

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): **February 12, 2025**

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 February 12, 2025, Aethlon Medical, Inc. (the “Company”) issued a press release regarding its financial results for the quarter ended December 31, 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 February 12, 2025.
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: February 12, 2025

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 Third Quarter Ended December 31, 2024 and Provides Corporate Update

Key Milestone Achieved: First Patient treated in Hemopurifier® Safety, Feasibility, and Dose Finding Study for Solid Tumors Not Responding to Anti-PD-1 Antibodies

Patient Enrollment Open at Two Australian for Hemopurifier® Cancer Trial

Operating Expenses Significantly Reduced

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

SAN DIEGO, February 12, 2025 -- 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 third quarter ended December 31, 2024 and provided an update on recent developments.

Company Updates

During the third quarter, and subsequently, the company made significant progress in its oncology trial efforts in Australia while executing cost-cutting measures to enhance operational efficiency. Management is pleased to highlight the following key developments:

Clinical Trials:

Steady progress in our Australian Oncology trial of the Hemopurifier in patients with solid tumors was made. To date, three patients have been enrolled. Two patients did not advance to the treatment phase due to pre-specified stopping criteria during the run-in period - one showed a clinical response to anti PD-1 therapy, while the other experienced toxicity related to anti-PD-1 therapy. The third patient, who did not respond to anti-PD-1 therapy, successfully underwent a single 4-hour Hemopurifier treatment at Royal Adelaide Hospital on January 29, 2025. The treatment was completed with no device-related issues or complications. Samples collected before and after treatment will be analyzed to assess extracellular vesicle removal and changes in anti-tumor T cell activity. This data will be available once all 3 patients in this patient cohort are treated.

Following the investigator meeting with the three clinical sites, Aethlon received valuable feedback suggesting protocol modifications that could possibly improve enrollment speed, reduce screen failures, and shorten the time to Hemopurifier treatment and time to data. In response, the Aethlon team swiftly developed a protocol amendment incorporating these recommendations.

Key changes include enrolling patients only after they have been confirmed not to be responding to anti-PD-1 therapy. This adjustment eliminates the need to identify patients within the first 2 weeks of starting anti-PD-1 therapy and removes the two-month run-in period previously required to assess response to therapy. Additionally, restrictions on commonly prescribed concomitant medications that do not impact patient safety have been lifted. The amended protocol also broadens eligibility to include patients receiving all approved dosing regimens of Pembrolizumab and Nivolumab, rather than limiting enrollment to specific schedules.

The company is pleased to announce that the Human Research Ethics Committees (HREC) and Research Governance Offices (RGO) have approved this amendment at all three clinical sites. The two currently active clinical sites, Royal Adelaide Hospital and Pindara Private Hospital, can enroll under the amended protocol. The third site, Genesis Care/ Royal North Shore Hospital, can begin enrollment under this amendment following a Site Initiation Visit (SIV) on February 14, 2025.

The company continues to pursue approval of a similar clinical trial in India. HREC approval has been obtained at Medanta Medicity Hospital, and we are currently awaiting approval from the regulatory agency CDSCO in India. Recent regulatory changes in India have introduced additional documentation requirements that were previously not necessary. Aethlon is actively responding to CDSCO's queries through the company's India CRO, Qualtran.

Operational Efficiency:

Aethlon has implemented strategic cost-cutting measures to optimize company resources, enabling it to maintain a strong focus on the high-impact oncology trials in both Australia and India. These initiatives are designed to improve resource allocation, reduce operational expenses, and support the continued advancement of our clinical programs.

“During the third fiscal quarter and subsequent period, we continued to advance our oncology trials, including treatment of the first patient at Royal Adelaide Hospital in late January. We are pleased to report that the patient tolerated the procedure without complications, making a critical milestone for the safety, feasibility and dose-finding trials of the Hemopurifier in patients with solid tumors who have not responded to anti-PD-1 antibodies” stated James Frakes, Chief Executive Officer and Chief Financial Officer of Aethlon Medical. “We currently have two clinical sites activated and open for enrollment in Australia, with a third site expected to be activated in February 2025. In addition, we have received ethics committee approval from a site in India. We also anticipate continued enrollments in our Hemopurifier cancer trial as these sites progress.

While two previously recruited patients were withdrawn from the study due to outcomes related to their anti-PD-1 therapies, we believe that the recent protocol amendment will shorten trial timelines and support improved patient enrollment. As previously announced, we believe these studies will help inform future oncology efficacy trials. Furthermore, we have implemented strategic cost-cutting measures to optimize company resources, enabling us to maintain a strong 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 is closely monitoring developments related to Bird Flu in the United States, Marburg virus in Rwanda and Ebola virus in Uganda. Aethlon has direct experience with these viruses, having previously generated in vitro viral binding data for all three viruses and treated an Ebola patient in Germany under Emergency Use conditions. Aethlon will continue to monitor these situations carefully and be poised to respond if currently available treatment strategies are deemed ineffective.

Financial Results for the Fiscal Third Quarter Ended December 31, 2024

As of December 31, 2024, Aethlon had a cash balance of approximately \$4.8 million.

Consolidated operating expenses for the fiscal quarter ended December 31, 2024, decreased by approximately \$1.8 million, or approximately 50%, to \$1.8 million compared to \$3.6 million for the fiscal quarter ended December 31, 2023. This reduction was driven by a \$1.3 million decrease in payroll and related expenses, a \$300,000 decrease in professional fees, and a \$200,000 decrease in general and administrative expenses.

The approximate \$1.3 million decrease in payroll and related expenses was primarily attributable to a reduction of \$900,000 in separation expenses related to the Separation Agreement with the former Chief Executive Officer that had been recorded in the December 2023 period, as well as a decrease of approximately \$400,000 due to a reduction in headcount. Of the approximate \$900,000 of separation expenses related to the departure of the former CEO, approximately \$400,000 related to the acceleration of vesting of stock options.

The approximate \$300,000 decrease in professional fees was primarily due to an approximate reduction of \$200,000 in legal fees resulting from the transition to a new legal firm, and a decrease of \$200,000 in scientific and operational consulting fees largely attributable to completed projects. These decreases were partially offset by an approximate \$100,000 increase in investor relations and accounting fees.

The approximate \$200,000 decrease in general and administrative expenses was primarily driven by a \$300,000 reduction in supplies, largely related to the raw materials and components used in the manufacturing of the Hemopurifier, with no comparable purchases during the current period. Additionally, there was an approximate \$100,000 decrease in insurance expenses associated with a reduced headcount and various other operating expenses. These reductions were partially offset by a \$200,000 increase in expenses related clinical trial expenses related to our ongoing oncology clinical trials in Australia and India.

As a result of the factors noted above, the company's net loss decreased to approximately \$1.8 million in the fiscal quarter ended December 31, 2024, from approximately \$3.5 million in the fiscal quarter ended December 31, 2023.

The consolidated balance sheet for December 31, 2024, and the consolidated statements of operations for the three- and nine-month periods ended December 31, 2024 and 2023 follow at the end of this release.

Conference Call

Management will host a conference call today, Wednesday, February 12, 2025, 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/10196811/fe7c419c9d>. 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 March 12, 2025. 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 7828175.

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 cure deficiencies and continue 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
Unaudited

ASSETS	December 31, 2024	March 31, 2024
CURRENT ASSETS		
Cash and cash equivalents	\$ 4,825,387	\$ 5,441,978
Deferred offering costs	54,750	277,827
Prepaid expenses and other current assets	88,270	505,983
TOTAL CURRENT ASSETS	4,968,407	6,225,788
Property and equipment, net	762,138	1,015,229
Operating lease right-of-use lease asset	673,315	883,054
Patents, net	688	1,100
Restricted cash	87,506	87,506
Deposits	33,305	33,305
TOTAL ASSETS	\$ 6,525,359	\$ 8,245,982
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 610,909	\$ 777,862
Due to related parties	781,899	546,434
Operating lease liability, current portion	307,326	290,565
Accrued professional fees	73,537	215,038
TOTAL CURRENT LIABILITIES	1,773,671	1,829,899
Operating lease liability, less current portion	417,522	649,751
TOTAL LIABILITIES	2,191,193	2,479,650
STOCKHOLDERS' EQUITY		
Common stock, par value of \$0.001; 60,000,000 shares authorized as of December 31, 2024; 13,986,669 and 2,629,725 issued and outstanding as of December 31, 2024 and March 31, 2024, respectively	13,987	2,629
Additional paid-in capital	166,037,129	160,337,371
Accumulated other comprehensive loss	(17,026)	(6,940)
Accumulated deficit	(161,699,924)	(154,566,728)
TOTAL STOCKHOLDERS' EQUITY	4,334,166	5,766,332
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 6,525,359	\$ 8,245,982

AETHLON MEDICAL, INC. AND SUBSIDIARY
Consolidated Statements of Operations and Comprehensive Loss
For the three and nine month periods ended December 31, 2024 and 2023
Unaudited

	<u>Three Months Ended 12/31/24</u>	<u>Three Months Ended 12/31/23</u>	<u>Nine Months Ended 12/31/24</u>	<u>Nine Months Ended 12/31/23</u>
OPERATING EXPENSES				
Professional fees	\$ 377,877	\$ 668,586	\$ 1,563,995	\$ 2,778,335
Payroll and related expenses	620,487	1,919,305	3,248,187	4,233,970
General and administrative	816,383	979,197	2,525,220	3,138,289
Total operating expenses	<u>1,814,747</u>	<u>3,567,088</u>	<u>7,337,402</u>	<u>10,150,594</u>
OPERATING LOSS	<u>(1,814,747)</u>	<u>(3,567,088)</u>	<u>(7,337,402)</u>	<u>(10,150,594)</u>
OTHER INCOME				
Interest Income	59,964	100,967	204,206	367,838
NET LOSS	(1,754,783)	(3,466,121)	(7,133,196)	(9,782,756)
OTHER COMPREHENSIVE INCOME/(LOSS)	(13,057)	7,951	(10,085)	4,522
COMPREHENSIVE LOSS	<u>\$ (1,767,840)</u>	<u>\$ (3,458,170)</u>	<u>\$ (7,143,281)</u>	<u>\$ (9,778,234)</u>
Basic and diluted loss per share attributable to common stockholders	<u>\$ (0.13)</u>	<u>\$ (1.37)</u>	<u>\$ (0.61)</u>	<u>\$ (3.95)</u>
Weighted average number of common shares outstanding - basic and diluted	<u>13,962,266</u>	<u>2,516,511</u>	<u>11,801,655</u>	<u>2,477,282</u>