AETHLON MEDICAL INC
Form 10-K
June 29, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

(MARK ONE)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended March 31, 2012

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For transition period from _____ to _____

COMMISSION FILE NUMBER 000-21846

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

NEVADA	13-3632859
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8910 University Center Lane, Suite 660, San Diego, California	92122
(Address of principal executive office)	(Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE (858) 459-7800

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE EXCHANGE ACT:

TITLE OF EACH CLASS	NAME OF EACH EXCHANGE ON WHICH REGISTERED
NONE	NONE

SECURITIES REGISTERED UNDER SECTION 12(g) OF THE ACT:

COMMON STOCK--$.001 PAR VALUE
(TITLE OF CLASS)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [_] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [_] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [_]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [_]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

Large accelerated filer [_]	Accelerated filer [_]
Non accelerated filer [_]	Smaller reporting company [X]
(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company. Yes [_] No [X]

The aggregate market value of the common stock held by non-affiliates of the Registrant as of September 30, 2011 was approximately $8.2 million, computed by reference to the closing sale price of the common stock of $0.06 per share on the OTC Bulletin Board on September 30, 2011. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the Common Stock of the registrant outstanding as of June 28, 2012 was 139,993,381.

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PART I

ITEM 1. DESCRIPTION OF BUSINESS

GENERAL OVERVIEW

The Aethlon Medical 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 is a technology platform that delivers therapeutic mechanisms that previously did not exist in the marketplace.

The Aethlon ADAPT™ product pipeline includes the Aethlon Hemopurifier® to address infectious disease and cancer, and HER2osome™ to target HER2+ breast cancer. We are also developing a medical device and delivery instrument to reduce the incidence of sepsis in combat-injured soldiers and civilians through a contract award from the Defense Advanced Research Projects Agency (DARPA). The Aethlon ADAPT™ (Adaptive Dialysis-Like Affinity Platform Technology) system converges affinity drug agents and plasma membrane technology to create selective therapeutic filtration devices that target the removal of disease-promoting factors from the entire circulatory system.

The Aethlon Hemopurifier®

Our lead product candidate, the Aethlon Hemopurifier® represents the genesis of the Aethlon ADAPT™ system. In pre-clinical studies, the Hemopurifier® has demonstrated broad-spectrum capabilities against viral pathogens, immunosuppressive glycoproteins, and exosomes that promote the spread of cancer and other life-threatening disease conditions. In human studies, safety of the device has been demonstrated in approximately 100 treatment experiences conducted at research hospitals, including the Apollo, Fortis, and Medanta Medicity Institute in India. Hemopurifier® therapy has been demonstrated to be well tolerated and capable of reducing viral load in HIV and hepatitis C virus (HCV) infected individuals without the administration of antiviral drugs. We are now advancing our Hemopurifier® as an adjunct strategy to improve the benefit of infectious disease and cancer treatment regimens. We have recently disclosed very promising results from Hemopurifier® therapy being administered to HCV-infected individuals in combination with interferon-ribavirin drug therapy. This study is being conducted at the Medanta Medicity Institute.

Based on studies conducted by both government and non-government research organizations, the Hemopurifier® has also demonstrated the ability to capture a broad-spectrum of viral bioterror and pandemic threats. The Hemopurifier® is a single-use disposable cartridge designed for implementation within the established infrastructure of dialysis machines and other blood pump systems already located in hospitals and clinics worldwide. To initiate Hemopurifier® therapy, blood circulation is accessed via a catheter or other blood access device. In design, the Hemopurifier® contains lectin affinity agents that bind to high-mannose structures unique to glycoproteins that coat viruses and immunosuppressive exosomes that are secreted by cancerous tumors. The lectin affinity agent is immobilized to surround approximately 2,800 porous hollow fibers that run the interior length of our device. During Hemopurifier® therapy, viral and exosomal targets are separated from circulation through the fiber walls and away from blood cells and other essential blood components. Once separated, viruses, immunosuppressive glycoproteins, and exosomes are then selectively bound from circulation by the immobilized lectin prior to the occurrence of cell and organ infection or apoptosis of immune cells.

In 2010, we established "good manufacturing practice" (GMP) for the manufacture of the Hemopurifier® in an FDA-approved facility in San Diego, California. We believe the HCV treatment study that we are currently conducting in India will lead to potential commercialization in India, and we are advancing strategies to initiate clinical programs in the United States and the European Union. We believe our Hemopurifier® is positioned to address four significant market opportunities:

1.) Cancer:

The Hemopurifier® addresses a major unmet medical need in cancer, the ability to inhibit the spread of tumor-secreted exosomes or microvesicles. Exosomes have recently emerged to become a vital therapeutic target as they play an instrumental role in promoting tumor progression by inducing programmed cell death of anti-cancer immune cells. As a result of inhibiting the immune response, exosomes increase the proliferation and spread of many forms of cancer. The particles also seed the spread of tumor metastasis, promote angiogenesis (essential for tumor survival and growth), increase tumor aggressiveness, and contribute to anti-cancer drug resistance. Exosomes have also been discovered to have immunosuppressive roles in infectious disease and may accelerate the pathogenesis of other disease conditions as they have been reported to induce or amplify inflammatory and pathological conditions including, cardiovascular disease, hypertension, neurodegenerative disorders, diabetes, and rheumatic diseases.

In vitro studies have documented that the Hemopurifier® captures ovarian, breast, lymphoma, melanoma, and colorectal cancer exosomes. Additionally, the capture of exosomes underlying HIV infection and tuberculosis has also been validated.

2.) Hepatitis-C Virus (HCV):

We are currently conducting an HCV clinical treatment program at the Medanta Medicity (Medicity), which is one of India's largest multi-super specialty institutes. The goal of our study is to demonstrate the utility of our Hemopurifier(R) as an adjunct therapy to accelerate viral load reduction when administered at the outset of standard of care drug therapy. We recently reported that the presence of HCV was undetectable in all infected patients that have been treated with the Aethlon Hemopurifier® in combination with peginterferon+ribavirin (PR) drug therapy and monitored for at least ninety days. In the Medicity study, HCV-infected individuals were enrolled to receive up to three, six-hour Hemopurifier® treatments during the first three days of PR drug therapy. To date, Hemopurifier® therapy has been well tolerated in the Medicity study and without device-related adverse events in nine treated patients. Of these nine patients, six patients were infected with HCV genotype-1; two patients were infected with HCV genotype-3; and one patient was infected with HCV genotype-5. Of the nine reported patients, seven had been monitored for more than ninety days. All seven currently maintain undetectable viral load, including three patients who have been monitored for more than 48-weeks. Two patients initiated Hemopurifier® therapy on April 18th and April 30th and have not yet been monitored for extended viral load suppression.

In addition to demonstrating safety and early efficacy against multiple HCV genotypes, a clinical objective of the Medicity study is to evaluate whether the Hemopurifier® can accelerate HCV eradication to levels associated with treated patients who achieve the highest rate of viral cure, including individuals that previously failed or relapsed PR drug regimens. In the study, we observed that viral load depletion during the Hemopurifier® + PR drug therapy phase was greatest in hard-to-treat genotype-1 patients with high viral load. In one treated patient, baseline HCV RNA dropped from 5,800,000 IU/ml to 1,840 IU/ml when measured after the third day of Hemopurifier® + PR therapy, representing a 3.49 log or 99.96% reduction of viral load. In another patient, baseline HCV RNA dropped from 8,760,000 IU/ml to 4,665 IU/ml when measured on day-3, representing a 3.27 log or 99.96% reduction. By contrast, a moderate viral load Hemopurifier® patient with baseline HCV RNA of 1,340,000 IU/ml dropped to 54,900 IU/ml when measured on day-3, representing a 1.38 log or 95.9% reduction.

As the result of July 2011 discussions with reviewers at the Center for Devices and Radiological Health (the FDA branch responsible for approving medical devices in the US), we expanded our Medicity protocol to establish a data point that would quantify the amount of HCV captured within the Hemopurifier® during a single treatment. In one analyzed cartridge, we reported that researchers recovered and measured that approximately 300 billion (300,000,000,000) copies of HCV had been captured within the Hemopurifier® during a single six-hour treatment at the Medicity. Beyond the impact of inhibiting progeny virus replication, we feel the viral capture data point defines the contribution Hemopurifier® therapy can provide to current and future antiviral drug treatment regimens. We believe such a data point is unprecedented as the previous ability to measure the benefit of HCV therapies has primarily been limited to measuring changes in the amount of virus that can be detected in circulation. We are now preparing to resubmit an investigational device exemption (IDE) to the FDA that will request permission to initiate human clinical studies in the United States.

3) Human Immunodeficiency Virus (HIV):

Antiviral drug regimens provide HIV infected patients with an effective tool to inhibit disease progression. However, many patients inevitably become resistant to their drug therapies and are left with limited treatment options. We believe our Hemopurifier(R) provides a device-based antiviral and immunotherapeutic mechanism to inhibit the spread of all HIV strains, thus providing fully drug resistant patients with a treatment strategy to inhibit disease progression. In a proof of principal treatment study, our Hemopurifier® reduced viral load by 93% in an HIV-AIDS infected individual without the administration of antiviral drug therapy. The study protocol provided for 12 Hemopurifier® treatments, each four hours in duration, that were administered over the course of one month. We have since discovered that the Hemopurifier® is able to capture exosomes that transport NEF protein, which is known

to suppress the immune response in HIV-infected individuals.

4.) Bioterror and Pandemic Threats:

Based on established human safety data and pre-clinical studies conducted by government and non-government research institutes, we believe our Hemopurifier® is an advanced broad-spectrum treatment countermeasure against bioterror and pandemic threats, and the sole therapeutic strategy against viral threats that are not treatable with drug or vaccine therapies. Pre-clinical in vitro studies have demonstrated the ability of our Hemopurifier® to capture Ebola Virus, Dengue Virus, Lassa Virus, West Nile Virus, Monkeypox Virus, H5N1 Avian Influenza Virus, the 2009 H1N1 Swine Flu Virus, and the reconstructed H1N1 Spanish Flu of 1918 virus.

EXOSOME SCIENCES, INC.

We established Exosome Sciences (ESI) in October of 2009 as a wholly owned subsidiary to advance diagnostic tools created by our researchers to identify the presence of exosomes in blood and other fluids. The research diagnostic tool resulting from the efforts of our researchers is ELLSA™, an Enzyme Linked Lectin Specific Assay that has been validated to identify the presence of exosomes underlying the human immunodeficiency virus (HIV), tuberculosis (TB), and various forms of cancer, including ovarian, melanoma, breast, lymphoma, and colorectal. While we have received product orders, our focus is directed toward therapeutic opportunities. As such, we plan to license or sell ELLSA™ and other related research diagnostic tools.

TRANSITION TO REVENUE STAGE ORGANIZATION

In May of 2011, we introduced and began marketing the Aethlon ADAPT™ system. On September 30th, 2011, we entered into a $6.8 million multi-year contract with the Defense Advanced Research Projects Agency (DARPA) resulting from our response to a program entitled “Dialysis-Like Therapeutics.” Under this contract, our tasks include the development of a dialysis-like device to prevent sepsis, a fatal bloodstream infection that is often the cause of death in combat-injured soldiers. As a result of achieving five contract milestones between October 1, 2011 and March 31, 2012, we reported $1,358,189 in contract revenue at our March 31 fiscal year end.

Only the base year (meaning the first year of the contract) is effective for the parties. Years two through five are subject to DARPA exercising its option to enter into contracts for those future years. The year one contract contains eight performance and payment milestones of which five have been achieved during the fiscal year ended March 31, 2012 as follows:

Milestone 2.2.1.1 – Write requirements definition for the extracorporeal blood purification system and acquire necessary equipment with a milestone payment of $358,284. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We worked on this concept for a number of months beginning with a presentation to DARPA in late 2010. We subsequently filed for IP protection on certain of the key concepts in March 2011 and our management visited selected potential vendors to work out many of the details in the summer of 2011 before we were awarded the contract on September 30, 2011. We ordered the breadboard device from one of our vendors before the milestone payment was made. We designed the breadboard prototype and then presented the design to DARPA in order to achieve the milestone. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. DARPA made the milestone payment in full.

Milestone 2.2.1.2 -- Fabricate breadboard prototypes for anticoagulation-free anti-sepsis extracorporeal system (ASEPSYS) device. Fabricate prototype blood tubing sets. Acquire anti-thrombogenic surface modified hollow fiber plasma separators with a milestone payment of $183,367. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. The consideration for this milestone covers the cost of having the breadboard prototype developed to our specifications, hiring an engineer to supervise the project, acquiring specially coated cartridges and associated overhead. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. DARPA made the milestone payment in full.

Milestone 2.2.2.1 – Begin to develop the ADAPT device to efficiently capture sepsis precursors and acquire important equipment and supplies with a milestone payment of $416,424. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. It was critically important to obtain certain pieces of lab equipment as early as possible after winning the contract in order to measure the binding ability of sepsis precursors. We demonstrated that we were able to capture one of the identified possible sepsis precursors as part of our submission for approval. The consideration was also designed to cover the salaries of new and existing scientists, lab space, materials as well as fringe and corporate overhead. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. DARPA made the milestone payment in full.

Milestone 2.2.2.2 - Perform initial screening of the different proposed capture agents by measuring binding affinity and kinetics using surface plasmon resonance (SPR) or biolayer surface interferometry (BLI) with a milestone payment amount of $216,747. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. We demonstrated that we were able to capture several of the identified possible sepsis precursors as part of our submission for approval. The consideration was also

designed to cover the salaries of new and existing scientists, lab space, materials as well as fringe and corporate overhead. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. DARPA made the milestone payment in full.

Milestone 2.2.1.3 - Assemble and test breadboard ASEPSYS devices. Evaluate the use of different techniques and approaches to eliminating anticoagulants. The milestone payment amount was $183,367. Management considers this milestone to be substantive as it was not dependent on the passage of time nor was it based solely on another party's efforts. The consideration for this milestone covers the cost of assembling and testing the breadboard prototype that we had developed to our specifications, hiring an engineer to supervise the project, testing specially coated cartridges and associated overhead. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. The report was accepted by the contracting officer's representative and the invoice was submitted thereafter. DARPA made the milestone payment in full.

While the above milestones were evaluated and approved by DARPA, there can be no assurance that even if DARPA elects to continue the contract in future years, that we will be able to achieve the required milestones in those future years on time, if at all, or that DARPA's evaluation of the milestone deliveries will result in full payment of the milestones in those future years, if at all.

CORPORATE HISTORY

On March 10, 1999, Aethlon, Inc., a California corporation ("Aethlon"), Hemex, Inc., a Delaware corporation ("Hemex"), the accounting predecessor to the Company, and Bishop, Inc. ("Bishop"), a publicly traded "shell" company, completed an Agreement and Plan of Reorganization (the "Plan") structured to result in Bishop's acquisition of all of the outstanding common shares of Aethlon and Hemex (the "Reorganization"). The Reorganization was intended to qualify as a tax-free transaction under Section 368(a)(1)(B) of the 1986 Internal Revenue Code, as amended. Under the Plan's terms Bishop issued 733,500 and 1,350,000 shares of its common stock to the common stock shareholders of Aethlon and Hemex, respectively, such that Bishop then owned 100% of each company. Upon completion of the transaction, Bishop was renamed Aethlon Medical, Inc.

In October 2009, we established a new wholly owned subsidiary, Exosome Sciences, Inc., a Nevada corporation, as a corporate vehicle for our exosome-related diagnostic activities.

RESEARCH AND DEVELOPMENT

The cost of research and development, all of which has been charged to operations, amounted to approximately $1,089,000 and $440,000 over in the fiscal years ended March 31, 2012 and 2011, respectively.

INTELLECTUAL PROPERTY

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

U.S. PATENTS

We have been exclusively assigned all rights to an invention and related patent rights for a method to treat cancer under an assignment agreement with the London Health Science Center Research, Inc. The invention provides for the "Depression of anticancer immunity through extracorporeal removal of microvesicular particles" (including exosomes) for which a patent was recently allowed by the U.S. Patent and Trademark Office (USPTO) and patent applications have been filed abroad. The agreement provides that we are responsible for paying certain patent application and filing costs as well as a 2% royalty on any future net sales. Under the license agreement, we own the patents outright.

We have also exercised an option to exclusively license a pending patent entitled, "Method to Inhibit Proliferation and Growth of Metastases" from The Trustees of Boston University. The license provides a rapid development strategy for new cancer therapies by uniting drug agents that inhibit the spread of cancer-related metastases with filtration techniques already proven in the Aethlon Hemopurifier(R). The resulting devices would inhibit tumor growth by reducing the presence of circulating growth factors without interfering with surgical wound healing or the recovery of tissue injured by radiation therapy. While the market for anti-growth factor drug agents exceeds $5 billion, there remains a significant unmet clinical need, as these drug agents may not be indicated for use in conjunction with surgical procedures or radiation treatment as they inhibit wound healing and tissue recovery. Depending on the applications, if we commercialize a product based upon this license, we will pay royalties up to a maximum of 3.5 percent of net sales.

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

PATENTS ISSUED IN THE UNITED STATES

PATENT #	PATENT NAME	ISSUANCE DATE	OWNED OR LICENSED
This patent was allowed in June 2012	Extracorporeal removal of microvesicular particles (exosomes)	This patent has been allowed and will issue later in 2012	Owned

7,226,429	Method for removal of viruses from blood by lectin affinity hemodialysis	01/20/04	Owned
6,528,057	Method for removal of HIV and other viruses from blood	03/04/03	Licensed

PATENT APPLICATIONS IN THE UNITED STATES

APPLICATION #	APPLICATION NAME	FILING DATE	OWNED OR LICENSED
11/756543	Method for removal of viruses from blood by lectin affinity hemodialysis	05/31/07	Owned
PCT/US2006/027746	Removal of growth factors during surgery	07/20/08	Licensed
12/600236	Device and method for purifying virally infected blood	5/12/11	Owned
13/351166	Affinity capture of circulating cancer biomarkers	1/16/12	Owned
13/049804	Methods and systems for reducing viral load of hepatitis C virus in hemodialysis patients	3/16/11	Owned
12/996000	Enhanced antiviral therapy methods and devices	5/26/11	Owned
61/537530	Methods and compositions for the treatment of breast cancer	9/21/11	Owned

INTERNATIONAL PATENTS:

INTERNATIONAL PATENTS ISSUED

PATENT #	PATENT NAME	ISSUANCE DATE	OWNED OR LICENSED
2,353,399	Method for removal of viruses from blood by lectin affinity hemodialysis	01/20/04	Owned
770,344	Method for removal of HIV and other viruses from blood	06/03/04	Licensed
69929986.1-08	Method for removal of HIV and other viruses from blood	02/22/06	Licensed
1,109,564	Method for removal of HIV and other viruses from blood	02/22/06	Licensed
1,109,564	Method for removal of HIV and other viruses from blood	02/22/06	Licensed
1,109,564	Method for removal of HIV and other viruses from blood	02/22/06	Licensed
1,109,564	Method for removal of HIV and other viruses from blood	02/22/06	Licensed
2342203	Method for removal of HIV and other viruses from blood		