitors 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.

OUR USE OF HAZARDOUS MATERIALS, CHEMICALS AND VIRUSES REQUIRES US TO COMPLY WITH REGULATORY REQUIREMENTS AND EXPOSES US TO POTENTIAL LIABILITIES.

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(R) cartridges and the infected plasma samples used in preclinical testing of the Hemopurifier(R). All 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 these damages. In addition, we may be required to incur significant costs to comply with regulatory requirements in the future.

WE ARE DEPENDENT FOR OUR SUCCESS ON A FEW KEY EXECUTIVE OFFICERS. OUR INABILITY TO RETAIN THOSE OFFICERS WOULD IMPEDE OUR BUSINESS PLAN AND GROWTH STRATEGIES, WHICH WOULD HAVE A NEGATIVE IMPACT ON OUR BUSINESS AND THE VALUE OF YOUR INVESTMENT.

Our success depends to a critical extent on the continued services of our Chief Executive Officer, James A. Joyce, and our Chief Science Officer, Richard H. Tullis. Were we to lose one or both of these key executive officers, 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 loss of Dr. Tullis would harm the clinical development of our products due to his unique experience with the Hemopurifier(R) technology. The loss of Dr. Tullis and/or Mr. Joyce would be detrimental to our growth as they possess unique knowledge of our business model and infectious disease which would be difficult to replace within the biotechnology field. We can give you no assurance that we can find satisfactory replacements for these key executive officers at all, or on terms that are not unduly expensive or burdensome to our company. Although Mr. Joyce and Dr. Tullis have signed employment agreements providing for their continued service to our company, these agreements will not preclude them from leaving our company. 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.

OUR INABILITY TO ATTRACT AND RETAIN QUALIFIED PERSONNEL COULD IMPEDE OUR ABILITY TO GENERATE REVENUES AND PROFITS AND TO OTHERWISE IMPLEMENT OUR BUSINESS PLAN AND GROWTH STRATEGIES, WHICH WOULD HAVE A NEGATIVE IMPACT ON OUR BUSINESS AND COULD ADVERSELY AFFECT THE VALUE OF YOUR INVESTMENT.

We currently have an extremely small staff comprised of four full-time employees consisting of our Chief Executive Officer, our Chief Science Officer, a research scientist and an executive assistant. We also employ a Senior Vice President - Finance, a Director of Business Development and a Director of Corporate Communications on a contract basis. 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. 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 personal. Competition for these individuals, especially in San Diego 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.

WE PLAN TO GROW RAPIDLY, WHICH WILL PLACE STRAINS ON OUR MANAGEMENT TEAM AND OTHER COMPANY RESOURCES TO BOTH IMPLEMENT MORE SOPHISTICATED MANAGERIAL, OPERATIONAL AND FINANCIAL SYSTEMS, PROCEDURES AND CONTROLS AND TO TRAIN AND MANAGE THE PERSONNEL NECESSARY TO IMPLEMENT THOSE FUNCTIONS. OUR INABILITY TO MANAGE OUR GROWTH COULD IMPEDE OUR ABILITY TO GENERATE REVENUES AND PROFITS AND TO OTHERWISE IMPLEMENT OUR BUSINESS PLAN AND GROWTH STRATEGIES, WHICH WOULD HAVE A NEGATIVE IMPACT ON OUR BUSINESS AND THE VALUE OF YOUR INVESTMENT.

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.

WE MAY HAVE DIFFICULTY IN ATTRACTING AND RETAINING MANAGEMENT AND OUTSIDE INDEPENDENT MEMBERS TO OUR BOARD OF DIRECTORS AS A RESULT OF THEIR CONCERNS RELATING TO THEIR INCREASED PERSONAL EXPOSURE TO LAWSUITS AND SHAREHOLDER CLAIMS BY VIRTUE OF HOLDING THESE POSITIONS IN A PUBLICLY HELD COMPANY.

The directors and management of publicly traded corporations are increasingly concerned with the extent of their personal exposure to lawsuits and shareholder 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. We currently do carry limited directors and officers liability insurance. Directors and officers liability insurance is expensive and difficult to obtain. If we are unable to continue or 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 as well as increased exposure to such risks. As a company with a limited operating history and limited resources, we will have a more difficult time attracting and retaining management and outside independent directors than a more established company due to these enhanced duties, obligations and liabilities.

OUR INABILITY TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS, INCLUDING OUR U.S. AND INTERNATIONAL PATENTS COULD NEGATIVELY IMPACT OUR PROJECTED GROWTH AND ABILITY TO GENERATE REVENUES AND PROFITS, WHICH WOULD HAVE A NEGATIVE IMPACT ON OUR BUSINESS AND THE VALUE OF YOUR INVESTMENT.

We rely on a combination of patents, patents pending, copyrights, trademark and trade secret laws, proprietary rights agreements and non-disclosure agreements to protect our intellectual properties. We cannot give you any assurance that these measures will prove to be effective in protecting our intellectual properties.

In the case of patents, we cannot give you any assurance that our existing patents will not be invalidated, that any patents that we currently or prospectively apply for will be granted, or that any of these patents will ultimately provide significant commercial benefits. Further, competing companies may circumvent any patents that we may hold by developing products which closely emulate but do not infringe our patents. While we intend to seek patent protection for our products in selected foreign countries, those patents may not receive the same degree of protection as they would in the United States. We can give you no assurance that we will be able to successfully defend our patents and proprietary rights in any action we may file for patent infringement. Similarly, we cannot give you any assurance that we will not be required to defend against litigation involving the patents or proprietary rights of others, or that we will be able to obtain licenses for these rights. Legal and accounting costs relating to prosecuting or defending patent infringement litigation may be substantial. We believe that certain patent applications filed and/or other patents issued more recently will help to protect the proprietary nature of the Hemopurifier(R) treatment technology.

The Hemopurifier(R) and related treatment approaches are protected by three issued U.S. patents and seven issued international patents. We have also applied for five additional U.S. patents and twenty-one additional international patents.

We also rely on proprietary designs, technologies, processes and know-how not eligible for patent protection. We cannot give you any assurance that our competitors will not independently develop the same or superior designs, technologies, processes and know-how.

While we have and will continue to enter into proprietary rights agreements with our employees and third parties giving us proprietary rights to certain technology developed by those employees or parties while engaged by our company, we can give you no assurance that courts of competent jurisdiction will enforce those agreements.

IF WE FAIL TO COMPLY WITH EXTENSIVE REGULATIONS OF DOMESTIC AND FOREIGN REGULATORY AUTHORITIES, THE COMMERCIALIZATION OF OUR PRODUCT CANDIDATES COULD BE PREVENTED OR DELAYED.

Our pathogen filtration devices, or Hemopurifier(R) 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 to be commercially marketed and sold. The process of obtaining and complying with FDA and other governmental regulatory approvals and regulations is costly, time consuming, uncertain and subject to unanticipated delays. Such regulatory approval (if any) and product development requires 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.

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 CLINICAL TRIALS COULD JEOPARDIZE OUR ABILITY TO OBTAIN REGULATORY APPROVAL OR MARKET OUR HEMOPURIFIER(R) PRODUCT CANDIDATES ON A TIMELY BASIS.

Our business prospects will depend on our ability to complete clinical trials, obtain satisfactory results, obtain required regulatory approvals and successfully commercialize our Hemopurifier(R) 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/or

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 Hemopurifier(R) 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.

THE INDEPENDENT CLINICAL INVESTIGATORS THAT WE RELY UPON TO CONDUCT OUR CLINICAL TRIALS MAY NOT BE DILIGENT, CAREFUL OR TIMELY, AND MAY MAKE MISTAKES, IN THE CONDUCT OF OUR CLINICAL TRIALS.

We depend on independent clinical investigators to conduct our clinical trials. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our product development programs. If independent investigators fail to devote sufficient time and resources to our product development programs, or if their performance is substandard, it may delay FDA approval of our medical device candidates. These independent investigators may also have relationships with other commercial entities, some of which may compete with us. If these independent investigators assist our competitors at our expense, it could harm our competitive position.

WE MAY FAIL TO OBTAIN GOVERNMENT CONTRACTS TO DEVELOP OUR HEMOPURIFIER(R) TECHNOLOGY FOR BIODEFENSE APPLICATIONS.

The U.S. Government has undertaken commitments to help secure improved countermeasures against bioterrorism. To date, we have been unsuccessful in obtaining grant income. As a result, future attempts to obtain grant income from the Federal Government will be sought through direct communication to government health and military agencies, and may include unsolicited proposals to provide the Hemopurifier(R) as a treatment countermeasure.

At present, the Hemopurifier(R) has not been approved for use by any U.S. Government agency, nor have we received any contracts to purchase the Hemopurifier(R). Since inception, we have not generated revenues from the sale of any product based on our Hemopurifier(R) technology platform. 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 U.S. Government grants or contracts utilizing our Hemopurifier(R) platform technology.

U.S. GOVERNMENT AGENCIES HAVE SPECIAL CONTRACTING REQUIREMENTS, WHICH CREATE ADDITIONAL RISKS.

Our business plan to provide biodefense product candidates may involve contracts with the U.S. Government. U.S. Government 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