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Aethlon Medical (AEMD-NASDAQ)

Focusing on Oncology, Infectious Disease & Organ Transplants

AEMD is studying lead product, the Hemopurifier®, in oncology, infectious disease & a recent initiative to determine the device's ability to improve the outcomes of organ transplantation. AEMD has formed a research collaboration with 34 Lives, a PBC focused on improving the kidney transplant process. AEMD is launching a blanket oncology study in Australia & studying the Hemopurifier to treat severe COVID-19 in India, where it is also considering adding an oncology trial.

OUTLOOK

AEMD's recently announced initiative to study the Hemopurifier's ability to improve the outcomes of organ transplantation will focus initially on the kidney transplant process. The NIH notes that kidneys are the most commonly transplanted organ. "In 2022, approximately 115,000 patients in the US were awaiting organ transplants. Of these, 96,000 were waiting for a kidney," according to 34 Lives. Moreover, 34 Lives also notes that "In 2022, over 7,800 kidneys were recovered with the intent to be transplanted but were unused." Reducing the number of unused organs could potentially lead to significant improvements in outcomes for patients, in our view, & AEMD is optimistic that the device can help increase the number of kidneys that are viable for transplant.

Current Price (8/11/23)	$0.34
Valuation	**$4.01**

SUMMARY DATA

52-Week High	**$1.39**
52-Week Low	**$0.23**
One-Year Return (%)	**-75**
Beta	**1.20**
Average Daily Volume (sh)	**317,895**
Shares Outstanding (mil)	**25**
Market Capitalization ($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 2024 Estimate	**N/A**
P/E using 2025 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	0.6 A	0.6 A
2024	0.0 A	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	-$0.11 A	-$0.59 A
2024	-$0.14 A	-$0.13 E	-$0.13 E	-$0.12 E	-$0.52 E

Quarters might not add to annual reflecting rounding

Disclosures on page 11

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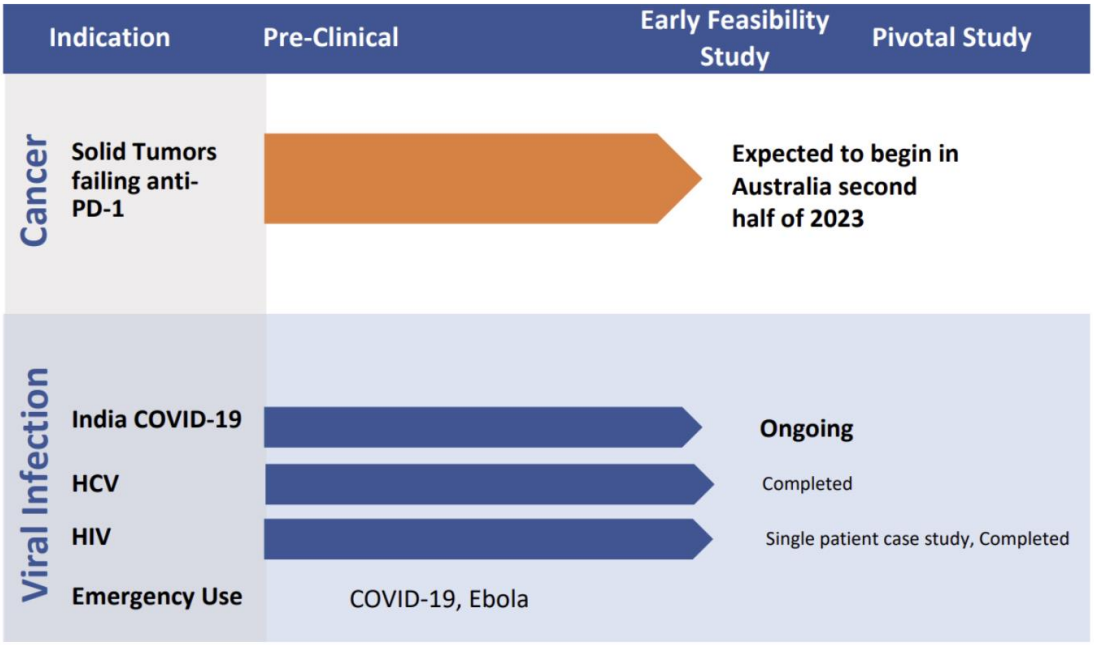
FOCUSING INITIAL EFFORTS ON ONCOLOGY, INFECTIOUS DISEASE, TRANSPLANTS

R&D spending expected to go further by conducting current clinical efforts in Australia & India

Aethlon Medical (NASDAQ: AEMD) provided a business update last week. As the company has indicated, AEMD's current focus for clinical studies of the Aethlon Hemopurifier®, its lead product, is in the areas of oncology, followed by infectious disease. AEMD also recently announced an initiative to determine the Hemopurifier's ability to improve the outcomes of organ transplantation in addition to its existing cancer and COVID-19 studies.

The company's goal is to maximize its R&D spending to advance the Hemopurifier. By recently shifting its clinical efforts to Australia and India for now, Aethlon expects to maximize its R&D dollars. 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. AEMD believes its recent initiatives can boost the company's potential to receive regulatory approval and funding to advance clinical research and accelerate time to market.

Aethlon Clinical Development Activities Target Multiple Indications



Source: Company presentation

Organ transplant initiative: potentially helping to increase the availability of viable organs

Aethlon will investigate the Hemopurifier's ability to remove viruses and exosomes from harvested organs to increase the number of organs that can be transplanted successfully. The company will study whether the Hemopurifier can remove viruses and exosomes from harvested organs when it is incorporated into a machine perfusion organ preservation circuit. In vitro studies using a scaled-down version of the Hemopurifier demonstrated the removal of multiple viruses and exosomes from buffer solutions. The company believes that if the Hemopurifier can remove these substances from the organs, the device could lower the risk of complications following transplantation, including potentially viral infection, delayed graft function and organ rejection. The objective is to position the Hemopurifier as an additive way to increase the supply of viable organs available to be transplanted.

By incorporating the Hemopurifier into a machine perfusion organ preservation circuit, the company will study whether the device can remove harmful viruses and exosomes from pre-transplant organs. The initial focused will be on kidneys and studies will be conducted through a research collaboration with 34 Lives, a PBC (public benefit company) that is focused on improving the kidney transplant process. The process potentially may reduce complications such as viral infection, delayed graft function and even rejection following transplant surgery. Because the Hemopurifier will be incorporated into the existing machine perfusion organ preservation circuit, it will

not extend the organ preservation timeline, which is critical given that organs have a short window during which they remain viable for transplantation.

Currently, the global transplantation market is in the multiple billions of dollars and is expected to grow substantially, driven by the aging of the population, higher rates of organ failure as people age and improvements in organ preservation and transplant procedures, among other factors. The NIH notes that kidneys are the most commonly transplanted organ. “In 2022, approximately 115,000 patients in the US were awaiting organ transplants. Of these, 96,000 [which equates to over 80%] were waiting for a kidney,” according to 34 Lives. Moreover, 34 Lives also notes that “In 2022, over 7,800 kidneys were recovered with the intent to be transplanted but were unused.” Reducing the number of unused organs could potentially lead to significant improvements in outcomes for patients waiting for organ transplant, in our view. AEMD is optimistic that the Hemopurifier can help increase the number of kidneys that are viable for transplant.

Australia – Studying the Hemopurifier in multiple cancers

The company created a wholly owned subsidiary in Australia to conduct clinical research, seek regulatory approval, and commercialize the Hemopurifier in Australia. The CRO (contract research organization) supervising this initiative is NAMSA, LLC, which is a prominent MedTech CRO that operates globally. Aethlon believes Australia offers several advantages for conducting clinical trials, including R&D tax incentives offered by the government. AETH is processing the paperwork to submit it to the rebate program, which enables companies to receive a 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.

AEMD is launching a blanket oncology trial to study the impact of the Hemopurifier on a variety of cancerous tumors. By focusing on multiple cancers, the company has also expanded the opportunities for patient enrollment by including patients with a variety of solid tumors and can build a database to support regulatory approval. 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 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. Thus, depending on the results of the study, the study could have broad commercial and economic implications for AEMD, in our view.

“The percentage of patients estimated to respond to checkpoint inhibitor drugs was 0.14% in 2011 and increased to 12.46% in 2018,” according to the NIH (National Institutes of Health). 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.

India - Initial COVID study, potentially adding oncology study

AEMD’s COVID-19 trial site in India is open and the company recently received approval to initiate a second site in the clinical trial studying the Hemopurifier to treat severe COVID-19 in India. In addition to the first venue, Medanta Medicity Hospital in Delhi, India, AEMD 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. The company is also considering the addition of an oncology study in India to benefit from the lower R&D costs the U.S.

Studying the Hemopurifier *in vitro* 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.

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 company reported FY 1Q24 (FY ends March) results last week. As of the end of the quarter, AEMD had a cash balance of about $12.9 million to further its clinical activities and no debt. The company believes the cash balance is sufficient to support operations for about a year, although we would not be surprised if AEMD raised additional funds earlier depending on market conditions. AEMD has an ATM (At The Market offering) in place for enhanced financial flexibility and raised about $1.1 million under it in the June quarter.

Chief Scientific Officer…

The company 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.

THE AETHLON HEMOPURIFIER

Medical device has been studied in vitro / other translational studies & single patient emergency use…

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

… Growing database on the efficacy & benefits of the Hemopurifier…

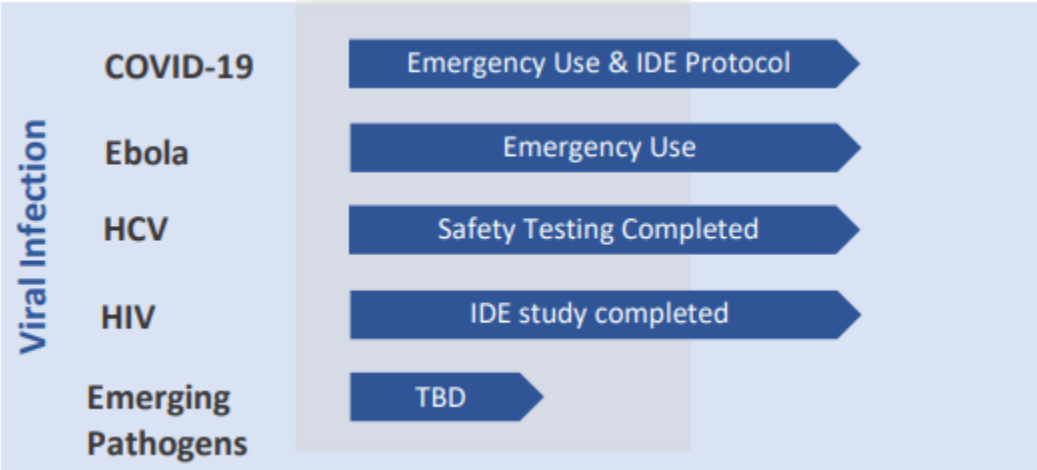
In vitro data adds to data supporting the efficacy of the Aethlon Hemopurifier® in binding and eliminating SARS-CoV-2 from the blood *in vivo*. The in vitro results add to a growing database on the efficacy and benefits of the Hemopurifier, including in treating patients with the COVID-19 virus. In 2021, AEMD was asked to use the Hemopurifier to treat two patients who were critically ill with COVID-19 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 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 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.

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.

RECENT RESULTS

The company is largely pre-revenue at this stage. In 1Q FY24, operating expenses were roughly $3.4 million, compared to $2.9 million for 1Q FY23. The increase primarily came from higher G&A expenses, reflecting the production of Hemopurifiers to support the company's clinical efforts and expenses related to the company's Australian subsidiary, among other factors. This was partially offset by lower clinical trial expenses and lower subcontract expense associated with government contracts. The company recorded a 1Q FY24 net loss of roughly $3.3 million, compared to $2.9 million in 1Q FY23.

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. We believe the potential could be higher if the Hemopurifier can be used, as management expects, in a broad range of oncology treatments. The $90 million forecast at this stage equates to a valuation of approximately $4 per share. We believe, however, that there could be a more meaningful revenue opportunity associated with expanding the number of treatment options for the Hemopurifier within the oncology space. Thus, we believe there could be upside to this valuation, depending on the potential benefits of the Hemopurifier in multiple types of cancers, as noted. 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. It does not incorporate potential from treatment of viruses such as Sars and Long Covid, among others, or in organ transplant applications. We believe if AEMD achieves certain milestones, there also could be near-term upside to the valuation. We believe near-term uncertainty around the company's clinical / commercialization timeline could overhang the shares.

RECENT NEWS

- The company announced 1Q FY24 results on August 10, 2023.
- The company announced its initiative to study the Hemopurifier to improve organ transplant supply and outcomes on June 21, 2023.
- The company received approval of a 2nd clinical site in India on May 22, 2023.
- On January 30, 2023, Aethlon announced a new contract with NAMSA to advance the Hemopurifier through clinical programs in cancer.
- 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®.
- On June 3, 2021, Aethlon published case studies of two critically ill COVID-19 patients who were treated with the Hemopurifier® (see appendix).

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.

APPENDIX

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

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

FINANCIAL MODEL

Aethlon Medical Inc.

AEMD ($000s)	2021 A	2022 A	1Q23 A	2Q23 A	3Q23 A	4Q23 A	2023 A	1Q24 A	2Q24 E	3Q24 E	4Q24 E	2024 E
Year ends March 31												
Revenue	$659.1	$294.2	$0.0	$0.0	$0.0	$574.2	$574.2	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	*1.4%*	*-54.8%*		*NM*	*-100.0%*	*NM*	*95.2%*					*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	$294.2	$0.0	$0.0	$0.0	$574.2	$574.2	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Margin	*NM*	*NM*		*NM*	*NM*	*NM*	*NM*					*NM*
OpEx	$6,477.0	$8,374.1	$2,047.7	$2,812.8	$2,291.5	$2,575.8	$9,727.9	$2,729.2	$2,742.9	$2,742.6	$2,742.3	$10,957.1
SG&A % of Prod Sales	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
R&D	$2,072.0	$2,341.0	$858.3	$852.5	$558.2	$476.0	$2,745.0	$678.9	$682.3	$682.2	$682.2	$2,725.7
R&D % Tot Sales	*314.4%*											
Operating Income	($7,889.9)	($10,420.9)	($2,906.1)	($3,665.3)	($2,849.8)	($2,477.5)	($11,898.6)	($3,408.2)	($3,425.2)	($3,424.9)	($3,424.5)	($13,682.7)
Operating Margin												
Total Other Expense	$1.6	$0.0	$0.0	$142.1	$0.0	($11.0)	$131.1	($125.0)	$0.0	$0.0	$0.0	($125.0)
Pre-Tax Income	($7,891.5)	($10,420.9)	($2,906.1)	($3,807.4)	($2,849.8)	($2,466.5)	($12,029.8)	($3,283.2)	($3,425.2)	($3,424.9)	($3,424.5)	($13,557.7)
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
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Minority interest	($4.8)	($4.8)	($0.4)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($7,886.7)	($10,416.1)	($2,905.7)	($3,807.4)	($2,849.8)	($2,466.5)	($12,029.8)	($3,283.2)	($3,425.2)	($3,424.9)	($3,424.5)	($13,557.7)
Net Margin												
EPS	($0.65)	($0.71)	($0.19)	($0.18)	($0.12)	($0.11)	($0.59)	($0.14)	($0.13)	($0.13)	($0.12)	($0.52)
Diluted Shares O/S	12,091	14,757	15,487	20,745	22,946	22,972	20,537	24,315	25,822	26,822	27,822	26,195

Source: Zacks *Pro forma for 10/20*

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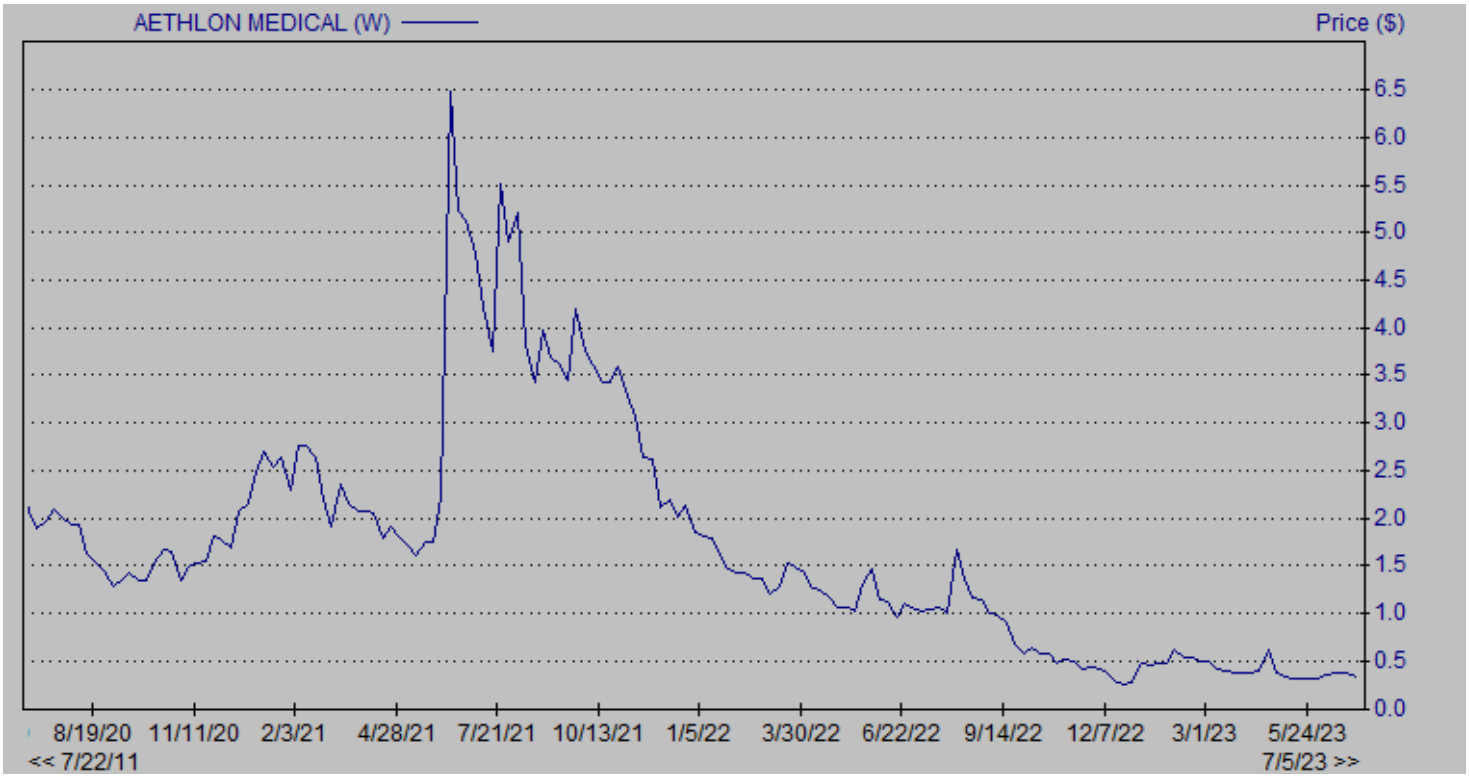
HISTORICAL STOCK PRICE



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