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Aethlon Medical (AEMD-NASDAQ)

AEMD: *No SAEs in Cohort 1 Post-Hemopurifier Treatment; Progressing Trial to Cohort 2*

Cohort 1 in AEMD's oncology trial of the Hemopurifier in patients with various solid tumors undergoing standard of care treatment has been treated & completed a 7-day safety follow-up. No serious adverse events (SAEs) or Dose-Limiting Toxicities (DLTs) related to the Hemopurifier have been reported to date. AEMD has commenced enrollment for Cohort 2 - participants will receive 2-Hemopurifier treatments over one week vs. one for the Cohort 1 arm. The trial is planned to evaluate the safety and feasibility of administering the Hemopurifier at varying dosing intervals.

OUTLOOK

The independent Data Safety Monitoring Board (DSMB) overseeing the AEMD clinical trial has completed its scheduled safety review, recommending that the trial progress to the next patient cohort without modification. The company believes overall results thus far support moving the Australia ongoing oncology study forward, launching a similar trial in India and potentially also points to other applications of the Hemopurifier in EV-associated diseases. Separately, AEMD, in collaboration with the UCSF Medical Center, has an abstract for poster presentation at the upcoming Keystone Symposium on Long COVID and Other Post-Acute Infection Syndromes.

Current Price (7/16/25)	$1.20
Valuation	**$4.55**

SUMMARY DATA

52-Week High	**$8.48**
52-Week Low	**$1.10**
One-Year Return (%)	**NA**
Beta	**NA**
Average Daily Volume (sh)	**220,144**
Shares Outstanding (mil)	**3**
Market Capitalization ($mil)	**$2.5**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2026 Estimate	**N/A**
P/E using 2027 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2023	0.0 A	0.0 A	0.0 A	0.6 A	0.6 A
2024	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2025	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2026	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E

Earnings / loss per share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2023	-$1.88 A	-$1.84 A	-$1.24 A	-$1.07 A	-$5.86 A
2024	-$10.80 A	-$9.77 A	-$10.99 A	-$7.71 A	-$38.87A
2025	-$2.76 A	-$1.61 A	-$1.01 A	-$3.10 A	-$8.58 A
2026	-$0.68 E	-$0.68 E	-$0.67 E	-$1.49 E	-$3.53 E

Quarters might not add to annual reflecting rounding, share counts

Disclosures on page 10 '24-25 PF

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PROGRESSING TRIAL IN AUSTRALIA TO COHORT 2; TRIAL IN INDIA PLANNED

Data Safety Monitoring Board Recommends AEMD Progress Trial Without Modification

Aethlon Medical's (NASDAQ: AEMD) current primary focus is on researching lead asset the Hemopurifier® therapeutic blood filtration system as a potential treatment in oncology. AEMD is conducting a basket oncology trial[1] to study the impact of the Hemopurifier in patients with various solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment. Unfortunately, only about 30% of cancer patients who receive pembrolizumab (Keytruda®) or nivolumab (Opdivo®) treatment for solid tumors have lasting clinical responses. The company's hypothesis is that using the Hemopurifier in conjunction with treatment of checkpoint inhibitors can increase the percent of patients who can benefit from combined treatment. The trial is intended to assess the Hemopurifier's safety, feasibility, and optimal dosing.

This week AEMD announced that the independent Data Safety Monitoring Board (DSMB) overseeing its clinical trial has completed its scheduled safety review and recommended that the company progress the trial to the next patient cohort without modification. The DSMB is composed of independent medical experts in nephrology and oncology.

The first three patients in Cohort 1 have been treated, completing a single 4-hour Hemopurifier treatment without device deficiencies or immediate complications. Participant #1 was treated with the Hemopurifier on January 29, 2025, for four hours on a single day and tolerated treatment without complications. Participants #2 and #3 received treatment in June 2025. All participants also completed a 7-day safety follow-up.

The primary endpoint of this trial is the incidence of adverse events and clinically significant changes in safety laboratory tests of Hemopurifier-treated patients. The DSMB reviewed data from Cohort 1 in which no serious adverse events (SAEs) or Dose-Limiting Toxicities (DLTs) related to the Hemopurifier have been reported to date.

Thus, following its evaluation, the DSMB reported finding no safety concerns related to the Hemopurifier and that the device continues to show a favorable safety and tolerability profile. AEMD has commenced enrollment for Cohort 2, in which participants will receive two Hemopurifier treatments over one week. The trial is planned to enroll about 9 to 18-participants and evaluate the safety and feasibility of administering the Hemopurifier at varying dosing intervals.

Checkpoint inhibitors are also used to treat a broad range of tumor types. In fact, checkpoint inhibitors such as Keytruda® have been used to treat 25+ different types of cancer. If the study shows the Hemopurifier to be beneficial in multiple cancer types, the company believes the data will support the broad utility of the device. The goal is to build its database in oncology to help with the development of the Hemopurifier as an oncology treatment.

The study protocol had been expanded earlier to reflect evolving immunotherapy standard of care such as combination therapy. While initially the Hemopurifier was being evaluated as an added therapy in conjunction with Keytruda or Opdivo, the device is also now also being evaluated as a treatment in conjunction with Keytruda or Opdivo in combination with other therapy. This is because Keytruda and other therapy are not only used as standalone treatment, but often used in combination with other therapies.

[1] Titled *Safety, Feasibility, and Dose-Finding Study of Aethlon Hemopurifier in Patients with Solid Tumors Who Have Stable or Progressive Disease While on a Treatment That Includes Pembrolizumab or Nivolumab*

With the earlier protocol modification, the AEMD trial will analyze whether the Hemopurifier can help decrease the concentration of EVs in cancer patients being treated with standard of care approaches and thereby improve overall patient outcomes. AEMD expects to announce the preliminary data from the first cohort of patients this month. Preliminary data to be reported includes the effects of Hemopurifier treatment combined with standard of care on EV removal and anti-tumor T-cell activity. The primary endpoint is safety. The study will also explore how many Hemopurifier treatments are needed to decrease the concentration of EVs, and whether potential changes in EV concentrations improve the body's natural ability to fight tumors. Findings will inform the design of future safety and efficacy trials, potentially including a Premarket Approval (PMA) study the FDA and other international regulatory agencies require.

The company expects the Hemopurifier, in conjunction with checkpoint inhibitor and combined therapy treatment can increase the percent of patients who can benefit from combined treatment and improve overall patient outcomes. In turn, this would show proof of concept about the Hemopurifier's benefits in treating solid tumors. AEMD anticipates that data from the first treatment cohort will support the Hemopurifier's potential ability to reduce tumor-derived EVs and enhance T-cell activity against tumors.

Study examining number of Hemopurifier treatments needed to decrease EV concentration

In addition to monitoring safety, the study is designed to examine the number of Hemopurifier treatments needed to decrease EV concentrations and if reduced EV concentrations improve the body's ability to fight tumors. EVs are released from the parent cell and tumor cells generally have more mannose compared to healthy cells. EVs have been shown to contribute to metasisis of the malignancy and to suppressing body's immune system from helping the body fight disease.

Company plana to open a similar trial in India

The ongoing trial is being conducted at three active clinical sites in Australia. AEMD also expects to commence a similar study in India. In June 2025, AEMD received formal approval from India's Central Drugs Standard Control Organization (CDSCO) to initiate a trial at Medanta Medicity Hospital in India similar to the one being conducted in Australia. The trial in India will begin following a Site Initiation Visit (SIV) that Qualtran, Aethlon's India-based CRO, will make.

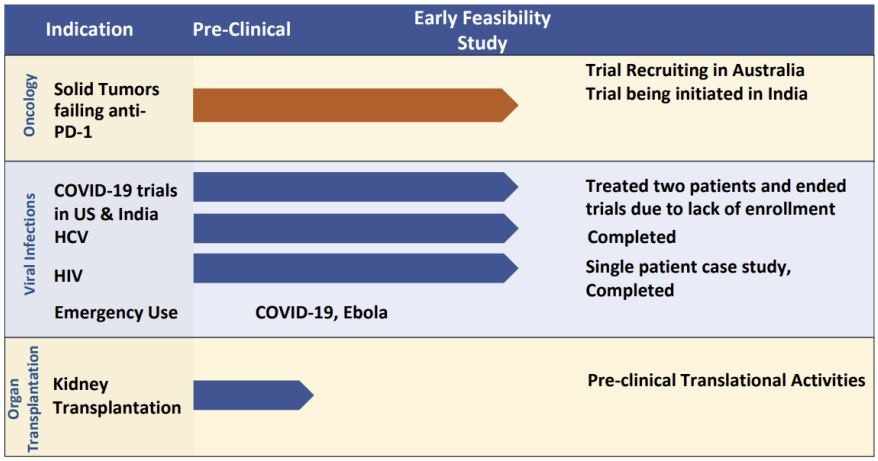
AEMD also expects to realize benefits from attractive economic incentives the Australian government provides for clinical development efforts and lower costs in India, where R&D expenses are substantially lower than in the U.S., according to management, and thereby maximize its R&D dollars. Australia offers an R&D tax incentives rebate program, which enables companies to receive a cash tax rebate of up to 43.5% on clinical trial related R&D costs and is expected to help it reduce costs, lower risk, and accelerate time to market.

MULTIPLE POTENTIAL APPLICATIONS OF THE HEMOPURIFIER

AEMD optimistic about potential of Hemopurifier in multiple medical areas

Excessive levels of PD-EVs (platelet -derived EVs) have been implicated in many diseases, including cancer, lupus, systemic sclerosis, multiple sclerosis, Alzheimer's disease, sepsis, acute and Long COVID. The Hemopurifier has been shown to remove EVs in preclinical ex vivo and also in patients with severe acute COVID-19 through emergency use application. While maintaining rigid cost controls generally, the company continues pre-clinical research and analysis of the Hemopurifier in areas outside of oncology. Given the company's focus on controlling costs, we estimate that expense associated with these efforts are de minimis. We also estimate that the data show results that warrant further study of the Hemopurifier for Long Covid and potentially other areas of infectious disease.

Pipeline Targeting Multiple Indications



Source: Company presentation

For example, the results from Aethlon's preclinical ex vivo study were published in bioRxiv on May 12, 2025, and the manuscript has been submitted for publication in a peer-reviewed journal. The results demonstrate that, using proprietary Galanthus nivalis agglutin (GNA) affinity resin, the Hemopurifier removed 98.5% of platelet -derived extracellular vesicles (PD-EVs) from human plasma during a time period equivalent to a 4-hour treatment with the device. The results also support the company move forward with its ongoing oncology study in Australia and point to other potential applications of the Hemopurifier in EV-associated diseases.

Separately, Aethlon collaborated with the UCSF (University of California San Francisco) Medical Center Long COVID clinic to evaluate plasma samples from participants with Long COVID and control participants who had fully recovered from COVID-19 to examine whether individuals with Long COVID would have EVs with the mannose target on their surface that would bind to the affinity resin in the Hemopurifier. EVs have been found to contain viral particles and other issues associated with abnormal blood clotting and inflammation and have been implicated in the pathogenesis of Long COVID. According to AEMD, more than $1 billion has been allocated to fund Long COVID research but no treatment has proven effective yet.

AEMD has had an abstract accepted for poster presentation at the Keystone Symposium on Long COVID and Other Post-Acute Infection Syndromes. The company's near-term focus is on assessing its lead asset, the Aethlon Hemopurifier®, as a potential treatment for oncology. The Hemopurifier is being evaluated in combination with checkpoint inhibitors as a potential treatment for patients suffering from various solid tumor types. Longer-term, AEMD continues to view the device as a potential tool in the treatment of viruses including Long Covid, organ transplants and other medical areas.

In the U.S., some 44 to 48 million people suffer from Long COVID, or persistent symptoms following the initial illness of acute SARs-CoV-2 infection (COVID-19). These symptoms can include fatigue, post-exertional malaise, shortness of breath, chest pain and cognitive difficulties and they sometimes last for up to a year or longer. Long COVID is estimated to lead to about $2 billion to $6.5 billion of related costs per annum, including costs related to lost productivity when people's work schedules are disrupted, according to a recent study published in the Journal of Infectious Diseases.

The company's Chief Medical Officer, Steven P. LaRosa, M.D, will present the data at the Keystone Symposium on August 12, 2025. The data presented will review the binding of both larger and smaller EVs to GNA lectin and the lectin-based affinity resin, respectively.

THE HEMOPURIFIER

The Hemopurifier® is an investigational extracorporeal device designed to bind and remove harmful extracellular vesicles (EVs), nanoparticles 50-500nm in diameter, from the blood through a combination of plasma separation, size exclusion and binding to a proprietary affinity resin. It is an extracorporeal device – in other words, it works outside the body, as illustrated in the figure below. The device is used on existing blood circulatory equipment such as dialysis and CRRT machines that are already installed in hospitals and clinics, making the Hemopurifier essentially a plug & play tool for medical centers.

The Hemopurifier has received FDA *Breakthrough Device* designation for two independent indications. The Hemopurifier has *Breakthrough Device* designation for the treatment of people with advanced or metastatic cancer who are either unresponsive to or cannot tolerate standard of care therapy, and with cancer types in which exosomes are indicated in the development or severity of the disease and also for life-threatening viruses that are not addressed with approved therapies. In addition to presenting the poster noted above in August, AEMD recently has published papers on preclinical data showing the Hemopurifier's ability to remove platelet-derived EVs from plasma and preclinical data on the Hemopurifier in the Transplant Immunology Journal.



Source: Aethlon Medical

VALUATION

Given the lack of truly effective cancer therapies, we think that there is reason to believe that a cancer indication for the Hemopurifier is an eventual realistic outcome. Clinical evidence supports the role of exosomes in the progression of cancer and, similarly, that removing tumor-derived exosomes from circulation might inhibit tumor growth and/or potentially improve the effectiveness of immunotherapies. As Aethlon pursues studies of the Hemopurifier in a potential cancer indication, we think a growing database of evidence could have important consequences, including potentially influencing key opinion leaders and regulators alike.

We believe the potential utility of the Hemopurifier could be in a broad range of oncology and other treatments. As the company continues to advance the Hemopurifier through clinical efforts towards regulatory approval and hit certain milestones, in turn likely leading to greater awareness and investor interest in the company, we would anticipate multiple expansion on AEMD shares.

As noted, the cancer treatment market unfortunately is large and growing and if clinical testing of the Hemopurifier supports its potential role as an oncology treatment, we would anticipate significant commercial potential. For instance, sales of Keytruda exceeded $20 billion in 2022, according to Merck.

If Aethlon's oncology trials warrants continuing to advance the Hemopurifier for treatment in this area, as management expects, we believe it would not be unreasonable to expect that the company could reach the $90 million revenue range by the 2028-2030 timeframe. Discounting back at about 12%-13% per annum and applying a confidence factor regarding timing and potential further share dilution from of about 25% to 30% leads to a current valuation of about $4.55 per share pro forma for the recent 1-for-8 reverse stock split, which also regained compliance with Nasdaq listing requirements.

We reiterate that our valuation is based on the company's current preliminary development state. It does not incorporate potential from treatment of viruses or in organ transplant or other applications. Moreover, AEMD shares have come under pressure reflecting, we believe, general market and economic uncertainty and the rising interest rate environment. We believe uncertainty could continue to overhang the shares in the near-term, similar to many other early stage pre-revenue life sciences companies, particularly as it is difficult to know the company's revenue arc at this early stage in the development of the Hemopurifier.

While we believe there could be a meaningful revenue opportunity associated with the Hemopurifier within the oncology space, depending on the potential benefits of the Hemopurifier in multiple types of cancers, we do not expect the shares to begin to reflect this at this early stage and, as noted, we believe uncertainty around the company's clinical / commercialization timeline and market / economic uncertainty could continue to overhang the shares in the near-term.

RECENT NEWS

- On July 15, 2025, Aethlon announced that enrollment for Cohort 2 has opened.
- Aethlon announced results on June 26, 2025.
- Aethlon announced on June 9, 2025, its upcoming presentation of new pre-clinical data at the Keystone Symposium on Long COVID and Other Post-Acute Infection Syndromes.
- Aethlon announced publication of preclinical data showing Hemopurifier®'s ability to remove platelet-derived EVs from plasma on May 14, 2025.
- On March 10, 2025, AEMD published preclinical data on the Hemopurifier® in Transplant Immunology Journal.
- On Jan 29, 2025, AEMD treated the first patient in its Hemopurifier® cancer trial in Australia.
- On November 11, 2024, AEMD enrolled the first patient in (FPI) in its Hemopurifier® cancer trial in Australia.
- AEMD received Ethics Committee approval in India for the Hemopurifier® trial on September 19, 2024.
- Aethlon received approval from the Bellberry Human Research Ethics Committee on August 12, 2024.
- On June 18, 2024, Aethlon received Ethics Committee approval from Central Adelaide Local Health Network.
- AEMD reported positive in vitro data on May 10, 2024.
- On February 21, 2024, Aethlon Entered into a materials transfer agreement for Santersus AG's NucleoCapture and HemoNucleoCapture devices.
- AEMD announced 3Q FY24 results on February 14, 2024.
- On November 13, 2023, the company announced that it had named James Frakes as interim CEO.

RISKS

Risks to Aethlon achieving its objectives, and to our valuation, include the following.

- AEMD might need to raise additional capital earlier than or at rates that are more dilutive than expected.
- There might be delays in the company's clinical and subsequent commercialization timelines.
- The clinical trials might not produce the results that management anticipates.
- Despite receiving two FDA Breakthrough Device designations, the FDA approval might take longer than expected or might not come at all.
- The company might not be able to advance the Hemopurifier in various programs.
- Other competing therapies might advance faster in clinical research than the Hemopurifier.

FINANCIAL MODEL

Aethlon Medical Inc.

AEMD ($000s)	1Q25 A	2Q25 A	3Q25 A	4Q25 A	2025 A	1Q26 E	2Q26 E	3Q26 E	4Q26 E	2026 E
Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth					*NM*					
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Margin					*NM*					
OpEx	$2,206.2	$2,640.6	$1,574.5	$708.0	$7,129.4	$1,362.8	$1,317.6	$1,243.0	$3,277.3	$7,200.7
SG&A % of Prod Sales					*NM*					
R&D	$414.7	$261.5	$240.2	$1,295.7	$2,212.0	$452.0	$497.2	$571.8	$713.2	$2,234.1
R&D % Tot Sales										
Operating Income	($2,620.9)	($2,902.1)	($1,814.7)	($2,003.6)	($9,341.4)	($1,814.7)	($1,814.7)	($1,814.7)	($3,990.5)	($9,434.8)
Operating Margin										
Total Other Expense	($49.4)	($95.1)	($60.0)	$4,251.3	$4,046.7	($60.0)	($57.0)	($59.2)	($61.6)	($237.8)
Pre-Tax Income	($2,571.4)	($2,807.0)	($1,754.8)	($6,255)	($13,388)	($1,754.8)	($1,757.8)	($1,755.5)	($3,929)	($9,197)
Other comprehensive inc		$3.8	($13.1)	($0.9)	($10.2)	($13.1)	($12.4)	($12.9)	($13.4)	($51.8)
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Minority interest	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($2,571.4)	($2,803.2)	($1,767.8)	($6,255.8)	($13,398)	($1,767.8)	($1,770.2)	($1,768.4)	($3,942.3)	($9,248.8)
Net Margin										
EPS	($2.76)	($1.61)	($1.01)	($3.10)	($8.58)	($0.68)	($0.68)	($0.67)	($1.49)	($3.53)
Diluted Shares O/S	932	1,742	1,745	2,020	1,561	2,595	2,610	2,625	2,640	2,618

Source: Zacks *Pro forma for reverse stock split*

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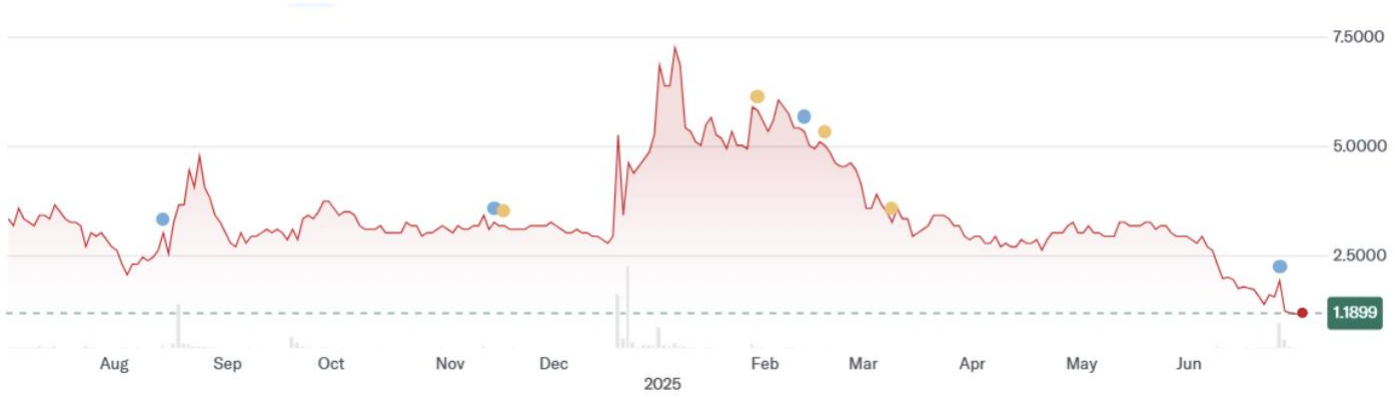
HISTORICAL STOCK PRICE



Source: Yahoo Finance

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