

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): **November 13, 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 2.02 Results of Operations and Financial Condition.

The information provided below in “Item 7.01 - Regulation FD Disclosure” of this Current Report on Form 8-K (this “Current Report”) is incorporated by reference into this Item 2.02.

Item 7.01 Regulation FD Disclosure.

On November 13, 2024, Aethlon Medical, Inc. (the “Company”) issued a press release regarding its financial results for the quarter ended September 30, 2024. A copy of that press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information set forth under Item 7.01 of this Current Report, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of such section. The information in Item 7.01 of this Current Report, including Exhibit 99.1, shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing, except as expressly set forth by specific reference in such a filing. This Current Report will not be deemed an admission as to the materiality of any information in this Current Report that is required to be disclosed solely by Regulation FD.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Description
99.1	Press Release, dated November 13, 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: November 13, 2024

Aethlon Medical, Inc.

By: /s/ James B. Frakes

Name: James B. Frakes
Chief Executive Officer and Chief Financial Officer



Aethlon Medical Announces Financial Results for the Fiscal Second Quarter Ended September 30, 2024 and Provides Corporate Update

Achieves Key Milestone with Enrollment of First Two Patients in the Safety, Feasibility, and Dose Finding Study of Aethlon's Hemopurifier® in Patients with Solid Tumors Not Responding to Anti-PD-1 Antibodies

Two Australian Sites Open For Patient Enrollment in Hemopurifier® Cancer Trial

Conference Call to be Held Today at 4:30 p.m. ET

SAN DIEGO, November 13, 2024 -- Aethlon Medical, Inc. (Nasdaq: AEMD), a medical therapeutic company focused on developing products to treat cancer and life-threatening infectious diseases, today reported financial results for its fiscal second quarter ended September 30, 2024 and provided an update on recent developments.

Company Updates

During the second quarter, and subsequently, the company advanced its oncology trial efforts in Australia, while implementing cost-cutting measures to streamline operations. Management is pleased to report positive progress on these initiatives, specifically:

Clinical Trials: The first two patients have now been enrolled at the Royal Adelaide Hospital in Adelaide, Australia. Additionally, Pindara Private Hospital, in the Gold Coast section of Australia, received ethics committee approval, was trained on Aethlon's Hemopurifier®, and is now open for patient enrollment. The company has also trained a third hospital in Australia, but has not yet received ethics committee approval for that institution and it has not yet begun patient enrollment.

In September, Aethlon received ethics committee approval from Medanta Medicity Hospital in Gurugram, India, for a similar nine to 18-patient, safety, feasibility and dose-finding trial of the Hemopurifier. The company is completing the necessary logistical steps before the site can open for patient enrollment.

Management Change: In October, Aethlon's board of directors appointed James Frakes to serve as the company's permanent Chief Executive Officer, after having served as Interim Chief Executive Officer since November 2023.

Operational Efficiency: Strategic cost-cutting initiatives have allowed for optimized resource allocation, enabling continued focus on high-impact areas of the oncology trial.

"During the second fiscal quarter and subsequent period, we continued advancing our oncology trials, earlier this week announcing enrollment of the first patient at Royal Adelaide Hospital, and now updating this news to report enrollment of a second patient. This represents a critical milestone for the safety, feasibility and dose-finding trials of the Hemopurifier in patients with solid tumors who have failed treatment with anti-PD-1 antibodies," stated James Frakes, Chief Executive Officer and Chief Financial Officer of Aethlon Medical. "We now have two sites open for patient enrollment in Australia, have received ethics committee approval from a site in India, and we expect to continue to enroll subjects in our Hemopurifier cancer trial. As previously announced, we believe these studies will help inform future oncology efficacy trials. Additionally, we have made strategic cost-cutting measures to optimize company resources, in order to focus on the high-impact oncology trials in both Australia and India."

As a reminder, the primary endpoint of the approximate nine to 18-patient, safety, feasibility and dose-finding trials, is safety. The trials 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 antibody 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 subsequent efficacy and safety trials, including a Premarket Approval (PMA) study required by the FDA and other regulatory agencies.

Currently, only approximately 30% of patients who receive pembrolizumab or nivolumab will have lasting clinical responses to these agents. Extracellular vesicles (EVs) produced by tumors have been implicated in the spread of cancers as well as the resistance to anti-PD-1 therapies. 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 EVs in cancer patient plasma samples.

The company also continues to explore opportunities to expand the use of the Hemopurifier as a treatment for life-threatening viral infections. In vitro, it has shown effectiveness in capturing viruses such as Ebola, Marburg virus, Zika, Lassa, MERS-CoV, Cytomegalovirus, Epstein-Barr, Herpes simplex, Chikungunya, Dengue, West Nile, H1N1 swine flu, H5N1 bird flu, and the reconstructed 1918 Spanish flu virus. The company's COVID-19 trial in India remains open to accommodate any potential COVID-19 admissions to the intensive care units at the two participating sites, Medanta Medicity Hospital and Maulana Azad Medical College. So far, one patient has been treated. The company is actively evaluating COVID-19 admissions and potential enrollment against the ongoing costs of maintaining the trial.

Financial Results for the Fiscal Second Quarter Ended September 30, 2024

As of September 30, 2024, Aethlon Medical had a cash balance of approximately \$6.9 million.

Consolidated operating expenses for the fiscal quarter ended September 30, 2024 were approximately \$2.9 million, compared to \$3.2 million for the fiscal quarter ended September 30, 2023. This decrease of approximately \$300,000, or 9%, in the 2024 period was due to a decrease of approximately \$600,000 in professional fees, partially offset by an increase of approximately \$200,000 in payroll and related expenses and an approximately \$100,000 increase in general and administrative expenses.

The approximate \$600,000 decrease in professional fees was primarily due to a \$300,000 reduction in legal fees following a transition to a new legal firm, a \$200,000 decrease in contract labor expenses due to project completions with contract manufacturing organizations and research and development consultants, and an \$81,000 decrease in accounting fees.

The approximate \$200,000 increase in payroll and related expenses was primarily due to an increase of \$500,000 in separation expenses related to severance agreements following the termination of an executive and a reduction in workforce. This increase was partially offset by a \$200,000 reduction in ongoing payroll expenses and a \$100,000 decrease in stock-based compensation as a result of the completion of vesting of existing stock options and reduced headcount.

The \$100,000 increase in general and administrative expenses in the fiscal quarter ended September 30, 2024 was primarily due a \$200,000 increase in costs associated with the company's ongoing oncology clinical trial. This increase was partially offset by reductions in a number of general and administrative expense items, including decreases in U.S. clinical trial expenses.

As a result of the factors noted above, the company's net loss decreased to approximately \$2.8 million in the fiscal quarter ended September 30, 2024, from approximately \$3.0 million in the fiscal quarter ended September 30, 2023.

The consolidated balance sheet for September 30, 2024, and the consolidated statements of operations for the three- and six-month periods ended September 30, 2024 and 2023 follow at the end of this release.

Conference Call

Management will host a conference call today, Wednesday, November 13, 2024, at 4:30 p.m. ET to review the company's financial results and recent corporate developments. Following management's formal remarks, there will be a question and answer session.

Interested parties can register for the conference call by navigating to <https://dpregrister.com/sreg/10194285/fdebe88214>. Please note that registered participants will receive their dial-in number upon registration.

Interested parties without internet access or unable to pre-register may dial in by calling:

PARTICIPANT DIAL IN (TOLL FREE): 1-844-836-8741

PARTICIPANT INTERNATIONAL DIAL IN: 1-412-317-5442

All callers should ask for the Aethlon Medical, Inc. conference call.

A replay of the call will be available approximately one hour after the end of the call through December 13, 2024. The replay can be accessed via Aethlon Medical's website or by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) or Canada toll free at 1-855-669-9658. The replay conference ID number is 10194285.

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 raise additional capital on terms favorable to the Company, or at all; the Company's ability to successfully complete development of the Hemopurifier; the Company's ability to successfully demonstrate the utility and safety of the Hemopurifier in cancer and infectious diseases and in the transplant setting; the Company's ability to achieve and realize the anticipated benefits from potential milestones; the Company's ability to obtain approval from the Ethics Committee of its third location in Australia, including on the timeline expected by the Company; the Company's ability to enroll additional patients in its oncology clinical trials in Australia and India, including on the timeline expected by the Company; the Company's ability to manage and successfully complete its clinical trials; the Company's ability to successfully manufacture the Hemopurifier in sufficient quantities for its clinical trials; unforeseen changes in regulatory requirements; the Company's ability to maintain its Nasdaq listing; 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, 2024, 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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AETHLON MEDICAL, INC. AND SUBSIDIARY
Condensed Consolidated Balance Sheets

	September 30, 2024	March 31, 2024
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 6,859,075	\$ 5,441,978
Deferred offering costs	–	277,827
Prepaid expenses and other current assets	279,008	505,983
TOTAL CURRENT ASSETS	7,138,083	6,225,788
Property and equipment, net	843,617	1,015,229
Operating lease right-of-use asset	743,994	883,054
Patents, net	825	1,100
Restricted cash	87,506	87,506
Deposits	33,305	33,305
TOTAL ASSETS	\$ 8,847,330	\$ 8,245,982
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 922,888	\$ 777,862
Due to related parties	1,011,544	546,434
Operating lease liability, current portion	301,680	290,565
Accrued Professional Fees	95,338	215,038
TOTAL CURRENT LIABILITIES	2,331,450	1,829,899
Operating lease liability, less current portion	496,772	649,751
TOTAL LIABILITIES	2,828,222	2,479,650
EQUITY		
Common stock, par value \$0.001 per share; 60,000,000 shares authorized as of September 30, 2024 and March 31, 2024; 13,961,998 and 2,629,725 shares issued and outstanding as of September 30, 2024 and March 31, 2024, respectively	13,962	2,629
Additional-paid in capital	165,954,256	160,337,371
Accumulated other comprehensive loss	(3,969)	(6,940)
Accumulated deficit	(159,945,141)	(154,566,728)
TOTAL STOCKHOLDERS' EQUITY	6,019,108	5,766,332
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 8,847,330	\$ 8,245,982

AETHLON MEDICAL, INC. AND SUBSIDIARY
Consolidated Statements of Operations and Comprehensive Loss
For the three and six month periods ended September 30, 2024 and 2023

	<u>Three Months Ended 9/30/24</u>	<u>Three Months Ended 9/30/23</u>	<u>Six Months Ended 9/30/24</u>	<u>Six Months Ended 9/30/23</u>
OPERATING COSTS AND EXPENSES				
Professional fees	570,845	1,133,111	1,184,927	2,109,749
Payroll and related expenses	1,372,899	1,191,426	2,627,701	2,314,665
General and administrative	958,375	850,809	1,709,228	2,159,092
Total operating expenses	<u>2,902,119</u>	<u>3,175,346</u>	<u>5,521,856</u>	<u>6,583,506</u>
OPERATING LOSS	<u>(2,902,119)</u>	<u>(3,175,346)</u>	<u>(5,521,856)</u>	<u>(6,583,506)</u>
OTHER INCOME				
Interest Income	95,146	140,890	143,442	266,871
NET LOSS	<u>\$ (2,806,973)</u>	<u>\$ (3,034,456)</u>	<u>\$ (5,378,414)</u>	<u>\$ (6,316,635)</u>
OTHER COMPREHENSIVE INCOME/(LOSS)	<u>3,804</u>	<u>(2,435)</u>	<u>2,971</u>	<u>(3,429)</u>
COMPREHENSIVE LOSS	<u>\$ (2,803,169)</u>	<u>\$ (3,036,891)</u>	<u>\$ (5,375,443)</u>	<u>\$ (6,320,064)</u>
Basic and diluted loss per share attributable to common stockholders	<u>\$ (0.20)</u>	<u>\$ (1.22)</u>	<u>\$ (0.50)</u>	<u>\$ (2.57)</u>
Basic and diluted weighted average number of common shares outstanding - basic and diluted	<u>13,937,595</u>	<u>2,483,649</u>	<u>10,715,446</u>	<u>2,457,711</u>