

AETHLON MEDICAL INC
Form 8-K
December 31, 2014

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): December 23, 2014

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)

9635 Granite Ridge Drive, Suite 100

92123

San Diego, California

(Zip Code)

(Address of principal executive offices)

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

Not applicable

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(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))

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 December 23, 2014, Aethlon Medical, Inc. ("Registrant" or the "Company") received notification from the U.S. Food and Drug Administration (the "FDA") that the FDA had approved the Company's Investigational Device Exemption ("IDE") supplement proposing use of the Aethlon Hemopurifier® to treat subjects infected with the Ebola virus. The Company previously reported, in a Current Report on Form 8-K filed on June 25, 2013, the FDA's approval of an IDE permitting the Company to initiate human feasibility studies of the Hemopurifier in the U.S. for the purpose of treating persons infected with the Hepatitis-C virus. The Company filed the IDE supplement request in order to establish a uniform protocol to clinically investigate the use of the Hemopurifier as a treatment for Ebola-infected individuals in the U.S.

The FDA has limited the investigational Ebola study to 10 U.S. clinical sites, and up to 20 U.S. subjects may be enrolled to receive the treatment protocol. The use of the Hemopurifier in the proposed Ebola treatment protocol will be a deviation from the Hepatitis-C virus protocol being used in the Company's clinical trials. The Company must clearly distinguish data collected in the supplement Ebola protocol study from data derived from the Company's Hepatitis-C virus trials. The Company may not combine data from the two studies.

The Company must also comply with specified patient protection procedures established by the applicable institution including its institutional review board prior to treating a patient under the supplement protocol and must report any unanticipated adverse events resulting from the supplement protocol to the FDA within 10 working days of the use of the device.

There can be no assurance that any Ebola-infected patients will be treated. Even if the Ebola treatment protocol is established for the Hemopurifier, and patients are treated, the results of such treatments may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval of the Hemopurifier for any uses associated with Ebola, or for approval to conduct expanded studies or clinical trials. In addition, the FDA's approval of the IDE supplement does not in any way ensure FDA clearance or approval of the Hemopurifier device for any purpose.

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 A. Joyce
James A. Joyce

Dated:
December 31, 2014
Chief Executive Officer

