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Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

Hemopurifier To Be Studied in a Variety of Solid Tumors

AEMD has been preparing to launch a blanket oncology trial to study the impact of the Hemopurifier on a variety of cancerous tumors. The company's goal is to build its database in oncology to help with the development of the Hemopurifier as an oncology treatment. AEMD is in fairly advanced discussions to select a new CRO to supervise the planned oncology study.

OUTLOOK

We believe the Hemopurifier's demonstrated pre-clinical positive results in treating tumors, infectious diseases & other conditions warrant further clinical development efforts. Given the device's ability to remove harmful exosomes, AEMD expects to generate positive clinical results safely with a variety of cancerous tumors. A newly launched subsidiary in Australia will conduct clinical research in that market, with an initial focus on oncology. Benefits AEMD sees from this initiative include government R&D tax incentives enabling eligible companies to receive tax rebates on clinical trial-related R&D costs of up to 43.5% & that data from clinical studies in Australia has often been accepted by the FDA. AEMD is also considering launching an oncology trial in India, where its COVID-19 trial site remains open and actively screening patients.

Current Price (11/15/22)	$0.50
Valuation	**$6.00**

SUMMARY DATA

52-Week High	**$3.00**
52-Week Low	**$0.45**
One-Year Return (%)	**-84.0**
Beta	**0.90**
Average Daily Volume (sh)	**293,468**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$10**
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 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**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)
2020	0.0 A	0.0 A	0.4 A	0.2 A	0.7 A
2021	0.0 A	0.0 A	0.6 A	0.0 A	0.7 A
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 E	0.0 E	0.0 E

Earnings / loss per share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	-$1.63 A	-$1.29 A	-$0.28 A	-$0.57 A	-$1.87 A
2021	-$0.15 A	-$0.15 A	-$0.20 A	-$0.16 A	-$0.65 A
2022	-$0.16 A	-$0.13 A	-$0.16 A	-$0.24 A	-$0.71 A
2023	-$0.19 A	-$0.18 A	-$0.18 E	-$0.19 E	-$0.74 E

Quarters might not add to annual reflecting rounding

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KEY POINTS: RECENT BUSINESS UPDATE

Studying the Hemopurifier in a range of cancers

Aethlon Medical (NASDAQ: AEMD) reported 2Q FY 2023 (ends June) results this week and provided a business update. AEMD has been working to launch a blanket oncology trial to study the impact of the Hemopurifier on a variety of cancerous tumors. The company's goal is to build its database in oncology to help with the development of the Hemopurifier as an oncology treatment. The company is fairly advanced in the selection of a new CRO (contract research organization) to supervise the planned oncology study in the U.S. and in Australia (see below). The results of such a trial, if positive, could have broad commercial and economic implications for AEMD, in our view.

Given the Hemopurifier's demonstrated ability to remove exosomes, management believes the device can be used to affect improved outcomes in a number of cancers and will be studied in conjunction with a checkpoint inhibitor such as Keytruda. Keytruda has been used to treat 25+ different types of cancer. 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's earlier trial focused exclusively on the head & neck cancer is being discontinued. Reflecting a lack of patient enrollment by the University of Pittsburgh Medical Center (UPMC) in that safety trial, the company and UPMC decided to terminate it.

Financial funding to move trials forward

The company's actions are intended to maximize its potential to receiving regulatory approval and funding to advance clinical research and accelerate time to market.

- AEMD had $19.6M of cash at the end of 2Q FY 2023 (which equates to about $1 per share).
- The company expects to realize cost savings of up to $5M by discontinuing the U.S. COVID study.
- AEMD intends to allocate the funds to advancing the oncology & potentially other studies.

Regarding the U.S. COVID-19 study, the company recently decided to terminate the agreement with its CRO due to a scarcity of COVID patients in intensive care units eligible for enrollment. AEMD will discontinue COVID clinical trial activity in the U.S., although its Investigational Device Exemption (IDE) related to severe viral infections remains open. The company expects the decision to discontinue this study to result in cost savings of up to $5 million in the next year. AEMD intends to allocate these funds to advancing the blanket oncology study.

Australia

The company launched a wholly owned subsidiary in Australia during the quarter. This subsidiary is designated to conduct clinical research, seek regulatory approval, and commercialize the Hemopurifier in Australia, beginning with an initial focus on the oncology market. The company expects a new CRO will supervise planned oncology studies in the U.S. and Australia.

Aethlon believes Australia offers several advantage for conducting clinical trials, including R&D tax incentives offered by the government. This program enables companies to receive a tax rebate of up to 43.5% on clinical trial related R&D costs. AEMD expects this program can help it reduce costs, lower risk, and accelerate time to market. The company's believes Australia provides a competitive research environment; management's comments indicate that data generated in Australia has generally been accepted by the FDA.

India

AEMD's COVID-19 trial site in India is open. AEMD will shift cartridges to India to use in the COVID-19 study there at Medanta Medicity Hospital, a multi-specialty hospital in Delhi, India. The venue has enrolled one patient in the COVID-19 trial and continues to screen patients actively. The company intends to enroll additional COVID-19 patients. Moreover, the CRO, Qualtran LLC, has identified other potential sites for the trial and is determining the feasibility of adding additional venues.

Separately, AEMD is also considering launching an oncology trial in India. Regulatory authorities in India have accepted a manufacturing change (see below) and the company plans to ship new cartridges to India for use in the company's clinical trials there.

The addition of a second supplier for Galanthus nivalis agglutinin (GNA) that AEMD uses in the resin of the Hemopurifier is pending FDA approval of a supplement to the company's IDE. The FDA has requested additional data, which might take several months to obtain. Although AEMD believes the FDA has mandated unexpectedly high testing requirements for a product in the safety and feasibility stage of development and is engaging the FDA's ombudsman, it is uncertain at this point that the company can help shorten its development timelines.

Future uses of the Hemopurifier include treatment of COVID-19, Monkeypox & other infectious diseases

The Hemopurifier's effectiveness has already been demonstrated in humans in single patient emergency use cases in COVID-19 and in *in vitro* analysis. AEMD intends to continue to demonstrate the effectiveness of the Hemopurifier in a broad range of viruses and conditions, including COVID-19 and various variants and Monkeypox, via in vitro methods and single patient emergency uses when warranted. The company has engaged a key testing lab in Columbus, Ohio, Battelle, to perform an in vitro study to examine the binding of the current Monkeypox strain to a miniature version of the Hemopurifier.

HEMOPURIFIER: BACKGROUND

AEMD's lead product, the Aethlon Hemopurifier®, is a therapeutic blood filtration system that can bind and remove harmful exosomes and life-threatening viruses from blood. The Hemopurifier is a cylindrical cartridge encased with hollow fibers and affinity (i.e. - lectin protein that can bind any particle, virus or exosome, that has mannose sugars on its surface membrane) binding agents. The device is used on existing blood circulatory equipment such as dialysis and CRRT machines that are already installed in hospitals and clinics. This makes the Hemopurifier essentially a plug & play device that can be leveraged easily. The Hemopurifier is designed to aid the body's ability to fight disease by removing viruses and other injurious substances from the blood. After the blood is cleansed, it is then returned to the bloodstream.

The company believes the Hemopurifier has potential applications in cancer, where cancer associated exosomes may promote immune suppression and metastasis, as well as in life-threatening infectious diseases, including removal of COVID-19 virus, associated variants, and related exosomes.

The Hemopurifier has demonstrated positive results in two severely ill patients (discussed below) under individual emergency use and in *in vitro* analysis. The Hemopurifier has produced positive results in binding seven variants of the SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) virus *in vitro*. AEMD's CEO Dr. Charles J. Fisher Jr. and the company's Chief Medical Officer Dr. Steven LaRosa contributed to an article[1] laying out data showing that the Hemopurifier's proprietary GNA (Galanthus nivalis agglutinin) affinity resin successfully was able to bind seven clinically relevant SARS-CoV-2 variants, including the Delta and Omicron variants that have been responsible for recent spikes in cases in multiple regions, *in vitro*.

In simple terms, the Hemopurifier was able to leverage the GNA affinity resin to secure and remove a majority of harmful material of the virus variants. The Hemopurifier is an extracorporeal (i.e. outside of the body) blood filtration device that is designed to selectively remove harmful particles from the circulatory system, using lectin affinity agents. The GNA affinity resin is a key component of the Hemopurifier®. GNA is a plant lectin that attaches to alpha 1,3 mannose sugar units in enveloped viruses. As blood flows through the Hemopurifier, it uses the lectin affinity agents to trap viruses and other target pathogens using the capability of the lectins to specifically bind to the unique high mannose structures of viral glycoproteins. This process, in turn, removes the virus and harmful viral glycoproteins from the body while allowing healthy cells to pass through and back into the circulatory system.

[1] Removal of Clinically Relevant SARS-CoV-2 Variants by An Affinity Resin Containing Galanthus nivalis Agglutinin, published in bioRxiv

Examples of successful use of the Hemopurifier

The company has already demonstrated that the Hemopurifier can be used to treat other viruses and harmful agents, including West Nile virus and Monkey pox, among many others. A laboratory version of the Hemopurifier has also been shown to clear multiple other viruses in vitro, including a model version of the Middle Eastern Respiratory Syndrome (MERS) virus that is a coronavirus from the same family as the SARS-CoV-2 virus that causes COVID-19. The Hemopurifier has previously been tested in patients with hepatitis C virus (HCV) infection and in one patient with Ebola virus infection. Given the demonstrated ability of the technology to bind and clear other coronavirus diseases, such as the recent MERS strain, and shown effectiveness against all highly glycosylated viruses with which it has been validated, it is conceivable that the device could have utility against COVID-19, as well. Importantly, COVID-19 potentially represents a new opportunity to provide additional proof-of-concept and validate the Hemopurifier against another deadly disease, as well as a possible revenue opportunity for the company.

The Hemopurifier has demonstrated effectiveness against monkey pox. In 2008, AEMD commissioned Battelle Memorial Institute to run a monkey pox virus (MPV) *in vitro* study. Results of that study demonstrated that high concentrations of MPV (approximately 35 thousand cpu/ml) were rapidly depleted from cell culture fluids that were circulated through the Hemopurifier. Within 20 hours, the Hemopurifier had removed nearly all (98%) of infectious MPV.

Monkey pox study: Hemopurifier infectious MPV removal

- 44% in the first hour of testing
- 82% after six hours
- 98% after 20 hours

Specifically, the data indicated that the Hemopurifier removed 44% of infectious MPV in the first hour of testing, 82% after six hours, and 98% after 20 hours. The studies were conducted in triplicate and data verification was provided by real-time polymerase chain reaction.

The recent *in vitro* study supports AEMD's hypothesis that the Hemopurifier's viral binding would be unaffected by spike protein mutations. In other words, the company believed the Hemopurifier would be effective treating most, if not all, COVID-19 virus mutations because the mutations all contain sugar mannose structures which the Hemopurifier can bind and remove without harming healthy cells. To test this hypothesis, known concentrations of seven clinically relevant SARS-CoV-2 variants were spiked in medium and passed three times over columns containing 1 gm of GNA affinity resin.

Growing database on the efficacy and benefits of the Hemopurifier

The in vitro data adds to data supporting the efficacy of the Aethlon Hemopurifier® in binding and eliminating SARS-CoV-2 from the blood *in vivo*. The in vitro results add to a growing database on the efficacy and benefits of the HP, including in treating patients with the COVID-19 virus. In 2021, AETH was asked to use the Hemopurifier to treat two patients who were critically ill with COVID-19[2] following other treatment therapies. Neither patient was expected to survive. The Hemopurifier therefore was used under the FDA emergency use authorization (EUA). In other words, the use of a treatment that has not yet been fully approved by the FDA was implemented because the doctors were out of options.

[2] See Removal of COVID-19 Spike Protein, Whole Virus, Exosomes and Exosomal microRNAs by the Hemopurifier® Lectin-Affinity Cartridge in Critically Ill Patients with COVID-19 Infection

RECENT RESULTS

AEMD did not recognize any revenue for the quarter ended September 30, 2022 as a result of not achieving certain milestones in NIH contracts. At the end of the period, the company had roughly $574,000 of deferred revenue related to NIH contracts. The NIH award contract ended on September 15, 2022. The company expects to recognize the $574,000 as revenue once the NCI completes the review of the contract. Operating expenses were roughly $3.7 million compared to $2.1 million for 2Q FY 2021. The 71% increase primarily reflected higher G&A, professional fees and payroll and related expenses to support R&D activities. In addition, reflecting the dissolution of ESI (Exosome Sciences Inc.) in September, formerly AEMD's subsidiary, the company recorded a non-cash charge of about $142,000. The company reported a net loss of about $3.8 million..

AEMD raised roughly $8.9 million in net proceeds under its existing ATM agreement in 1H FY 2023 and had a cash balance of about $19.6 million, as noted, at the end of the period. We note that the company's cash translates into cash per share of about $1, which is well above the current price of AEMD shares.

VALUATION

Following the recent dissolution of Exosome Sciences, Inc. (ESI), which had formed a part of our sum-of-the-parts valuation, we modify our overall valuation for AEMD shares. Historically, we have valued AEMD shares based primarily on the estimated fair value of the Hemopurifier in cancer, virus, pathogen and other applications at about $90 million, which remains unchanged.

We believe there could be upside to this valuation, depending on the potential benefits of the Hemopurifier in multiple types of cancers. Given the unfortunate prevalence of cancer and lack of truly effective 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.

This equates to a valuation of approximately $5 per share at this stage plus about $1 per share of cash on hand, for a valuation of about $6 per share. We reiterate that our valuation is based on the company's current preliminary development state and could change with achievement of certain milestones. Moreover, we believe that there could be a more meaningful revenue opportunity associated with expanding the number of treatment options for the Hemopurifier within the oncology space. We believe near-term uncertainty around the company's clinical / commercialization timeline could overhang the shares.

RECENT NEWS

- The company announced 3Q FY 2023 results on November 14, 2022.
- The FDA approved a supplement to AEMD'S COVID-19 trial on July 6, 2022.
- The company announced results of the Hemopurifier on *in vitro* COVID-19 variants on May 2, 2022.
- Aethlon Medical, Inc. appointed Angela Rossetti to its board on Mar 28, 2022.
- On October 12, 2021, AEMD announced the peer-reviewed publication of two case studies of critically ill COVID-19 patients who were treated with the Hemopurifier®.
- Aethlon Medical Announces Contracting with PPD to Advance Hemopurifier Clinical Programs on September 30, 2021.
- On June 3, 2021, Aethlon published case studies of two critically ill COVID-19 patients who were treated with the Hemopurifier®.
- Aethlon expanded its leadership team with the appointment of two key positions on January 6, 2021.

RISKS

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

- AEMD might need to raise additional capital earlier than expected.
- COVID-19 might delay the company's clinical and subsequent commercialization timelines.
- Other factors might also impact the clinical study 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)	2018 A	2019 A	2020 A	2021 A	1Q22 A	2Q22 A	3Q22 A	4Q22 A	2022 A	1Q23 A	2Q23 A	3Q23 E	4Q23 E	2023 E
Year ends March 31														
Revenue	$149.6	$229.6	$650.2	$659.1	$132.0	$132.0	$17.1	$13.1	$294.2	$0.0	$0.0	$14.7	$15.3	$30.0
YOY Growth		*53.5%*	*183.2%*	*1.4%*	*NM*	*NM*	*-97.3%*	*-61.8%*	*-54.8%*		*NM*	*-14.0%*	*17.0%*	*-95.4%*
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	$0.0	$0.0	$0.0
Gross Income	$149.6	$229.6	$650.2	$659.1	$132.0	$132.0	$17.1	$13.1	$294.2		$0.0	$14.7	$15.3	$30.0
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*NM*		*NM*	*NM*	*NM*	*NM*		*NM*	*NM*	*NM*	*NM*
OpEx	$4,394.7	$5,332.6	$5,653.2	$6,477.02	$1,642.59	$1,662.6	$2,190.5	$2,878.4	$8,374.1	$2,047.73	$2,812.85	$2,965.58	$2,995.24	$10,821.40
SG&A %of Prod Sales	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
R&D	$586.0	$896.0	$927.0	$2,072.0	$587.7	$478.2	$354.6	$920.5	$2,341.0	$858.3	$852.5	$948.4	$957.9	$3,617.2
R&D %Tot Sales	*391.7%*	*390.2%*	*142.6%*	*314.4%*	*445.3%*	*362.3%*	*2071.5%*	*7036.7%*						
Operating Income	($4,831.1)	($5,999.0)	($5,930.0)	($7,889.9)	($2,098.3)	($2,008.8)	($2,527.9)	($3,785.8)	($10,420.9)	($2,906.1)	($3,665.3)	($3,899.3)	($3,937.9)	($14,408.5)
Operating Margin	-	-												
Total Other Expense	$868.7	$220.5	$450.1	$1.6	$0.1	$0.0	$0.0	$0.8	$0.0	$0.0	$142.1	$0.5	$0.5	$143.1
Pre-Tax Income	($5,699.8)	($6,219.5)	($6,380.1)	($7,891.5)	($2,098.4)	($2,008.8)	($2,527.9)	($3,786.6)	($10,420.9)	($2,906.1)	($3,807.4)	($3,899.8)	($3,938.4)	($14,551.7)
Taxes (benefit)	$0.0	$0.0	$0.0	$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%*	*100.0%*	*200.0%*	*300.0%*	*400.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Minority interest	($20.3)	($24.8)	($6.1)	($4.8)	$1.1	($0.8)	($2.2)	($2.9)	($4.8)	($0.4)	$0.0	$0.0	$0.0	($0.4)
Net Income	($5,679.6)	($6,194.8)	($6,374.0)	($7,886.7)	($2,099.6)	($2,008.0)	($2,525.7)	($3,783.7)	($10,416.1)	($2,905.7)	($3,807.4)	($3,899.8)	($3,938.4)	($14,551.3)
Net Margin			*-980.3%*											
EPS	($6.92)	($5.13)	($1.87)	($0.65)	($0.16)	($0.13)	($0.16)	($0.24)	($0.71)	($0.19)	($0.18)	($0.18)	($0.19)	($0.74)
Diluted Shares O/S	821	1,208	3,415	12,091	12,829	15,386	15,397	15,447	14,757	15,487	20,745	21,945	20,351	18,757

Source: Zacks *Pro forma for 10/2019 reverse stock split*

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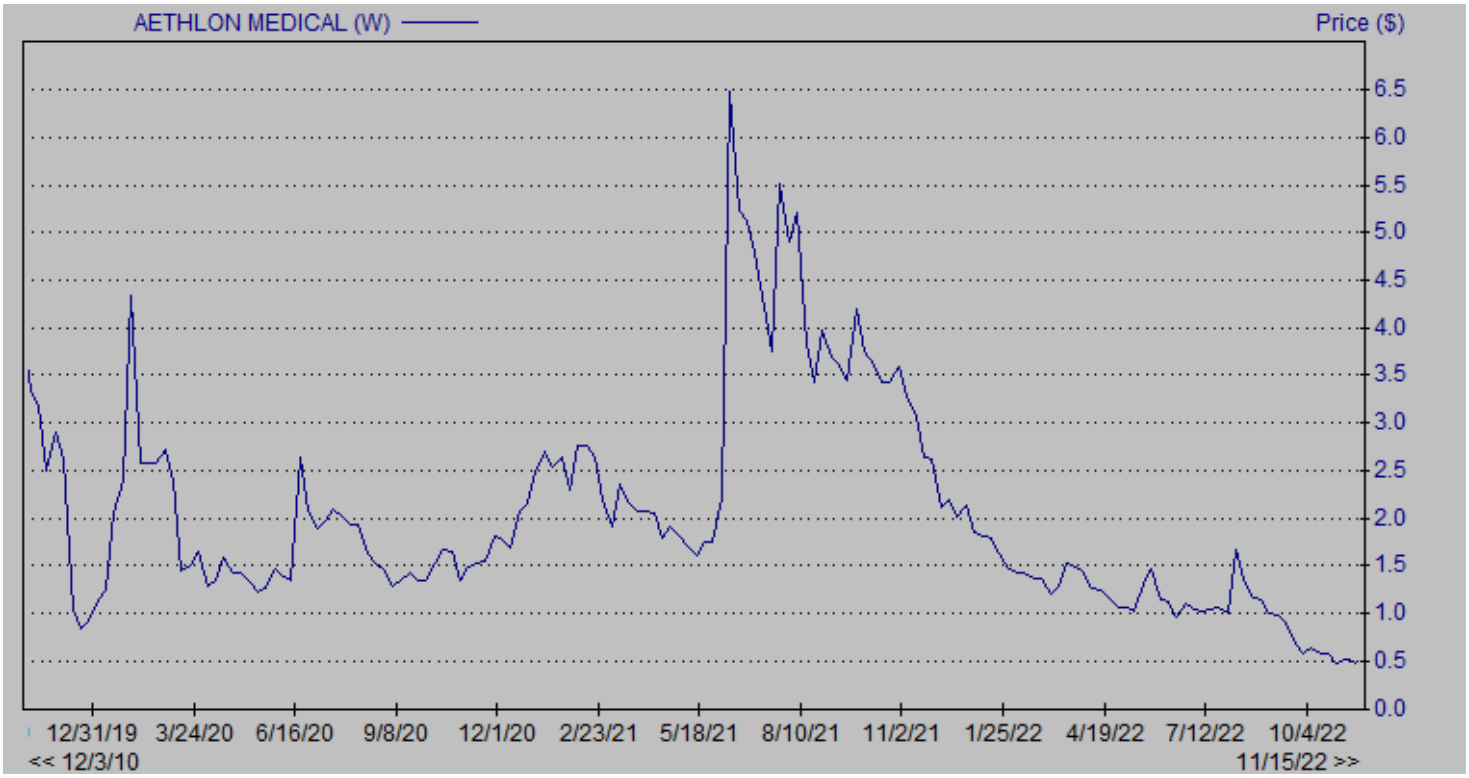
HISTORICAL STOCK PRICE



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