#### 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): April 25, 2024

#### **AETHLON MEDICAL, INC.**

(Exact name of Registrant as Specified in Its Charter)

001-37487

13-3632859

Nevada (State or Other Jurisdiction of Incorporation)

(Commission File Number)

(IRS Employer Identification No.)

92121

(Zip Code)

11555 Sorrento Valley Road, Suite 203

San Diego, California

(Address of Principal Executive Offices)

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 April 25, 2024, Aethlon Medical, Inc. (the "Company") updated its corporate presentation for use in meetings with investors, analysts and others. The presentation is available through the Company's website and a copy is attached as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits.

<u>Exhibit No.</u>	<b>Description</b>
99.1	Company Presentation, dated April 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: April 25, 2024

#### Aethlon Medical, Inc.

By: /s/ James B. Frakes

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



## **Corporate Presentation**

## April 2024

Nasdaq: AEMD www.AethlonMedical.com

### FORWARD LOOKING STATEMENTS

This investor presentation contains forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safer harbor" created by those sections. All statements other than statements of historical fact contained in this presentation are forward-looking statements, including, without limitation, statements regarding: Aethlon's ability to enroll patients in Aethlon's ongoing and planned clinical trials; Aethlon's ability to successfully complete Aethlon's clinical trials and achieve the endpoints for the trials, or any future clinical trials with Aethlon's Hemopurifier® or to successfully develop and commercialize the Hemopurifier®; Aethlon's ability to demonstrate the removal of nanoparticles (NPs), extracellular vesicles (EVs) and their associated cargo with the Hemopurifier<sup>®</sup>; the potential synergistic use of the Hemopurifier with chemotherapy, immunotherapy and targeted agents; Aethlon's ability to successfully demonstrate the benefit of Aethlon's Hemopurifier® in the organ transplant setting; and Aethlon's ability to raise additional capital and to maintain Aethlon's listing on the Nasdaq Capital Market (Nasdaq); and Aethlon's ability to establish and maintain collaborations. These forward looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of Aethlon's clinical trials and preclinical research with the Hemopurifier® in the organ transplant setting; Aethlon's ability to enroll patients in Aethlon's ongoing and planned clinical trials on a timely basis, or at all; Aethlon's dependence on Aethlon's CROs and other third parties; Aethlon's ability to manufacture Aethlon's Hemopurifiers®; Aethlon's ability to obtain regulatory approvals within the timeframes expected, or at all; complications associated with product development and commercialization activities; the size and growth of the market(s) for the Hemopurifier® and the rate and degree of market acceptance thereof; Aethlon's ability to raise additional capital; Aethlon's ability to remain listed on Nasdaq; and Aethlon's ability to attract and retain key management, and members of Aethlon's board of directors. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of Aethlon's Form 10-K filed with the Securities and Exchange Commission (SEC) on June 28, 2023, subsequent filings with the SEC on Forms 10-Q and 8-K, and other filings that Aethlon makes with the SEC from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and Aethlon's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this presentation and are based on information available to Aethlon as of the date of this presentation, and Aethlon undertakes no duty to update such information except as required under applicable law. All third-party brand names and logos appearing in this presentation are trademarks or registered trademarks of their respective holders. Any such appearance does not necessarily imply any affiliation with or endorsement of the Company.



## **Investment Highlights**

- · Developing novel, patented Hemopurifier blood purification device
  - Early clinical trials have demonstrated virus and EV (extracellular vesicles, which include exosomes) clearance both in vitro and in patients
- The FDA has designated the Hemopurifier<sup>®</sup> as a "Breakthrough Device"
  - · The treatment of individuals with advanced or metastatic cancer
  - · The treatment of life-threatening viruses that are not addressed with approved therapies
- · Focused on multiple therapeutic targets in cancer, viral disease and organ transplantation
  - Solid tumors failing anti-PD1
  - COVID-19
  - · Proof-of-concept studies underway in organ transplantation
- · U.S. and international clinical trials
  - · Planned oncology trials in Australia and in India
  - Open COVID-19 trial in India
- Broad patent portfolio
- · Experienced management team

**The Aethlon Hemopurifier®** FDA Designated "Breakthrough Device" In Viral And Oncology Indications



1. Aethlon clinical safety database

- Safely administered in 164 Hemopurifier sessions in 38 patients<sup>1</sup>
- Proprietary, patented technology
- Has demonstrated clearance of life-٠ threatening viruses
- · Designed to clear tumor-derived EVs, and their associated cargo (Oncology)

## The Hemopurifier<sup>®</sup> Is Designed To Capture Viruses And Extracellular Vesicles From A Patient's Blood Via Extracorporeal Circuit



#### Potential Therapeutic Applications:

- Cancer
- Life-threatening viral infections
- Organ Transplantation

## **Pipeline Targeting Multiple Indications**



## The Rationale Exists For The Removal Of Tumor-derived Extracellular Vesicles By Aethlon's Hemopurifier® To Treat Cancer

Extracellular Vesicles (EVs) are small membrane-bound particles that serve as key mediators of cell-cell communication. They carry lipids, proteins, and nucleic acids, and are released by most cell types, including tumor cells.

Specifically, EVs and their cargo :

- Have been shown to contribute to the spread of cancer (metastases)<sup>1</sup>
- Play a role in immune system evasion by the tumor<sup>1</sup>
- Facilitate chemotherapy resistance<sup>1</sup>
- Interfere with antibody-based treatments (e.g., PD-1 antibody therapies such as Keytruda® and Opdivo®)<sup>2</sup>

We believe the removal of harmful EVs and their associated cargo may enhance existing cancer treatments

### The Hemopurifier<sup>®</sup> has demonstrated clearance of EVs in vitro and in patients<sup>3</sup>

1. Zhang L, Yu D. Biochim Biophys Acta Rev Cancer. 2019 Apr;1871(2):455-468

Rasihashemi SZ, Gavgani ER, Majidazar R, et al. J Cell Physiol 2021:1-13.
 Amundson DE, Shah US, de Necochea-Campion R, et al Front Med (Lausanne). 2021 Oct 8;8:744141.

## In Vitro Removal Of Cancer-Derived EVs from Buffer Has Been Demonstrated<sup>1</sup>

- · Tumor derived EVs were isolated from cancer patient plasma and suspended in buffer
- Samples were circulated over a scaled-down version of the Hemopurifier<sup>®</sup>
- · EV counts were quantified before and after passage over the scaled down device
- The scaled down Hemopurifier was effective for clearing 92-99% of EVs suspended in buffer
- Demonstrated capture of EVs from diverse tumor types including head and neck cancer, melanoma, ovarian cancer, esophageal cancer and breast cancer

## Aethlon is exploring the therapeutic potential of removing tumor-derived EVs in cancer patients with the Hemopurifier®

1. Marleau AM, Jacobs MT, Gruber N, et al. Cancer Res 2020;80 (16\_Supplement):4509.

## **Clinical Development Plans Underway In Oncology**

- A new safety phase clinical trial in oncology is planned to include multiple tumor types, as well as dosing
  intervals, to help direct the development of Aethlon's Hemopurifier<sup>®</sup> as a treatment option in oncology
- Aethlon has contracted with North American Science Associates, LLC (NAMSA), a major global contract research organization (CRO), to direct the planned oncology study in Australia and the U.S.
- Aethlon has contracted with Qualtran LLC, a CRO focused on India, to direct the planned oncology trial in India
- Interested sites have been identified in Australia and India with next step being Ethics Committee approvals in those countries
- · Aethlon needs to complete binding studies prior to the interested sites asking for Ethics Committee approvals

## Recent Scientific & Clinical Literature Provides A Rationale For Hemopurifier Treatment In Severe COVID–19 Infections

- COVID viremia is detected in ~34% of patients and is associated with severity, requirement for ICU stay, development of multi-organ failure and poor outcomes<sup>1</sup>
- Direct viral injury to non-pulmonary organs has been noted in a COVID post-mortem study<sup>2</sup>
- Viremia in COVID is associated with immune dysregulation, endothelial injury, coagulopathy and complement activation<sup>3</sup>
- EVs and exosomal miRNAs may play a role in the spread of infection as well as ongoing inflammation, development of coagulopathy and lung injury<sup>4</sup>
- Aethlon's proprietary Galanthus nivalis agglutinin (GNA) affinity resin has been shown to bind multiple clinically relevant SARS-CoV-2 variants<sup>5</sup>

## Demonstrated removal of SARS-CoV-2, EVs and miRNAs in patients treated with the Hemopurifier®

Tang K, Wu L, Luo Y, Gong B. J Med Virol. 2021 May;93(5):3165-3175.
 Deinhardt-Emmer S, Wittschieber D, et al. Elife. 2021 Mar 30;10:e60361.
 Berneig-Martin JF, González-Rivers M, et al. Crit Care. 2020 Dec: 142:42(1):691.

Barberis E, Vanella VV, Falasca M, et ol. Front Mol Biosci. 2021 Feb 22;8:632290.
 Gooldy M, Roux CM, LaRosa SP, et al. PLoS One. 2022 Jul 28;17(7):e0272377.

# In Vitro Removal of Clinically Relevant SARS-CoV-2 Variants by an Affinity Resin Bearing GNA<sup>1</sup> Has Been Demonstrated

Seven SARS-CoV2 variants (10<sup>4</sup> PFU/mL) in Phosphate Buffered Saline (PBS) buffer passed 3X over column of GNA affinity resin (1g)

Table 2. Average Column Capture Efficiency for SARS-CoV-2 Variants		
Variant ID	Capture Efficiency (%)	
NR 54009 (South Africa)	69.3 ± 11.4	
NR 54000 (UK)	69.8 ± 4.7	
NR 54982 (Brazil)	89.0 ± 3.7	
NR 55672 (B.1.672 Delta)	78.8 ± 1.9	
NR 55657 (Lambda)	70.5 ± 3.6	
NR 55691 (AY.1 Delta)	53.2 ± 11.6	
NR 56461 (Omicron)	89.9 ± 2.1	

1. Gooldy M, Roux CM, LaRosa SP, et al. PLoS One. 2022 Jul 28;17(7):e0272377.



## Evidence of In Vivo Removal of SARS-CoV-21

Viremic Emergency Use patient in the ICU with critical disease

- Request received from Hoag Newport Beach Hospital (Usman Shah, M.D.) on 14 JAN 2021
- · 67-year-old male with PMH of Tetralogy of Fallot, CAD and DM admitted on 6 JAN 2021 with hypoxia and SOB
- Confirmed diagnosis of COVID-19 by PCR
- Progressed to multi-organ system failure (CV, Respiratory and Kidney) despite Remdesivir, Dexamethasone, Convalescent plasma, Baricitinib and full dose anticoagulation
- · Required two vasopressors to maintain blood pressure
- · On mechanical ventilation in the prone position with FIO2 of 90% and PEEP on 8
- · On CRRT for renal replacement therapy
- SOFA score 13-Predicted risk of mortality ~80%
- · Reduced patient's viral load by 58.4% during the treatment

### Decrease in COVID-19 viral load following Hemopurifier<sup>®</sup> treatment; Hemopurifier<sup>®</sup> treatment was well tolerated

1. Amundson DE, Shah US, de Necochea-Campion R, et al Front Med (Lausanne). 2021 Oct 8;8:744141.

## Evidence of SARS-CoV-2 Capture and Clearance by Hemopurifier®1

- Independent Physician Assessment confirmed request for emergency use 14 JAN 2021
- IRB approval and Signed Inform Consent obtained (14 JAN 2021)
- Patient underwent 6-hour 15 minute Hemopurifier session between (0645-1300 hours)
- · No cartridge evidence of hemolysis or thrombosis
- · Patient had fluctuating BP and required increased O2 during session
- Patient Removed from Hemopurifier<sup>®</sup> without incident
- Blood pressure noted to start dropping after new CRRT circuit placed with precipitous drop in Oxygenation and BP at 1400 hours
- Patient developed refractory shock and hypoxia and expired due to a PEA arrest at 1549

1. Amundson DE, Shah US, de Necochea-Campion R, et al Front Med (Lausanne). 2021 Oct 8;8:744141.

VIRAL COPIES NORMALIZED TO RNase P		
	Plasma (Copies/mL)	
Pre-HP plasma	1558.6	
Post-HP plasma	648.1	

### 58% reduction of SARS-CoV-2 plasma viral load

## Demonstrated Reduction Of Total EVs And Harmful Cargo In An Emergency Use COVID-19 Patient Treated With Hemopurifier®1







miR-424 is associated with COVID-associated coagulopathy (excessive blood clotting) miR-16 is associated with acute lung injury

COVID-19 plasma viral load was undetectable at onset of Hemopurifier treatment

1. Amundson DE, Shah US, de Necochea-Campion R, et al Front Med (Lausanne). 2021 Oct 8;8:744141.

2. Exosomes are a subpopulation of extracellular vesicles, nanosized particles, lipid bilayer-enclosed, naturally secreted from cells after the fusion of intracellular Multivesicular bodies with the plasma membrane. Di Bella MA. Biology 2022 Jun; 11(6): 804.

## COVID-19 India Trial Update: Treatment Of SARS-CoV-2 Infection In Humans With Hemopurifier<sup>®</sup> Device

• Regulatory agency in India approved the use of Hemopurifier® devices for clinical trial use

- · Studying ICU patients with severe or life-threatening disease
- · Designed to include up to 15 patients at up to three centers
- · One patient enrolled and treated
- · Added a second hospital site in India in 2023
- · Trial remains open for enrollment

## Hemopurifier<sup>®</sup> Clinical Development Summary

## Oncology

- Safety, feasibility and dose finding study in solid tumors failing anti-PD-1 antibodies
- Planned to be initiated first in Australia and India and then in the United States



### Viral Infections

- Clinical trial of Hemopurifier<sup>®</sup> in severe COVID-19 infection
- · Currently underway in India

## In vitro data highlights potential Hemopurifier® applications in organ transplantation<sup>1</sup>

- · Recovered deceased donor kidneys are typically placed on machine perfusion for preservation and transport to the transplant recipient
- In vitro data using the Hemopurifier to filter kidney perfusates removes noxious agents<sup>1</sup>
  - · Extracellular vesicles<sup>2</sup> and harmful cargos
  - Virus and viral particles (e.g., HCV)
  - RNA molecules
  - · Cytokines, chemokines and other inflammatory molecules
- · These early findings suggest that Hemopurifier filtration of organ perfusates may provide benefits
  - · Improved graft function / reduction in graft rejections
  - · Maintain or improve organ viability prior to transplantation
  - · Potential to reduce the number of kidneys rejected for transplant
- Additional preclinical experiments are planned and underway

<sup>1.</sup> Aethlon internal research, unpublished data 2. Exosomes are a subpopulation of extracellular vesicles, nanosized particles, lipid bilayer-enclosed, naturally secreted from cells after the fusion of intracellular Multivesicular bodies with the plasma membrane. Di Bella MA. Biology 2022 Jun; 11(6): 804.

## Hemopurifier<sup>®</sup> filtration of deceased donor kidneys recovered for transplantation represents an exciting opportunity

- In the United States in 2023, approximately 30,000 kidneys were recovered from 15,417 deceased donors for transplantation<sup>1</sup>
  - Number of deceased donor kidneys is expected to grow to approximately 60,000 by 2034<sup>1</sup>
- Hypothermic machine perfusion (HMP) has been shown to reduce delayed graft function and improve one-year graft survival compared to cold static storage<sup>2</sup>
  - · HMP continuously circulates a preservation solution through the organ at temperatures between 1 and 10 degrees C
  - · Historically, static cold storage in liquid ice was the predominant preservation technique
- Today, most recovered deceased donor kidneys are placed on hypothermic machine perfusion (HMP) for organ preservation and transportation to recipients
- Hemopurifier use during HMP may have the potential to provide additional benefits
  - e.g., greater utilization of recovered kidneys, improvements in delayed graft function in transplant recipients, etc.
  - · Clinical studies will be required to show any potential benefits

1. Organ Procurement & Transplantation Network data reported for 2023; annual donor growth rate of 6% 2016-2023; assumed 2 kidneys were recovered per deceased donor 2. Jiao, B, et al. PLOS One. 2023 Dec 10;8(12):e81826

## Aethlon's patent portfolio provides protection until as early as 2029 (issued patents) and late as 2042 (if pending applications grant)

#### **United States**

#### Issued Patents:

- 3 US patents issued covering extracorporeal removal of microvesicular particles, patent protection until 2029
- 2 US patents issued covering removal of viruses, patent protection until 2025
- Patent Applications:
  - 2 US applications pending covering removal of Covid-19 viral particles and associated exosomes
  - · Patent protection until 2042 if granted

#### International

#### Issued Patents:

- 24 foreign patents covering exosomes and microvesicular particle removal
- Patent protection extending to 2031 in Germany, France, Great Britain, and Spain
- Patent protection extending to 2027 in Canada, Switzerland, Italy, Netherlands, Sweden, Hong Kong, Demark and Ireland

#### • Patent Applications:

- 12 pending foreign applications directed to removal of Covid-19 viral particles and associated exosomes, patent protection to 2042 if granted
- 1 pending international application directed to removal of exosomes, ectosomes, miRNAs, circulating nucleic acids, and viral particles associated with tissues selected for transplantation, patent protection to 2044 if granted

## **Key Financial Highlights**

- Approximately \$8.0 million in cash as of December 31, 2023
- No debt on balance sheet
- Approximately 2.6 million shares outstanding as of April 5, 2024

- Market capitalization of \$4.5 million as of April 5, 2024
- Trading on Nasdaq under the ticker "AEMD"

## Senior Management Team Has Extensive Experience With Both Medical Devices And Therapeutics

#### James B. Frakes, MBA, Interim CEO & Chief Financial Officer

- Over 30 years public company CFO experience
- Investment banking & venture capital

#### Guy Cipriani, MBA, Chief Operating Officer

· 20 years transactional and operational experience with public and private biotech & device companies

#### Steven P. LaRosa, MD, Chief Medical Officer

 25 years clinical and research experience in infectious diseases, critical care, coagulation, inflammation, and extracorporeal devices

#### Lee Arnold, PhD, Chief Scientific Officer

- Over 30 years experience in molecularly-targeted drug discovery:
- 94 published patents and applications, and more than 39 peer-reviewed publications



## **Contact Information**



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This presentation may contain predictions, estimates, and other forward looking statements that involve risks and uncertainties, including: whether and when our products may be successfully developed and introduced; the anticipated market acceptance of the Aethlon Hemopurifier®; and the likelihood of regulatory or manufacturing delays. These risks and uncertainties are detailed in our SEC filings, which are accessible at www.sec.gov or on our website, www.AethlonMedical.com