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Aethlon Medical (AEMD-NASDAQ)

Maximizing R&D Spending to Facilitate Clinical Efforts, Advance Hemopurifier

To advance its lead product, the Hemopurifier® medical device, the company's current focus for clinical studies is in the areas of oncology and infectious disease. Recent measures include pivoting clinical efforts to Australia & India, where AETH expects clinical spending will go further. Aethlon is launching a blanket oncology study in Australia & recently received approval to initiate a 2nd site in its trial studying the Hemopurifier to treat severe COVID-19 in India.

OUTLOOK

Studying the Hemopurifier in multiple cancer types is expected to facilitate trial enrollments & augment the database supporting the benefits of the Hemopurifier on a variety of cancerous tumors. Given the Hemopurifier's demonstrated ability to remove exosomes, management believes that using the Hemopurifier to remove exosomes, in conjunction with checkpoint inhibitor treatment, can increase the percent of patients who can benefit from combined treatment, with data expected to support the Hemopurifier's broad utility. By focusing clinical efforts in Australia and India and subsequently the U.S., the company expects to realize cost savings and maximize its R&D spending.

Current Price (6/7/23)	$0.36
Valuation	**$5.00**

SUMMARY DATA

52-Week High	**$2.46**
52-Week Low	**$0.23**
One-Year Return (%)	**-68**
Beta	**1.18**
Average Daily Volume (sh)	**884,547**
Shares Outstanding (mil)	**23**
Market Capitalization ($mil)	**$8**
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 2023 Estimate	**N/A**
P/E using 2024 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)
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 A	0.0 E	0.0 E
2024	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)
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	-$0.12 A	-$0.16 E	-$0.65 E
2024	-$0.13 E	-$0.14 E	-$0.14 E	-$0.14 E	-$0.55 E

Quarters might not add to annual reflecting rounding

Disclosures on page 10

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KEY POINTS: FOCUSING CLINICAL ACTIVITIES IN INDIA & AUSTRALIA

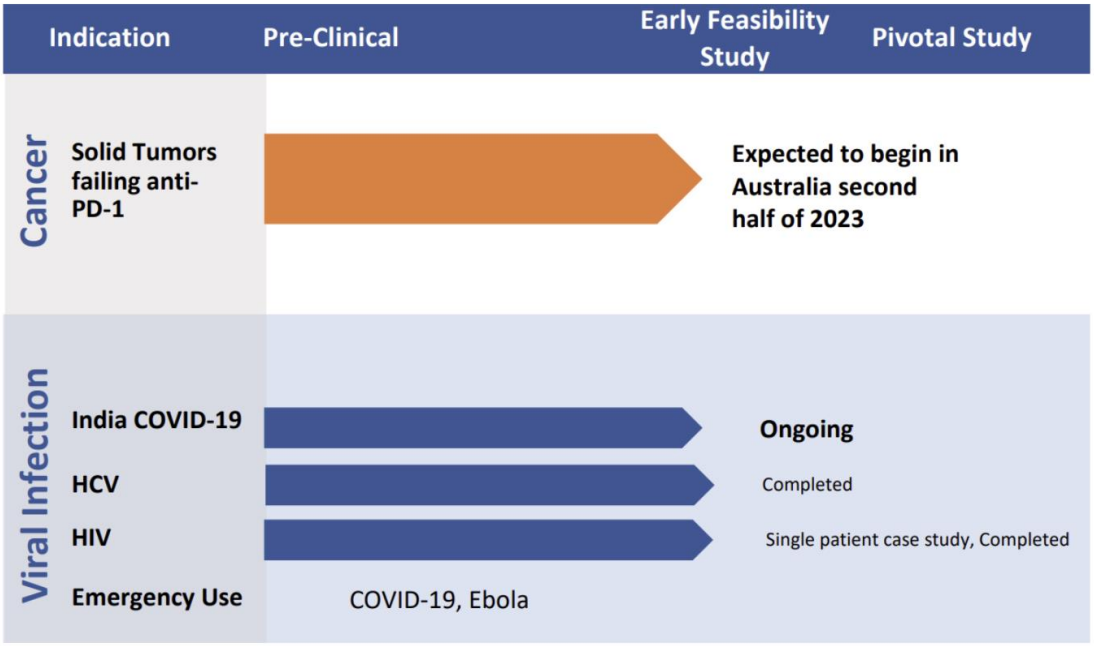
Aethlon Medical (NASDAQ: AEMD) has implemented several recent initiatives to maximize its R&D spending in order to advance its lead product, medical device the Aethlon Hemopurifier®, through clinical studies towards obtaining regulatory approval and commercialization. The company's current focus for clinical studies of the HemoPurifier is in the areas of oncology and infectious disease. Recent measures Aethlon has taken include:

- Pivoting clinical efforts to Australia & India, where AETH expects clinical spending will go further
- Launching blanket oncology study in Australia
- Sars-Cov-2 clinical trials in India; received approval for a 2nd hospital site
- New Chief Scientific Officer
- Materials transfer agreement to study the HemoPurifier in "Long COVID-19"

Maximizing R&D spending …

By terminating the prior head-and-neck study and shifting its clinical efforts to Australia, while maintaining efforts in India, the company's actions are intended to maximize its R&D spending. The company expects to realize cost savings of up to $5M by discontinuing a U.S. cancer and COVID study and benefit from attractive economic incentives the Australian government provides for clinical development efforts. AEMD believes its recent initiatives can boost the potential to receive regulatory approval and funding to advance clinical research and accelerate time to market. AEMD intends to maintain its clinical efforts in India, where the cost of R&D is substantially below that in the U.S., according to management.

Aethlon Clinical Development Activities Target Multiple Indications



Source: Company presentation

As of the end of the December quarter, AEMD had a cash balance of about $17.5 million to further its clinical activities and no debt. The cash balance translates into cash per share of about $0.76, which is well above the current price of AEMD shares.

India
Initially studying the Hemopurifier in COVID ICU patients

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 and treated one patient in the COVID-19 trial and continues to screen patients. Along with its CRO, Qualtran LLC, the company intends to enroll additional COVID-19 patients and recently received approval to initiate a second site in the clinical trial studying the Hemopurifier to treat severe COVID-19 in India.

AETH will add the Maulana Azad Medical College (MAMC) as a second site for its clinical trial of the Hemopurifier to treat severe COVID-19 in India. Established in 1958, MAMC is located in New Delhi, India and is affiliated with the University of Delhi. With ongoing cases of COVID-19 infection that require hospitalization, the company views the addition of MAMC as a second clinical venue that expands its prospects for patient enrollment. The clinical trial of the Hemopurifier in patients with SARS-CoV-2 in the ICU with severe or life-threatening disease is designed to enroll up to 15 patients at up to three centers in India.

Australia
Studying the Hemopurifier in a range of cancers

AEMD is launching a blanket oncology trial to study the impact of the Hemopurifier on a variety of cancerous tumors. By shifting its focus from studying the Hemopurifier in only head-and-neck cancer (an earlier study at the University of Pittsburgh Medical Center that focused exclusively on head & neck cancer was terminated), the company believes it has improved prospects for patient enrollments and for building a database to support regulatory approval. The company expects multiple medical centers to participate in the study, which expands the opportunities for patient enrollment. Moreover, the company has also expanded the opportunities for patient enrollment by including patients with a variety of solid tumors. 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.

According to the NIH (National Institutes of Health), "The percentage of patients estimated to respond to checkpoint inhibitor drugs was 0.14% in 2011 and increased to 12.46% in 2018." AEMD places the percentage higher at this point, at an estimated roughly 30%. That means that the majority of patients do not respond to checkpoint inhibitors. The company's hypothesis is that using the Hemopurifier to remove exosomes, in conjunction with treatment of checkpoint inhibitors, can increase the percent of patients who can benefit from combined treatment.

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. Checkpoint inhibitors such as Keytruda, which specifically has been used to treat 25+ different types of cancer, have proven effective in some patients, but many (the majority) do not benefit. 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 created a wholly owned subsidiary in Australia to conduct clinical research, seek regulatory approval, and commercialize the Hemopurifier in Australia. Aethlon believes Australia offers several advantages 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; importantly, management's comments indicate that data generated in Australia has generally been accepted by the FDA.

in vitro
Studying the Hemopurifier in Long COVID-19…

AEMD has entered into a materials transfer agreement with the UCSF Medical Center for the study of Post-acute Sequelae of COVID-19 infection (PASC), or "Long COVID-19." The objective is to perform in vitro analysis of exosomes to determine the viability of PASC as a therapeutic target for the Hemopurifier. The company will receive plasma samples from patients with PASC and from patients with prior COVID-19 without PASC symptoms to conduct in vitro analysis.

In terms of COVID-19 generally, the Hemopurifier's effectiveness has already been demonstrated in humans in single patient emergency use cases in COVID-19 and in *in vitro* analysis. Recent *in vitro* analysis supports AEMD's hypothesis that the Hemopurifier's viral binding would be unaffected by spike protein mutations of the SARS-CoV-2 virus. 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 to advance Hemopurifier …

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 optimistic that the results of the study will support the utility of the Hemopurifier for a range of oncology indications. Thus, depending on the results of the study, the study could have broad commercial and economic implications for AEMD, in our view.

The company has selected a new CRO (contract research organization) to supervise the planned oncology study in Australia and in the U.S. AEMD recently contracted with NAMSA, LLC, a prominent MedTech CRO that operates globally. The new oncology clinical trial is planned to be a safety, feasibility and dose finding trial in solid tumors failing anti-PD-1 antibodies.

Chief Scientific Officer

The company also recently named Lee Arnold, PhD. as its new Chief Scientific Officer. Dr. Arnold has 36 years of experience in molecularly-targeted drug discovery and has worked in big pharma and several start-up biotech firms. He began his career in pharma research at Syntex, Inc. and also has worked at Pfizer, OSI Pharmaceuticals and BASF, among other big pharma companies. Prior to joining Aethlon, he was the CSO and cofounder of Pardes Biosciences, Inc., which was launched as the COVID pandemic got underway. Pardes Bioscience discovered and advanced the oral protease inhibitor, pomotrelvir, into clinical trials for SARS-CoV2. Overall, his experience and leadership contributions have resulted in an approved drug, and 16 additional development candidates undergoing clinical trials in oncology, immunology and virology.

At Pfizer, he invented Tarceva® (erlotinib) for non-small cell lung cancer. At BASF/Abbott Bioresearch Center, he launched and headed two multinational multidisciplinary projects in angiogenesis that ultimately resulted in linifanib (ABT-869). As VP of Research at OSI Pharmaceuticals, his teams discovered four oncology development candidates, including linsitinib (IGF-1R), and ASP7486 (TORC1/2). He has authored multiple papers in the areas of biophysics and biochemistry.

GROWING DATABASE SUPPORTS HEMOPURIFIER'S BROAD POTENTIAL

The Aethlon Hemopurifier® is a therapeutic blood filtration system that can bind and remove harmful exosomes and life-threatening viruses from blood. The device, which has received FDA *Breakthrough Device* designations, 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.

As noted, 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. Data from previous pre-clinical efforts, clinical trials, in vitro studies and single use emergency cases support multiple benefit of the Hemopurifier.



Source: Company presentation

Efficacy & benefits of the Hemopurifier from in vitro data, single use emergency data

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 Hemopurifier, 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[1] 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.

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[2] 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*.

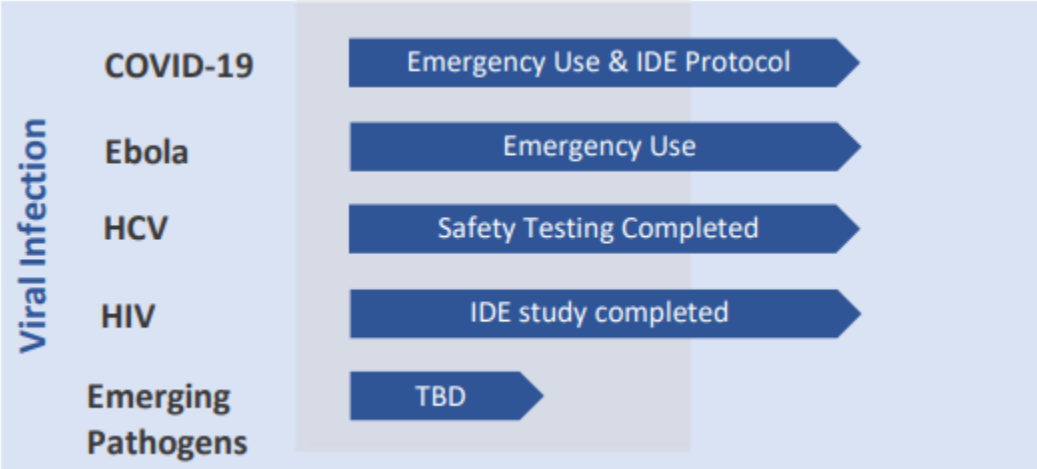
In simple terms, the Hemopurifier was able to leverage the GNA affinity resin to secure and remove a majority of harmful material of the virus variants. The Hemopurifier is an extracorporeal (i.e. outside of the body) blood filtration device that is designed to selectively remove harmful particles from 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] 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

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

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.

Hemopurifier® Growing Database



Source: Company presentation

… other viruses and conditions

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. 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 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 and intends to continue to demonstrate the effectiveness of the Hemopurifier in a broad range of viruses and conditions via in vitro methods and single patient emergency uses when warranted.

VALUATION

We value AEMD shares based primarily on the estimated fair value of the Hemopurifier in cancer, virus, pathogen and other applications at about $90 million. This equates to a valuation of approximately $5 per share at this stage. 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.

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. We note that AETH had about $0.76 per share of cash on hand at the end of calendar 2022.

RECENT NEWS

- The company received approval of a 2nd clinical site in India on May 22, 2023.
- The company announced 3Q FY 2023 results on February 13, 2023.
- On January 30, 2023, Aethlon announced a new contract with NAMSA to advance the Hemopurifier through clinical programs in cancer.
- The company announced 2Q 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®.

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)	2021 A	1Q22 A	2Q22 A	3Q22 A	4Q22 A	2022 A	1Q23 A	2Q23 A	3Q23 A	4Q23 E	2023 E	2024 E
Year ends March 31												
Revenue	$659.1	$132.0	$132.0	$17.1	$13.1	$294.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	*1.4%*	*NM*	*NM*	*-97.3%*	*-61.8%*	*-54.8%*		*NM*	*-100.0%*	*-100.0%*	*-100.0%*	*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	$0.0
Gross Income	$659.1	$132.0	$132.0	$17.1	$13.1	$294.2		$0.0	$0.0	$0.0	$0.0	$0.0
Gross Margin	*NM*		*NM*	*NM*	*NM*	*NM*		*NM*	*NM*	*NM*	*NM*	*NM*
OpEx	$6,477.02	$1,642.59	$1,662.6	$2,190.5	$2,878.4	$8,374.1	$2,047.73	$2,812.85	$2,291.53	$2,995.24	$10,147.35	$10,299.56
SG&A %of Prod Sales	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	
R&D	$2,072.0	$587.7	$478.2	$354.6	$920.5	$2,341.0	$858.3	$852.5	$558.2	$669.87	$2,938.9	$3,003.7
R&D %Tot Sales	*314.4%*	*445.3%*	*362.3%*	*2071.5%*	*7036.7%*							
Operating Income	($7,889.9)	($2,098.3)	($2,008.8)	($2,527.9)	($3,785.8)	($10,420.9)	($2,906.1)	($3,665.3)	($2,849.8)	($3,665.1)	($13,086.2)	($13,303.2)
Operating Margin												
Total Other Expense	$1.6	$0.1	$0.0	$0.0	$0.8	$0.0	$0.0	$142.1	$0.0	$0.5	$142.6	$0.0
Pre-Tax Income	($7,891.5)	($2,098.4)	($2,008.8)	($2,527.9)	($3,786.6)	($10,420.9)	($2,906.1)	($3,807.4)	($2,849.8)	($3,665.6)	($13,228.9)	($13,303.2)
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
Tax Rate	*0.0%*	*100.0%*	*200.0%*	*300.0%*	*400.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Minority interest	($4.8)	$1.1	($0.8)	($2.2)	($2.9)	($4.8)	($0.4)	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($7,886.7)	($2,099.6)	($2,008.0)	($2,525.7)	($3,783.7)	($10,416.1)	($2,905.7)	($3,807.4)	($2,849.8)	($3,665.6)	($13,228.9)	($13,303.2)
Net Margin												
EPS	($0.65)	($0.16)	($0.13)	($0.16)	($0.24)	($0.71)	($0.19)	($0.18)	($0.12)	($0.16)	($0.64)	($0.55)
Diluted Shares O/S	12,091	12,829	15,386	15,397	15,447	14,757	15,487	20,745	22,946	23,114	20,573	24,024

Source: Zacks *Pro forma for 10*

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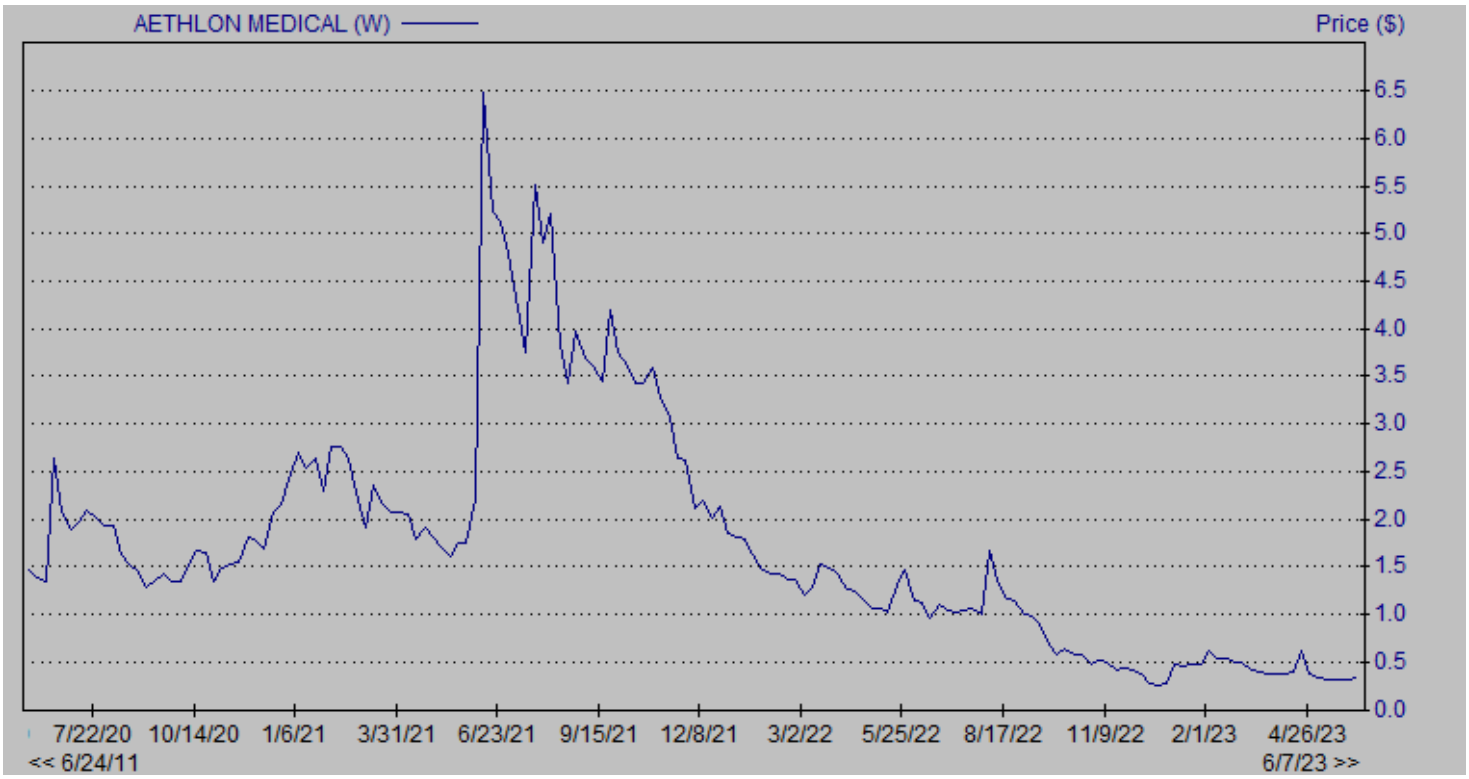
HISTORICAL STOCK PRICE



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