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Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

AEMD: *Oncology Trial Moves Forward as Patient Enrollments Begin, Positive on Cost Containment Measures*

AEMD's lead asset, the Hemopurifier®, is being evaluated in combination with checkpoint inhibitors as a potential treatment for patients suffering from various solid tumor types. With three medical centers in Australia beginning or about to begin patient enrollments, the company has enrolled the first two patients in its basket oncology trial. Separately, James Frakes been named CEO. We view this positively and believe his commitment to cost-cutting measures will enable AEMD to optimize funds available for clinical activities.

OUTLOOK

AEMD recently made some headcount reductions and other cost reductions and stands to benefit from the up to 43.5% cash tax rebate on clinical trial-related R&D costs in Australia. Moreover, conducting studies in both Australia and India will lower overall clinical spending and also enable the company to determine the Hemopurifier's impact on diverse patient populations. The primary endpoint of the trial is safety and it will also assess feasibility and optimal treatment levels. AEMD is optimistic that the trial will show the Hemopurifier's ability in conjunction anti-PD1 agents to improve the body's ability to fight cancer. Longer-term, AEMD continues to view the Hemopurifier as a potential tool in the treatment of viruses, organ transplants and other medical areas.

Current Price (11/13/24)	$0.40
Valuation	**$0.70**

SUMMARY DATA

52-Week High	**$0.98**
52-Week Low	**$0.24**
One-Year Return (%)	**NA**
Beta	**1.75**
Average Daily Volume (sh)	**1,585,448**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$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 2025 Estimate	**N/A**
P/E using 2026 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)
2022	0.1 A	0.1 A	0.0 A	0.0 A	0.3 A
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 E	0.0 E	0.0 E

Earnings / loss per share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	-$1.59 A	-$1.28 A	-$1.57 A	-$2.44 A	-$7.06 A
2023	-$1.88 A	-$1.84 A	-$1.24 A	-$1.07 A	-$5.86 A
2024	-$1.35 A	-$1.22 A	-$1.37 A	-$0.96 A	-$4.86 A
2025	-$0.34 A	-$0.20 A	-$0.23 E	-$0.24 E	-$1.10 E

Quarters might not add to annual reflecting rounding, share counts

Disclosures on page 11

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POSITIVE TAKEAWAYS RECENT INITIATIVES

Patient enrollments begin for AEMD's basket oncology trial

Aethlon Medical (NASDAQ: AEMD) announced FY 2Q results and provided a business update yesterday. The company has made significant strides in moving its clinical activities forward over the past few weeks. The company has enrolled the first two patients in its oncology trial (see below) at the Royal Adelaide Hospital in Australia. Another site that will participate in the study, Pindara Private Hospital in Australia, has also received ethics committee approval and training on the Aethlon Hemopurifier® and is now initiating patient enrollment. The company has also trained staff at a third hospital in Australia and expects this facility to receive formal ethics committee approval in the near-term and begin patient enrollments. Overall, we present our key takeaways in this note.

Key takeaways

- Lead asset the Aethlon Hemopurifier® is being evaluated in combination with checkpoint inhibitors as a potential treatment for patients suffering from various solid tumor types
- With three medical centers in Australia beginning or about to begin patient enrollments, the company has enrolled the first two patients in its basket oncology trial
- James Frakes been named CEO. We view this positively and believe his commitment to cost-cutting measures will enable AEMD to optimize funds available for clinical activities
- AEMD recently made some headcount reductions and other cost reductions and also stands to benefit from the up to 43.5% cash tax rebate on clinical trial-related R&D costs in Australia
- Conducting studies in both Australia and India will lower overall clinical spending and also enable the company to determine the Hemopurifier's impact on diverse patient populations.
- The trial's primary endpoint is safety and it will also assess feasibility and optimal treatment levels
- AEMD is optimistic that the trial will show the Hemopurifier's ability in conjunction anti-PD1 agents to improve the body's ability to fight cancer
- Longer-term, AEMD continues to view the Hemopurifier as a potential tool in the treatment of viruses, organ transplants and other medical areas

In addition, James Frakes, the company's longtime Chief Financial Officer and recently its Interim Chief Executive Officer, has officially been named CEO. We view this positively, reflecting his experience with the company and understanding of the steps needed to move the Hemopurifier forward, as well as his knowledge of financial markets. He is committed to cost-cutting measures to streamline operations and allocate funds primarily to clinical activities. Reflecting this initiative, the company made certain headcount reductions and other cost-cutting measures. In addition, the up to 43.5% cash tax rebate on clinical trial-related R&D costs are expected to optimize spending, as well.

Specifically, AEMD 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. Aethlon had cash of about $6.9 million at the end of the September 2024 quarter to support its efforts and also has an ATM (at the market) mechanism in place. Moreover, Aethlon has a clean capital structure, with no debt and a single share class.

The company's lead asset, the Aethlon Hemopurifier®, is being evaluated as a potential treatment for cancer and life threatening infectious diseases and for use in organ transplantation. The Hemopurifier 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 device 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. The Aethlon Hemopurifier fulfills three primary important relevant functions. The Hemopurifier:

- Separates the plasma
- Size-excludes molecules that are smaller than 200-500 nanometers
- Affinity-binds – i.e. blood enters through one of the device's two ports and then AEMD's proprietary GNA affinity resin isolates structures that have sugar on their surfaces, binds and removes them from the plasma before the plasma is rejoined to the blood and the blood returns to the patient.

Patient enrollments begin for AEMD's basket oncology trial

AEMD's primary focus currently is on researching the Hemopurifier therapeutic blood filtration system as a potential treatment in oncology. AEMD has launched a basket oncology trial 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. It is a phase 1 safety, feasibility and dose-finding study. With a basket trial, the company will administer Hemopurifier treatment to patients suffering from various solid tumor types. 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. Moreover, by focusing on multiple cancers and including patients with a variety of solid tumors, the company has also expanded the opportunities for patient enrollment and can build a database to support regulatory approval. Including both Keytruda and Opdivo® is also expected to facilitate patient enrollments. The goal is to build its database in oncology to help with the development of the Hemopurifier as an oncology treatment.

The clinical activities are being conducted in Australia and India, which has multiple advantages. Clinical development costs generally are lower in both markets. In addition, assessing participants in both markets will also enable the company to determine the Hemopurifier impact on diverse patient populations. Each patient will be its own control, as a patient's EV level pre- and post Hemopurifier treatment will be monitored. If there is a quantifiable decrease in EV levels, the Hemopurifier treatment is expected to improve their T-cell's ability to fight the cancer.

The Aethlon Hemopurifier



Source: Aethlon Medical

Primary endpoint safety; trial will also assess safety, feasibility, dose-finding

The primary endpoint of the roughly 9-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 following two months of PD-1 antibody, Keytruda® or Opdivo® monotherapy. Patients who do not respond to the PD-1 therapy will be eligible to participate in AEMD's Hemopurifier study.

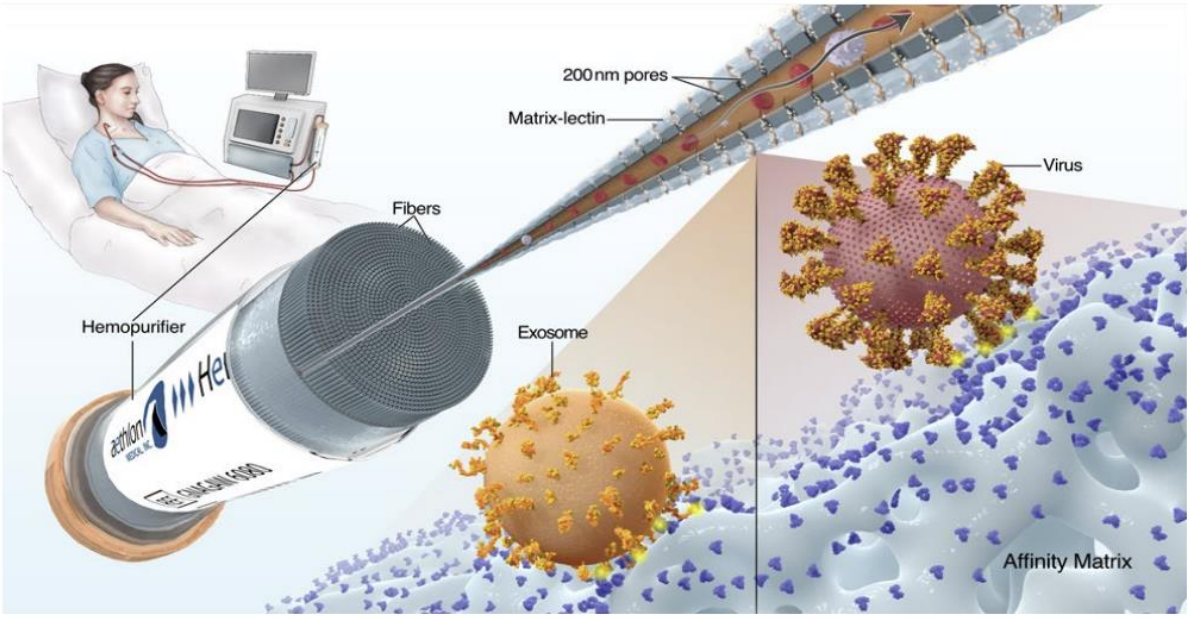
We would expect AEMD to announce that the first patient has been treated possibly by year-end 2024 or early 2025. Subsequently, we would expect AEMD to announce that it has received all the data from the first cohort of patients once the data has come through.

The company's trial will analyze whether the Hemopurifier can help decrease the concentration of EVs in cancer patients and thereby improve overall patient outcomes, as noted. The company's objective in designing the trial was to test the Hemopurifier in a patient population that is already receiving checkpoint inhibitor treatment but could obtain incremental benefit from the Hemopurifier. 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 company expects the Hemopurifier, in conjunction with an inhibitor, can help improve overall patient outcomes and demonstrate proof of concept about the device's benefits in treating solid tumors. The company is optimistic that the trial will show the Hemopurifier's ability in conjunction with Optivo or Keytruda that block anti-PD1 to improve body's cancer fighting ability.

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. Participating patients will be assigned to one of three different cohorts: cohort 1 will receive one Hemopurifier treatment during a one-week period, cohort 2 will receive two treatments and cohort 3 will receive three treatments during a one-week period. Analysis of the data generated from this study will be used to inform the design of a subsequent efficacy and safety, Premarket Approval (PMA), study to move toward regulatory approval. Following completion of treatment, the company will continue to follow patient participants.

Hemopurifier Designed to Remove Harmful Particles From Blood

The Hemopurifier Is designed to capture harmful elements such as viruses and extracellular vesicles (EVs) from a patient's blood, which the company believes could potentially have treatment applications in oncology, for life-threatening viral infections and organ transplantation, among other areas. Aethlon's near-term focus, as noted, is in the oncology space.



Source: Aethlon Medical

Oncology market unfortunately is large

If Aethlon can demonstrate the ability of the Hemopurifier to improve outcomes of cancer patients suffering from a variety of different cancer types, we would anticipate strong commercial prospects for the Hemopurifier. AEMD believes it can generate data to support the Hemopurifier's ability when combined with checkpoint inhibitor treatment to improve outcomes in multiple tumor types where cancer associated extracellular vesicles, or EVs, may promote immune suppression and resistance to anti-PD-1 antibodies. The Hemopurifier has demonstrated the ability to remove exosomes; management believes the device can be used to affect improved outcomes in a number of cancers.

Unfortunately, the oncology population is large. Some 40% of all cancer patients are eligible for checkpoint inhibitor treatment, according to AEMD, with about two million patients treated annually with Keytruda and an additional patient population with Optivo. However, as noted, currently, only about 30% of cancer patients who receive these treatments for solid tumors have lasting clinical responses. If the Hemopurifier, in conjunction with these treatments, can improve outcomes for a higher percentage of patients, the benefits would be substantial, in our view, as would the expected commercial prospects of the Hemopurifier.

The company has indicated that while a few smaller public companies are also developing extracorporeal medical devices, but none are conducting clinical activities in the oncology space. One privately-held company apparently might be entering the oncology space, but the mechanism of action of its device is different from that of the Hemopurifier, according to management.

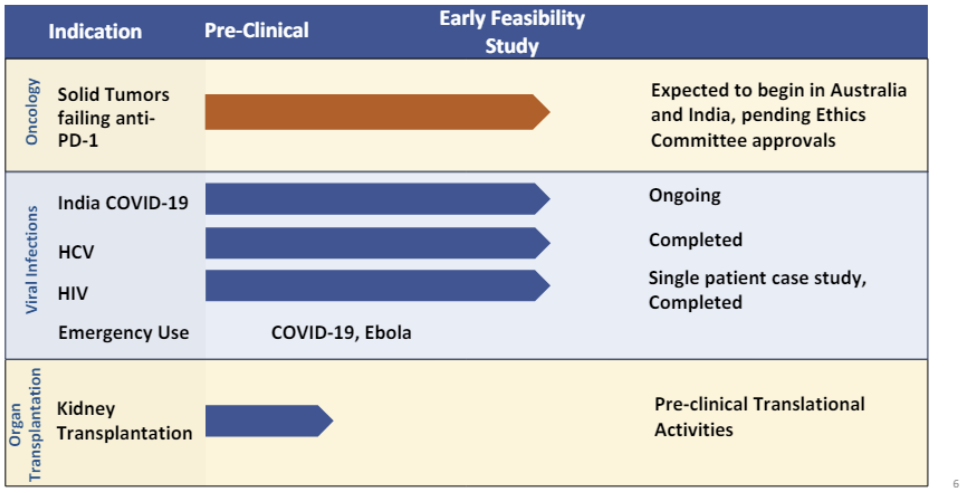
Longer-term Hemopurifier could serve as treatment for a range of indications

Longer-term, the company believes its proprietary GNA affinity resin creates a competitive edge that could make the device beneficial for treatment of a range of indications. The Hemopurifier has demonstrated the potential to remove harmful exosomes and exosomal particles from biological fluids utilizing its proprietary lectin-based technology. This action has potential applications in the area of oncology, where exosomes and exosomal particles are thought to promote immune suppression and metastasis, and in life-threatening infectious diseases.

The company has completed substantial preclinical, in vitro and in human analysis of the Hemopurifier. These activities have demonstrated virus and EV (which include exosomes) clearance both in vitro and in patients. In humans, the Hemopurifier has been administered safely and was well tolerated in 38 patients in an aggregate 164 sessions. The company also recently completed an *in vitro* binding study of relevant oncology targets, to provide pre-clinical evidence to support the upcoming trial design.

AEMD's *in vitro* binding study indicated positive results supporting that the Hemopurifier removes EVs from plasma and provides pre-clinical evidence to support the planned phase 1 safety, feasibility and dose-finding clinical trials in patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment, such as Keytruda® or Opdivo®. 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 the body's immune system from helping the body fight disease. If the Hemopurifier can remove a quantifiable amount of EVs, it is expected it can help improve responses to standard-of-care cancer therapy.

Pipeline Targeting Multiple Indications



Source: Company presentation

Conducting studies in Australia & India helps maximize R&D spending

As noted, the company's believes Australia provides a competitive research environment; importantly, management's comments indicate that data generated in Australia has generally been accepted by the FDA. AEMD is optimistic that the results of the study will support the utility of the Hemopurifier for a range of oncology indications. In addition, overall costs for clinical activities in India is also generally lower. Thus, depending on the results of the study, the study could have broad commercial and economic implications for AEMD, in our view.

VALUATION

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 planned initial oncology trials warrant 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. We are lowering our confidence factor regarding timing to 20% to 25% from 25% to 30% before. Applying this new range leads to a current valuation of about $0.70 per share, revised for the share count following the recent offering. Our confidence factor largely reflects the potential timeline. As noted, 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 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

- Aethlon announced FY 2Q results and provided a business update on November 13, 2024.
- 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 name James Frakes as interim CEO.
- On October 10, 2023, the company announced the receipt of clearance from the Drug Controller General of India for a potential Phase 1 trial of the Hemopurifier® in oncology.
- Aethlon announced a reverse stock split on October 4, 2023.
- The company announced its initiative to study the Hemopurifier to improve organ transplant supply and outcomes on June 21, 2023.

RISKS

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

- AEMD might need to raise additional capital earlier 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.

FINANCIAL MODEL

Aethlon Medical Inc.

AEMD ($000s)	2023 A	1Q24 A	2Q24 A	3Q24 A	4Q24 A	2024 A	1Q25 A	2Q25 A	3Q25 E	4Q25 E	2025 E
Revenue	$574.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	*95.2%*					*NM*					*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	$0.0
Gross Income	$574.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Marain	*NM*					*NM*					*NM*
OpEx	$9,727.9	$2,729.2	$2,546.9	$2,973.7	$1,866.7	$10,116.6	$2,206.2	$2,640.6	$2,859.2	$2,896.9	$10,345.0
SG&A % of Prod Sales	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*					*NM*
R&D	$2,745.0	$678.9	$628.4	$593.4	$619.2	$2,520.0	$414.7	$261.5	$438.2	$446.9	$2,743.6
R&D % Tot Sales											
Operating Income	($11,898.6)	($3,408.2)	($3,175.3)	($3,567.1)	($2,486.0)	($12,636.6)	($2,620.9)	($2,902.1)	($3,297.4)	($3,343.8)	($13,838.6)
Operating Margin											
Total Other Expense	$131.1	($125.0)	($140.9)	($101.0)	($61.6)	($428.4)	($49.4)	($95.1)	($50.2)	($50.6)	($284.5)
Pre-Tax Income	($12,029.8)	($3,283.2)	($3,034.5)	($3,466.1)	($2,424.4)	($12,208.2)	($2,571.4)	($2,807.0)	($3,247.2)	($3,293.2)	($13,554.1)
Other comprehensive inc				$8.0	($8.8)	($0.8)					
Taxes (benefit)	$0.0	$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%*	*0.0%*
Minority interest	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($12,029.8)	($3,283.2)	($3,034.5)	($3,458.2)	($2,424.4)	($12,209.0)	($2,571.4)	($2,807.0)	($3,247.2)	($3,293.2)	($13,554.1)
Net Margin											
EPS	($5.86)	($1.35)	($1.22)	($1.37)	($0.96)	($4.86)	($0.34)	($0.20)	($0.23)	($0.24)	($1.10)
Diluted Shares O/S	2,054	2,431	2,484	2,517	2,515	2,513	7,458	13,938	13,977	13,987	12,340

Source: Zacks *Pro forma for reverse stock split*

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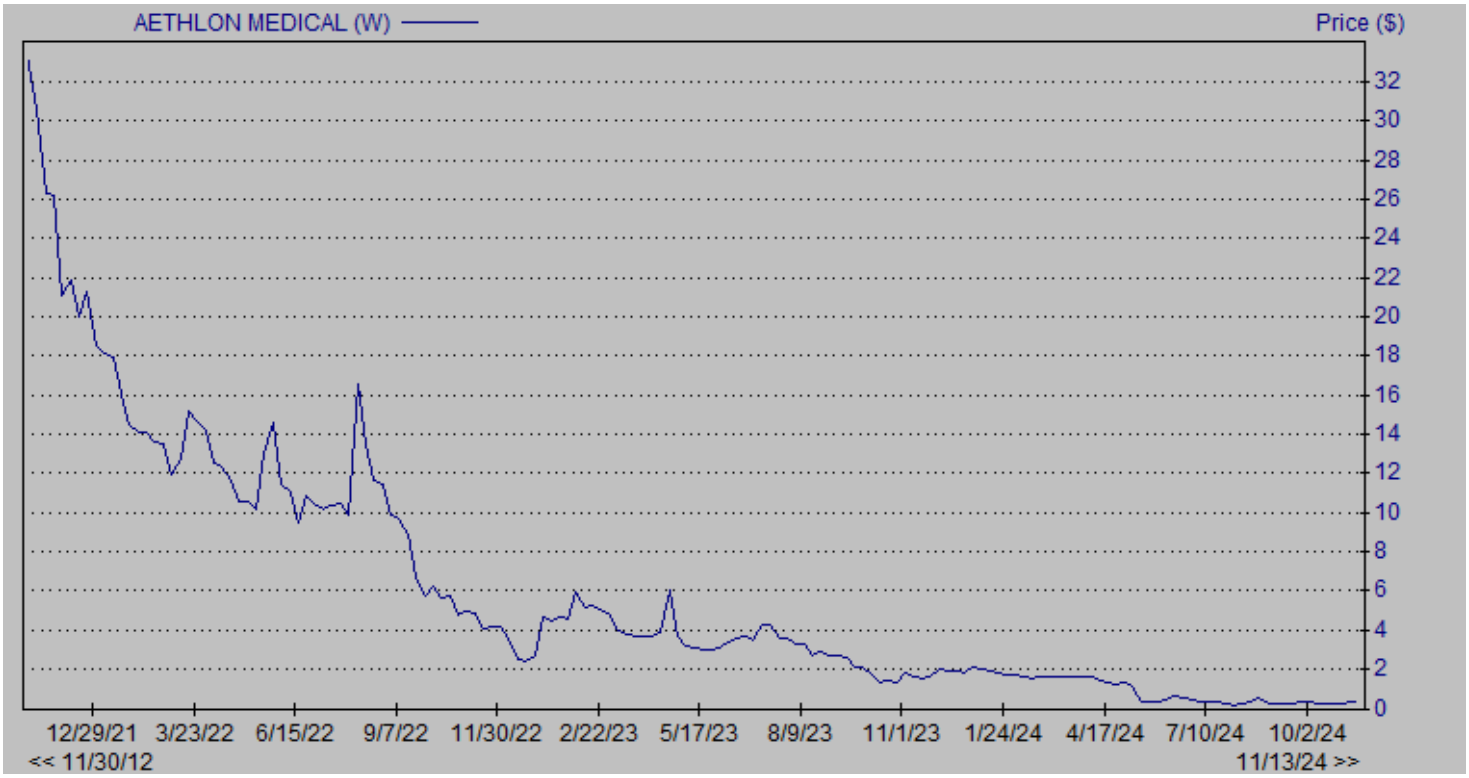
HISTORICAL STOCK PRICE



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