

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 19, 2014

AETHLON MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction
of incorporation)

000-21846
(Commission File Number)

13-3632859
(IRS Employer
Identification Number)

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

92122
(Zip Code)

Registrant's telephone number, including area code: (858) 459-7800

Not applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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FORWARD-LOOKING STATEMENTS

This Form 8-K and other reports filed by Registrant from time to time with the Securities and Exchange Commission (collectively, the "Filings") contain or may contain forward-looking statements and information that are based upon beliefs of, and information currently available to, Registrant's management as well as estimates and assumptions made by Registrant's management. When used in the Filings the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan" or the negative of these terms and similar expressions as they relate to Registrant or Registrant's management identify forward-looking statements. Such statements reflect the current view of Registrant with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to Registrant's industry, Registrant's operations and results of operations and any businesses that may be acquired by Registrant. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Although Registrant believes that the expectations reflected in the forward-looking statements are reasonable, Registrant cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, Registrant does not intend to update any of the forward-looking statements to conform these statements to actual results.

ITEM 1.01 Entry into a Material Definitive Agreement

On May 19, 2014, Aethlon Medical, Inc. ("Registrant" or the "Company") entered into a definitive agreement (the "Agreement") with Total Renal Research, Inc., dba DaVita Clinical Research ("DCR"). Pursuant to the Agreement, DCR will conduct site management administrative services for a study site in connection with a planned clinical safety study of the Aethlon Hemopurifier® in certain patients with Hepatitis-C virus infection. The clinical trial is to be conducted at DaVita MedCenter Dialysis in Houston, Texas, and up to ten patients meeting applicable eligibility requirements will be permitted to enroll in the study. The Principal Investigator for the study will be Dr. Stephen Z. Fadem, who is co-medical director of DaVita MedCenter Dialysis.

The Agreement requires Registrant to pay certain expenses related to the study projected to be less than \$200,000, including certain start-up and close-out costs, patient compensation and a project management fee to be paid to DCR calculated as five percent of total invoiced patient and site costs. Registrant also will be responsible for the fees for any third-party consulting physicians, including Dr. Fadem, utilized in connection with the study and other pass-through expenses if incurred. The Agreement is effective as of May 16, 2014 and will continue in effect until completion of the services being provided by DCR pursuant to the Agreement.

ITEM 8.01 Other Events

On May 20, 2014, Registrant disseminated the Press Release attached to this Current Report as Exhibit 99.1, which announced, among other things, Registrant's entry into the Agreement with DCR discussed above in Item 1.01.

On May 21, 2014, Registrant disseminated the Press Release attached to this Current Report as Exhibit 99.2, which announced, among other things, high rapid virologic response and sustained virologic response rates in Hepatitis-C virus infected individuals who were administered therapy with the Aethlon Hemopurifier®.

The foregoing descriptions of the Press Releases do not purport to be complete and are qualified in their entirety by the Press Releases attached as Exhibits 99.1 and 99.2 hereto. Readers should review the Press Releases for a complete understanding of their content and the matters announced and described in the Press Releases.

ITEM 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release dated May 20, 2014
99.2	Press Release dated May 21, 2014

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AETHLON MEDICAL, INC.

By: /s/ James B. Frakes

James B. Frakes

Chief Financial Officer

Dated: May 23, 2014



Aethlon Medical® Announces Definitive Agreement with DaVita Clinical Research and Site Location and Principal Investigator of Hepatitis C Virus (HCV) Clinical Study

SAN DIEGO, May 20, 2014 /PRNewswire/ -- Aethlon Medical, Inc. (OTCQX:AEMD), the pioneer in developing selective therapeutic filtration devices to address infectious disease, cancer and other life-threatening conditions, announced today that it has entered into a definitive agreement with DaVita Clinical Research (DCR) to provide clinical management services to support the forthcoming feasibility study of the Aethlon Hemopurifier®. The Hemopurifier is a first-in-class therapeutic device that targets the rapid elimination of circulating viruses and tumor-secreted exosomes that suppress the immune system of cancer patients. Aethlon further announced that the Principal Investigator for this study will be Dr. Stephen Z. Fadem.

The clinical trial site location will be DaVita MedCenter Dialysis in Houston. Dr. Fadem is co-medical director of DaVita MedCenter Dialysis and this center is one of the three largest dialysis centers in the country with 72 treatment stations.

Aethlon previously disclosed that the United States Food and Drug Administration (FDA) had approved an Investigational Device Exemption (IDE) that allows the Company to initiate human feasibility studies of the Aethlon Hemopurifier in the United States. Under the feasibility study protocol, Aethlon is to treat ten ESRD patients infected with Hepatitis C virus (HCV) to demonstrate the safety of Hemopurifier therapy. Successful completion of the feasibility study will set the stage for Aethlon to conduct pivotal studies required for market clearance to treat HCV and potentially other disease indications.

"The combination of DCR, DaVita MedCenter Dialysis, and Dr. Fadem provides Aethlon with the ideal team of professionals and infrastructure with which to conduct our infectious disease clinical study. Additionally, their proximity to M.D. Anderson Cancer Center and other specialty facilities located within the Texas Medical Center provide for a unique location to conduct future clinical investigations of Hemopurifier® therapy in a variety of life-threatening health conditions," stated Aethlon Medical CEO Jim Joyce.

DCR is a specialty contract research organization (CRO) with experience in conducting more than 300 early phase clinical trials. As a subsidiary of DaVita Healthcare Partners Inc, DCR has access to one third of the total U.S. ESRD patient population and maintains a network that exceeds 150 investigative physicians' practices at more than 250 clinical sites.

Dr. Fadem is a practicing Houston nephrologist and is currently the Chief Medical Officer at Kidney Associates, PLLC and the Medical Director for the Houston Kidney Center Integrated Service Network at DaVita Kidney Care, a division of DaVita HealthCare Partners Inc. He began practice in 1978 after completing a renal fellowship at The University of Texas Health Science Center in San Antonio. He is a graduate of the University of Oklahoma College of Medicine, and did his internal medicine residency at The University of Texas and MD Anderson Hospital in Houston. He is a Clinical Professor of Medicine at Baylor College of Medicine.

He is a Fellow of the American College of Physicians, Fellow of the American Society of Nephrology, diplomat of the American Board of Quality Assurance and Utilization Review Physicians (CHCQM - Certified Health Care Quality Management), and a member of the International Society of Nephrology, Renal Physicians Association, the American Association of Kidney Patients and The National Kidney Foundation. He is active in quality management, credentialing and peer review for his dialysis centers.

On a national level, he is co-chairman of the Medical Advisory Board of the American Association of Kidney Patients, and a past vice-president of the Board of Directors. He has also served on the Board of Directors of the Renal Physicians Association, and actively serves on two national RPA committees, the Government Affairs Committee and the Health Finance Committee. Dr. Fadem has been active in the Forum of ESRD (end stage renal disease) Networks and was a member of the CMS Clinical Performance Measures Committee. He lectures frequently on dialysis management, preventive nephrology, vascular calcification, anemia, patient education, CKD education, computer technology and computer security. Dr. Fadem is a co-editor of AAKP Renalife and is a reviewer for several peer reviewed journals.

Dr. Fadem has been nationally recognized by receiving the American Association of Kidney Patient's Nova Award, the National Kidney Foundation's Distinguished Service Award. He has also received the National Kidney Foundation's Presidents Award and the Myron L. Jenkins Award. He has been awarded the Peter Lundin Award for his contributions to patient education and The Visionary Award for his contributions to CKD education. He is the 2013 winner of the DaVita Core Value Award for Continuous Improvement. He has been named as one of America's Top Doctors by Castle Connolly and US News and World Report, and is consistently ranked as a Top Doctor in Houston by Texas Magazine.

About DaVita Kidney Care

DaVita Kidney Care is a division of DaVita HealthCare Partners Inc., a Fortune 500® company that, through its operating divisions, provides a variety of health care services to patient populations throughout the United States and abroad. A leading provider of dialysis services in the United States, DaVita Kidney Care treats patients with chronic kidney failure and end stage renal disease. DaVita Kidney Care strives to improve patients' quality of life by innovating clinical care, and by offering integrated treatment plans, personalized care teams and convenient health-management services. As of March 31, 2014, DaVita Kidney Care operated or provided administrative services at 2,098 outpatient dialysis centers located in the United States serving approximately 165,000 patients. The company also operated 75 outpatient dialysis centers located in 10 countries outside the United States. DaVita Kidney Care supports numerous programs dedicated to creating positive, sustainable change in communities around the world. The company's leadership development initiatives and social responsibility efforts have been recognized by Fortune, Modern Healthcare, Newsweek and WorldBlu. For more information, please visit DaVita.com.

About Aethlon Medical, Inc.

Aethlon Medical creates innovative medical devices to address life-threatening diseases. The Aethlon ADAPT™ (Adaptive Dialysis-like Affinity Platform Technology) establishes the basis for a new class of therapeutics that target the rapid elimination of disease enabling particles from the circulatory system of treated patients. The lead Aethlon ADAPT™ product is the Hemopurifier®, a device that addresses a broad-spectrum of viral pathogens as well as tumor-secreted exosomes that suppress the immune system of cancer patients. Aethlon is also operating under two government contracts with the Defense Advanced Research Projects Agency (DARPA) related the development of a medical device to reduce the incidence of sepsis. Exosome Sciences, Inc. is a majority owned Aethlon subsidiary that is advancing exosome-based strategies to diagnose and monitor cancer and infectious disease progression. Additional information can be found at www.AethlonMedical.com.

Certain statements herein may be forward-looking and involve risks and uncertainties. Such forward-looking statements involve assumptions, known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aethlon Medical, Inc. to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such potential risks and uncertainties include, without limitation, that the ESI will not be able to commercialize its future products, that the FDA will not approve the initiation of the Company's existing or future clinical programs or provide market clearance of the company's products, future human studies whether revenue or non-revenue generating of the Aethlon ADAPT™ system or the Aethlon Hemopurifier® as an adjunct therapy to improve patient responsiveness to established cancer or hepatitis C therapies or as a standalone cancer or hepatitis C therapy, the Company's ability to raise capital when needed, the Company's ability to complete the development of its planned products, the Company's ability to manufacture its products either internally or through outside companies and provide its services, the impact of government regulations, patent protection on the Company's proprietary technology, the ability of the Company to meet the milestones contemplated in the DARPA contract, product liability exposure, uncertainty of market acceptance, competition, technological change, and other risk factors. In such instances, actual results could differ materially as a result of a variety of factors, including the risks associated with the effect of changing economic conditions and other risk factors detailed in the Company's Securities and Exchange Commission filings. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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SOURCE Aethlon Medical, Inc.



Aethlon Medical® Reports Rapid and Sustained Virologic Response Rates in Hepatitis C (HCV) Treated Patients

SAN DIEGO, May 21, 2014 /PRNewswire/ -- Aethlon Medical, Inc. (OTCQX:AEMD), the pioneer in developing selective therapeutic filtration devices to address infectious disease, cancer and other life-threatening conditions, today announced high rapid virologic response (RVR) and sustained virologic response (SVR) rates in Hepatitis-C virus (HCV) infected individuals who were administered Hemopurifier® therapy.

The Aethlon Hemopurifier® is a first-in-class medical device that selectively targets the rapid clearance of viral pathogens and tumor-secreted exosomes from the entire circulatory system to improve the benefit of drug therapies administered to infectious disease and cancer patients. In HCV care, the device is positioned to address drug resistance associated with emerging all-antiviral therapies and also targets to accelerate HCV RNA depletion at the outset of peginterferon+ribavirin (PR) therapy.

Aethlon recently disclosed that the United States Food and Drug Administration (FDA) approved an Investigational Device Exemption (IDE) that now allows the Company to initiate HCV human feasibility studies of Hemopurifier® therapy in the United States. Aethlon announced yesterday that its first U.S. clinical study will be conducted at the DaVita MedCenter Dialysis in Houston, Texas. It is estimated that approximately 170 million people worldwide are infected with HCV, which leads to chronic liver disease or cirrhosis, and is a leading cause of liver transplantation.

In the reported study, HCV-infected individuals were enrolled to receive three six-hour Hemopurifier® treatments during the first three days of a 48-week peginterferon+ribavirin (PR) treatment regimen. The study was conducted under the leadership of Dr. Vijay Kher at the Medanta Medicity, a multi-specialty medical institute established to be a premier center for medical tourism in India. Aethlon reported that Hemopurifier® therapy was well tolerated and without device-related adverse events in twelve treated patients. Of these twelve patients, nine completed the Hemopurifier-PR treatment protocol, including seven genotype-1 patients and two genotype-3 patients. Seven of the nine patients (n=7/9) achieved a sustained virologic response (SVR), which is the clinical definition of treatment cure and is defined as undetectable HCV RNA 24-weeks after the completion of the 48-week PR drug regimen. Both genotype-3 patients achieved a SVR (n=2/2), while five of the seven genotype-1 patients achieved a SVR (n=5/7).

Of the nine patients that completed the protocol, five (n=5/9) also achieved a rapid virologic response (RVR), defined as undetectable HCV RNA at day 30 of therapy. RVR represents the clinical endpoint that best predicts SVR cure rates. As a point of reference, the landmark IDEAL Study of 3,070 HCV genotype-1 patients documented that only 10.35% (n=318/3070) of PR treated patients will achieve a RVR. However, patients that achieved a RVR had SVR rates of 86.2% (n=274/318) versus SVR rates of 32.5% (n=897/2752) in non-RVR patients.

Data from three patients were not included in the reported dataset. Among the three patients was a genotype-5 patient who discontinued PR therapy at day 180, yet remained undetectable at 1.5 years after initiation of therapy. The second was a genotype-3 patient who was unable to tolerate PR therapy and, as a result, discontinued PR therapy at day-90, yet was still undetectable one year after initiating therapy. The third patient, who had the genotype-1 virus, was reported undetectable at the completion of the 48-week PR treatment regimen, but SVR results are not due on that patient until September of this year.

"It appears the intermittent application of Hemopurifier® therapy during just the first three days of a 48-week interferon regimen can significantly influence treatment outcomes," stated Aethlon Chairman and CEO, Jim Joyce. "We now look forward to the clinical advancement of Hemopurifier® protocols against infectious viral pathogens and cancer indications in the United States."

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