

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 12, 2024**

Aethlon Medical, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation)

001-37487

(Commission File Number)

13-3632859

(IRS Employer Identification No.)

**11555 Sorrento Valley Road, Suite 203
San Diego, California**

(Address of principal executive offices)

92121

(Zip Code)

Registrant's telephone number, including area code: **(619) 941-0360**

N/A

(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:

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	AEMD	The Nasdaq Capital Market

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.

Item 8.01 Other Events.

On August 12, 2024, Aethlon Medical, Inc. (the “Company”) issued a press release announcing that the Bellberry Human Research Ethics Committee has granted full ethics approval to the Pindara Private Hospital for a safety, feasibility and dose-finding clinical trial for the Company’s Hemopurifier® in patients with solid tumors not responding to anti-PD-1 antibodies. A copy of that press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated August 12, 2024
104	Cover Page Interactive Data File (embedded within the inline XBRL Document)

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.

Date: August 12, 2024

Aethlon Medical, Inc.

By: /s/ James B. Frakes

Name: James B. Frakes

Interim Chief Executive Officer and Chief Financial Officer



Aethlon Medical Receives Second Ethics Committee Approval for Hemopurifier® Cancer Trial

Bellberry Human Research Ethics Committee Granted Full Ethics Approval to the Pindara Private Hospital for a Safety, Feasibility, and Dose Finding Study of Aethlon's Hemopurifier® in Patients with Solid Tumors Not Responding to Anti-PD-1 Antibodies

SAN DIEGO, August 12, 2024 - Aethlon Medical, Inc. (Nasdaq: AEMD), a medical therapeutic company focused on developing products to treat cancer and life-threatening infectious diseases, today announced that, on August 6, 2024, the Bellberry Human Research Ethics Committee (BHREC) granted full ethics approval to the Pindara Private Hospital for a safety, feasibility and dose-finding clinical trial of the Hemopurifier® in patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment, such as Merck's Keytruda® (pembrolizumab) or Bristol Myers Squibb's Opdivo® (nivolumab) (AEMD-2022-06 Hemopurifier Study). The approval is valid for one year, until August 6, 2025. The trial will be conducted by Dr. Marco Matos and his staff at the Pindara Private Hospital, located in Queensland, Australia.

"We are quite pleased that the BHREC accepted our responses to their thoughtful questions during their review and determined that our study meets the requirements of the National Statement application. Dr. Matos and his research team have a proven track record of enrollment in device trials in oncology patients that provides momentum to these trials," stated Steven LaRosa, MD, Chief Medical Officer of Aethlon Medical. "This is the second ethics committee approval we have received for our oncology trial in Australia after receiving approval from the ethics committee for Royal Adelaide Hospital in June."

Dr. LaRosa continued, "The next step is to receive approval from the Research Governance Office at each hospital which reviews indemnities and insurance. Once these approvals are obtained, Aethlon, in concert with our Australian Contract Research Organization, ReSQ, will conduct Site Initiation Visits (SIVs), after which patient enrollment may proceed."

Currently, only approximately 30% of cancer patients who receive pembrolizumab or nivolumab treatment for solid tumors will have lasting clinical responses to these agents. Extracellular vesicles (EVs) produced by tumors have been implicated in resistance to anti-PD-1 therapies as well as the spread of cancers. The Aethlon Hemopurifier has been designed to bind and remove these EVs from the bloodstream, which may improve therapeutic response rates to anti-PD-1 antibodies. In preclinical studies, the Hemopurifier has been shown to reduce the number of exosomes in cancer patient plasma samples.

The primary endpoint of the approximate nine to 18-patient, safety, feasibility and dose-finding trial is safety. The trial will monitor any adverse events and clinically significant changes in lab tests of Hemopurifier treated patients with solid tumors with stable or progressive disease at different treatment intervals, after a two-month run in period of PD-1 antibody, Keytruda® or Opdivo® monotherapy. Patients who do not respond to the PD-1 therapy will be eligible to enter the Hemopurifier period of the study, where sequential cohorts will receive 1, 2 or 3 Hemopurifier treatments during a one-week period. In addition to monitoring safety, the study is designed to examine the number of Hemopurifier treatments needed to decrease the concentration of EVs and if these changes in EV concentrations improve the body's own natural ability to attack tumor cells. These exploratory central laboratory analyses are expected to inform the design of a subsequent efficacy and safety, Premarket Approval (PMA), study required by regulatory agencies.

About Aethlon and the Hemopurifier®

Aethlon Medical is a medical therapeutic company focused on developing the Hemopurifier, a clinical stage immunotherapeutic device which is designed to combat cancer and life-threatening viral infections and for use in organ transplantation. In human studies, the Hemopurifier has demonstrated the removal of life-threatening viruses and in pre-clinical studies, the Hemopurifier has demonstrated the removal of harmful exosomes from biological fluids, utilizing its proprietary lectin-based technology. This action has potential applications in cancer, where exosomes may promote immune suppression and metastasis, and in life-threatening infectious diseases. The Hemopurifier is a U.S. Food and Drug Administration (FDA) designated Breakthrough Device indicated for the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease. The Hemopurifier also holds an FDA Breakthrough Device designation and an open Investigational Device Exemption (IDE) application related to the treatment of life-threatening viruses that are not addressed with approved therapies.

Additional information can be found at www.AethlonMedical.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks and uncertainties. Statements containing words such as “may,” “believe,” “anticipate,” “expect,” “intend,” “plan,” “project,” “will,” “projections,” “estimate,” “potentially” or similar expressions constitute forward-looking statements. Such forward-looking statements are subject to significant risks and uncertainties and actual results may differ materially from the results anticipated in the forward-looking statements. These forward-looking statements are based upon Aethlon’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Factors that may contribute to such differences include, without limitation, the Company’s ability to successfully complete development of the Hemopurifier and to successfully demonstrate the utility and safety of the Hemopurifier in patients with solid tumors in our planned oncology clinical trials; the Company’s ability to obtain the approval by the respective Ethics Boards of interested clinical trial sites in India and in Australia; the Company’s ability to obtain approvals from Research Governance Offices at relevant hospitals and complete site initiation visits in a timely manner; the Company’s ability to recruit patients for and manage its clinical trials and studies; unforeseen changes in regulatory requirements; and other potential risks. The foregoing list of risks and uncertainties is illustrative but is not exhaustive. Additional factors that could cause results to differ materially from those anticipated in forward-looking statements can be found under the caption “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended March 31, 2023, and in the Company’s other filings with the Securities and Exchange Commission, including its quarterly Reports on Form 10-Q. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except as may be required by law, the Company does not intend, nor does it undertake any duty, to update this information to reflect future events or circumstances.

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