AETHLON MEDICAL INC
Form 8-K
August 14, 2017

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): August 14, 2017

AETHLON MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Nevada	000-21846	13-3632859
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

8910 University Center Lane, Suite 660	92122
San Diego, California	(Zip Code)
(Address of principal executive offices)	

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 checkmark 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.

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 14, 2017, Aethlon Medical, Inc. (the “Company”) received a formal receipt from the U.S. Food and Drug Administration (FDA) for its Expedited Access Pathway (EAP) program submission that was submitted to the FDA last week. The submission formally requests that the Aethlon Hemopurifier be included in the FDA EAP program.

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.

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. 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.

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
Dated: August 14, 2017 Chief Financial Officer