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): September 8, 2017

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

Nevada	001-37487	13-3632859
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

9635 Granite Ridge Drive, Suite 100 San Diego, California (Address of principal executive offices)	92123 (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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 8.01 Other Events

On August 11, 2017, we submitted an Expedited Access Pathway (EAP) program submission to The Center for Devices and Radiological Health (CDRH) of the United States Food and Drug Administration (FDA). A criterion for EAP program eligibility includes medical devices that represent breakthrough technologies with the potential to address life threatening disease conditions for which no approved or cleared treatment alternatives exist. In our EAP submission, we proposed the “indication for use” for our lead therapeutic candidate to be, "The Hemopurifier is a single-use device indicated for the treatment of life-threatening highly glycosylated viruses that are not addressed with an approved treatment."

On September 8, 2017, we received a letter from the FDA informing us that our combination product and proposed “indication for use” meets the EAP criteria and that our Hemopurifier has been granted EAP designation. Under the EAP program, we will work collaboratively with FDA to design a data development plan and regulatory pathway intended to achieve FDA-approval of the device, and through this process, we believe the regulatory advancement of our device with the FDA will be accelerated.

The FDA established the EAP program for medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions that are subject to premarket approval applications (PMA), premarket notification (510[k]) or requests for De Novo designation. Under EAP, the FDA works with device sponsors to try to reduce the time and cost from development to marketing decision without changing the FDA's PMA approval standard of reasonable assurance of safety and effectiveness.

The Aethlon Hemopurifier is a medical device designed for the single-use removal of viral pathogens from circulatory system of infected individuals. Based on clinical and preclinical study outcomes, the Hemopurifier is a candidate to treat a broad-spectrum of life threatening viruses for which no approved or cleared treatment alternatives exist.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Letter from the FDA to the Registrant, dated September 8, 2017

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: September 12, 2017

Exhibit 99.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 8, 2017

Aethlon Medical, Inc.
% Ronald S. Warren
Senior Director Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110

Re: Q171414
Trade/Device Name: Aethlon Hemopurifier
Received: August 14, 2017

Dear Ronald S. Warren:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received the above submission dated August 11, 2017, including your request for Expedited Access Pathway (EAP) designation. The proposed indications for use includes "The Hemopurifier is a single-use device indicated for the treatment of life-threatening highly glycosylated viruses that are not addressed with an approved treatment." We are pleased to inform you that your combination product and proposed indication for use meets the criteria and has been granted EAP designation. Please refer to the guidance entitled, "Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions" available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu ments/UCM393978.pdf and section 3051 of the 21st Century Cures Act for additional information. As noted in the EAP Guidance, "Combination products may raise unique scientific and regulatory challenges."

We recommend you use the Pre-Submission review process, as described in the Pre-Submission guidance, to request any additional feedback from FDA on any issues related to this submission. When submitting any new requests, please reference Q171414. Any new submission should include two copies (one hardcopy and a valid ecopy), the FDA reference number for this submission, and should be submitted to the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
IDE Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You are reminded that it is imperative that the information used to support a premarket submission meets the requirements of valid scientific evidence (21 CFR 860.7). You are further advised that the granting of EAP designation and priority review does not guarantee that the application will ultimately be approved.

If you have any questions, please contact Elizabeth Gonzalez, Ph.D. at (301) 796-6826 or Elizabeth.Gonzalez@fda.hhs.gov.

Sincerely,

/s/ Joyce M. Whang - S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health