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M. Marin
mmarin@zacks.com
Ph (312) 265-9211

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Aethlon Medical (AEMD-NASDAQ)

First Ever *In Vivo* Removal of COVID Virus From Bloodstream of An Infected Patient

Last week Aethlon announced that the Hemopurifier® produced positive results in treating two critically ill COVID-19 patients. Neither was expected to survive; the Hemopurifier was used under FDA EUA. A 59-year-old female whose oxygenation did not improve after mechanical ventilation improved after Hemopurifier treatment, showing that elimination of exosomes likely contributed to the patient's recovery. The other patient illustrated the first-ever *in vivo* removal of SARS-CoV-2 virus from the blood stream of an infected patient.

OUTLOOK

AEMD has two Early Feasibility Studies (EFS) of the Hemopurifier underway: one treating COVID patients and one treating patients with head and neck cancer. With two different studies of different diseases, we believe AEMD potentially has expanded the commercial opportunity for the device and possibly shortened the path to approval. Critical need for new breakthrough treatments in oncology means the cancer study could be an important catalyst, depending on the clinical results. The potential sizable commercial market for cancer treatment is illustrated by the strong revenue trajectory of Keytruda, which has already become Merck's most important product and is on-track for continued growth.

Current Price (6/7/21) \$2.20
Valuation \$8.00

SUMMARY DATA

52-Week High \$3.73
52-Week Low \$1.22
One-Year Return (%) 43.79
Beta 0.51
Average Daily Volume (sh) 370,589

Shares Outstanding (mil) 12
Market Capitalization (\$mil) \$26
Short Interest Ratio (days) N/A
Institutional Ownership (%) 3
Insider Ownership (%) 1

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 2021 Estimate N/A
P/E using 2022 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)
2019	0.1 A	0.0 A	0.0 A	0.1 A	0.2 A
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	0.5 E	1.1 E
2022					1.2 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2019	-\$0.90 A	-\$1.17 A	-\$1.67 A	-\$1.39 A	-\$5.13 A
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	-\$0.21 E	-\$0.71 E
2022					-\$1.20 E

Quarters might not add to annual reflecting rounding

Disclosures on page 10

KEY POINTS

Growing Database Supporting Hemopurifier's Positive Treatment of COVID-19

Last week Aethlon Medical (NASDAQ: AEMD) announced that the Aethlon Hemopurifier® produced positive results in treating two patients who were critically ill with COVID-19¹. 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.

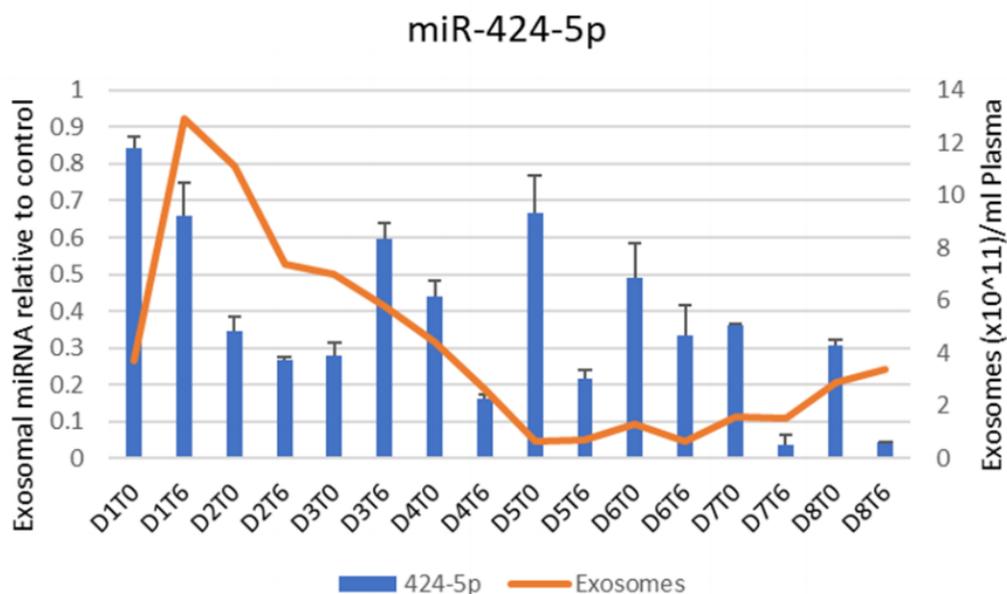
Case #1

Case #1 involved a 59-year-old female patient with a medical history of obesity, hypertension, hyperlipidemia, alcohol abuse, and heart valve replacement. She was admitted to the hospital in July 2020 with COVID-19 pneumonia for treatment with oxygen and other therapies. Her respiratory failure worsened. She developed acute respiratory distress syndrome (ARDS) and was transferred to the ICU for intubation. Her oxygenation did not improve after intubation, mechanical ventilation and prone positioning.

After about three weeks, her doctors requested Hemopurifier treatment under EUA. She received daily Hemopurifier treatment for four days (hospital days 22-25). Importantly, she tolerated the procedure well, with no evidence of allergic reaction, thrombotic complications or hemolysis.

Following Hemopurifier treatment, the patient was observed without demonstrable COVID-19 viremia. The presence of viremia – or the active virus circulating in the blood – has been associated with disease severity and the development of multi-organ failure.

Following the initial four treatments, she showed improvement in COVID-19-associated coagulopathy² (CAC), lung injury, inflammation, and tissue injury. AEMD believes that the improvements reflected the Hemopurifier's removal of exosomes with noxious microRNA cargo and that the removal of exosomes contributed to the patient's recovery. MicroRNAs are involved in mRNA degradation and inhibition of protein translation.



Source: Company reports

¹ [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 Coagulopathy is a condition where blood clotting is impaired.

There were observed decreases in total exosomal concentration in the patient compared to prior to the Hemopurifier treatment from days 2-to-7 of treatment. The concentration of exosomal miR-16 dropped over the first four Hemopurifier treatments and then remained at low levels, while the patient's acute lung injury improved. At the beginning of Hemopurifier treatment, the total exosome concentration increased on the first day. Concentration also increased on the eighth day of treatment, which requires further study.

The patient received eight Hemopurifier treatments without complications and eventually was weaned from a ventilator and discharged from the hospital. The findings suggest that benefits from the Hemopurifier in COVID-19 may extend beyond viral removal and might also reflect the elimination of exosomes. Just as the Hemopurifier is being evaluated for the ability to remove exosomes to treat cancer patients (see below), treatment in Case #1 demonstrates that exosomes are also involved in the cell to cell spread of COVID-19 infection and its associated inflammation, coagulopathy and complement activation.

Case #2

The second patient was a 67-year-old man with a history of coronary artery disease and newly diagnosed diabetes, among other disorders, who also had acute kidney injury. The case is notable for the first-ever demonstration of *in vivo* removal of SARS-CoV-2 virus from the blood stream of an infected patient. The patient completed a six hour Hemopurifier® treatment without complications and was placed on Continuous Renal Replacement Therapy (CRRT). Although the patient ultimately died after CRRT because his disease was at an advanced stage, the Hemopurifier treatment showed that it could be beneficial.

The patient received 6 hours and 15 minutes of Aethlon Hemopurifier treatment in series with CRRT. The patient had fluctuations in his oxygenation and blood pressure during the completed HP session. The patient was disconnected from the Hemopurifier without incident.

In summary, the two case studies indicate that the Hemopurifier® successfully cleared SARS-CoV-2 virus and associated exosomes from the blood stream. This resulted in a potential benefit for one of the critical COVID-19 patients treated. The two patients tolerated a total of nine Hemopurifier treatments without side effects. Moreover, AEMD also demonstrated the removal of COVID-19 from a viremic patient for the first time ever with Hemopurifier treatment. Additionally, total exosome concentrations and noxious exosomal microRNAs associated with coagulopathy and acute lung injury decreased with Hemopurifier treatments.

Hemopurifier® benefits

- Successfully cleared SARS-CoV-2 virus from the blood stream of an infected patient.
- Successfully cleared associated exosomes from the blood stream of an infected patient.
- Patients tolerated Hemopurifier treatment without side effects
- Lowered noxious exosomal microRNAs associated with coagulopathy and acute lung injury

We believe the company continues to build its database of positive outcomes using the Hemopurifier. The growing database is expected to, in turn, contribute to potential FDA regulatory approval. Moreover, given the several beneficial outcomes noted with the two EUA patients also point to the potential versatility of the Hemopurifier that could also imply a growing commercial opportunity.

EFS

In addition to the two case studies noted above, the safety and feasibility of the Aethlon Hemopurifier® is being evaluated in an active Early Feasibility Study (EFS) that will enroll up to 40 COVID-19 ICU patients. This is one of two clinical studies of the Hemopurifier currently underway. The other clinical trial is an important study of patients with head and neck cancer exploring the impact of clinical depletion of exosomes using the Aethlon Hemopurifier along with standard of care treatment, Keytruda.

The EFS is for the treatment of the SARS-CoV-2 virus (COVID-19) in humans using the Hemopurifier. COVID-19 could represent another opportunity and path to approval for the Hemopurifier, with the FDA having approved a supplement to AEMD's IDE for the Hemopurifier in viral disease to permit the testing of the device in patients with SARS-CoV-2/COVID-19 in another new feasibility study.

Earlier examples of successful use of the Hemopurifier

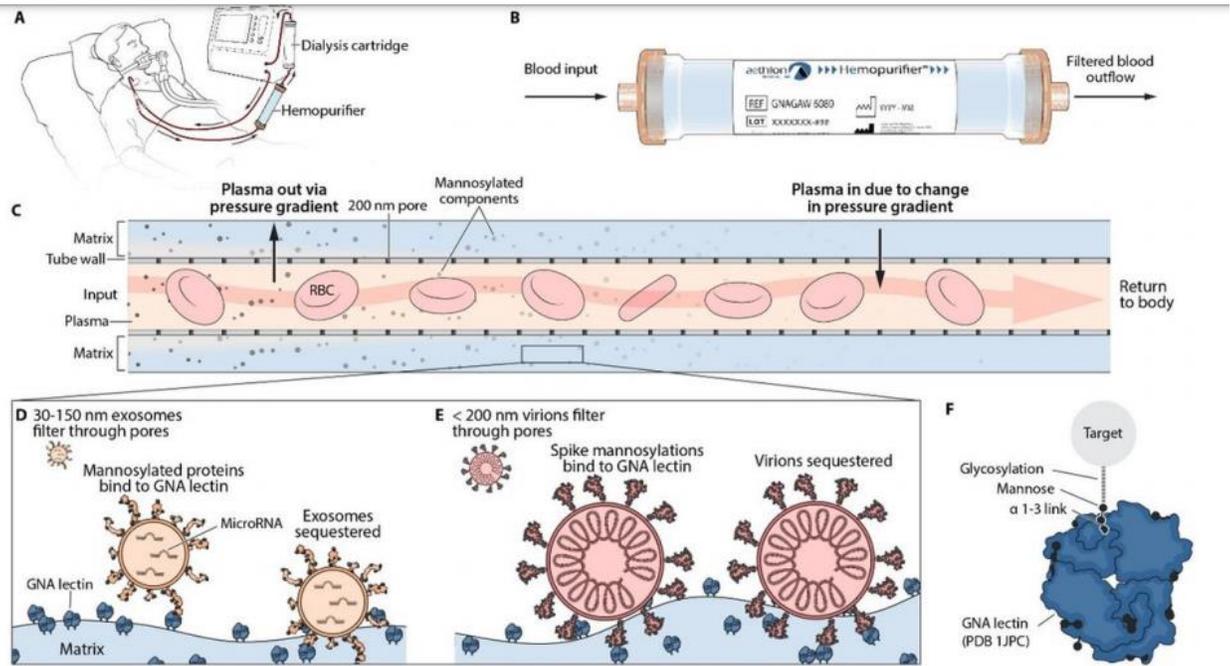
Moreover, the company has already demonstrated that the Hemopurifier can be used to treat other viruses. A laboratory version of the Hemopurifier has also been shown to clear multiple other viruses in vitro, including a model version of the Middle Eastern Respiratory Syndrome (MERS) virus that is a coronavirus 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 is used with existing dialysis, blood pump and continuous renal replacement therapy (CRRT) equipment. It is important to note that use of the Hemopurifier does not require dialysate - chemicals used in dialysis to pull fluids out of the bloodstream and to replenish the body. As the Hemopurifier discriminately captures harmful agents, it reduces loss of essential blood components and therefore does not require the use of replacement fluids. This is a key differentiator compared to other extracorporeal pathogen clearing technologies that are focused on molecule size that remove the healthy blood components as they eliminate infected ones. A patient's entire circulatory system can flow through the Hemopurifier in about 15 minutes. Clinical programs have demonstrated safety of the Hemopurifier in four-hour and six-hour treatment studies. The device is covered by five U.S. and 33 international patents. AEMD has 17 patent applications pending.

THE HEMOPURIFIER

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. It is a single-use cylindrical cartridge containing immobilized lectin affinity agents that surround approximately 2,800 hollow fibers. Lectins are sugar-binding proteins that attach themselves to the glycoprotein structure of cell membranes or the membranes of sub-cellular particles. Certain viruses envelop themselves with glycoproteins, disguising them from the body's immune system. These viral glycoproteins are also often shed by the virus, which can bind to antibodies and suppress the body's immune response. As blood flows through it, the Hemopurifier uses the lectin affinity agents to trap viruses and other target pathogens. The device uses immobilized lectins that specifically bind to the unique high mannose structures of viral glycoproteins that are derived from the host. This process, in turn, removes the virus and harmful viral glycoproteins from the body while allowing for healthy cells to pass through and back into the circulatory system. The Hemopurifier pores are 200 nanometers so any particles smaller than 200 nanometers will flow through.

Hemopurifier Mechanism



Source: Company reports

The Hemopurifier targets the elimination of infectious viruses and cancer-promoting exosomes from the blood system. It 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 illustrated above.

FINANCIAL FLEXIBILITY & STRONG MANAGEMENT TO ADVANCE DEVELOPMENT

AEMD finished the 3Q of fiscal 2021 (which ended December 2020) with about \$12.1 million in cash and no debt. AEMD also has been adept at leveraging National Cancer Institute (NCI) and government funding for research studies. The combination of cash on hand and government grants and awards are expected to help AEMD continue to advance and build inventory of the Hemopurifier for the two above-noted studies.

Moreover, in 4Q FY2021, the company entered into an agreement to sell shares from time to time depending on market conditions. AEMD filed a prospectus to offer up to roughly \$5.1 million. The registration agreement will enable AEMD to raise funds in order to move its clinical trials forward and advance the Hemopurifier towards potential regulatory approval and commercial launch.

The company noted that its intent is to use the net proceeds from the share issuance primarily for working capital and general corporate purposes, including R&D. In addition, AEMD might also use some of the proceeds for strategic M&A and / or asset acquisitions, although no candidates were in the pipeline at the time of the registration.

With several potential opportunities on the horizon, as illustrated in the company's pipeline above, Aethlon recently has expanded its executive team in order to support the many opportunities the company has ahead. For instance, earlier this year, AEMD hired a new Chief Business Officer and new Chief Medical Officer who together have a combined nearly 40 years of industry experience. Guy Cipriani was named SVP and Chief Business Officer responsible for overseeing business development and partnerships, while also contributing to fundraising and corporate development.

Steven LaRosa, M.D. was named Chief Medical Officer. He is responsible for the clinical development of Aethlon's Hemopurifier®, including leading clinical operations and regulatory strategy. The addition of these senior team members follows the October 2020 appointment of Charles J. Fisher, Jr., M.D. as AEMD's CEO.

Prior to joining AEMD, Dr. Fisher held various senior level positions, including as Head, Section of Critical Care Medicine at The Cleveland Clinic Foundation, among many others. Research conducted under his lead in sepsis, inflammation, host defense and endothelial dysfunction led to Eli Lilly & Co. recruiting him to lead the Xigris Global Product Team that successfully registered the first drug approved for the treatment of sepsis. Other senior positions included VP for Global Pharmaceutical Development at Abbott Laboratories where he was instrumental in the registration of Humira. Dr. Fisher's extensive industry background has given him experience in financing, structuring corporate partnerships and deals, clinical development and regulatory strategy.

VALUATION

As we have noted in prior reports, we see fair value of the Hemopurifier in cancer, virus, pathogen and other applications at about \$90 million. We value AEMD's majority position in Exosome Sciences, Inc. (ESI) at about \$30 million. ESI is focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases, including in patients who are at risk or have been diagnosed with a range 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 this describes the basis for Aethlon's pursuit 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.

Additionally, the ongoing COVID-19 outbreak could represent a new opportunity in this space for AEMD to generate data that offers proof-of-concept of the Hemopurifier's efficacy. As more is learned about the disease, answers to key questions related to the possibility of even testing the Hemopurifier against the virus should become more apparent. So, while COVID-19 potentially represents a new opportunity to validate Hemopurifier against another deadly disease, we do not view it as a likely near-term revenue opportunity for the company, although depending on the success of testing the Hemopurifier against the virus, this view could change, implying possible upside to our current valuation.

Our sum-of-the-parts analysis therefore values AEMD at approximately \$120 million, or over \$8 per share on a fully diluted basis. We note that our valuation is based on the company's current preliminary development state and could change with achievement of certain milestones.

RECENT NEWS

- On June 3, 2021, Aethlon published case studies of two critically ill COVID-19 patients who were treated with the Hemopurifier®.
- On February 10, 2021, Aethlon Medical announced 2Q FY 2021 operating results and provided a corporate update.
- Aethlon expanded its leadership team with the appointment of two key positions on January 6, 2021.
- On December 16, 2020, Aethlon announced the first patient treated in its first-in-human clinical trial of the Hemopurifier in head and neck cancer.
- AMED appointed Charles J. Fisher, Jr., M.D. as CEO on November 3, 2020.
- Aethlon Medical announced a collaboration with the University of Pittsburgh on an NIH grant for head and neck cancer on August 6, 2020.
- On June 22, 2020, Aethlon presented Hemopurifier® Data at the American Association for Cancer Research 2020 Annual Meeting.
- Aethlon announced FDA approval of the IDE supplement for COVID-19 patients on June 18, 2020.
- On March 24, 2020, Aethlon announced the Issuance of a European patent for the Hemopurifier® in cancer.

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.
- 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.

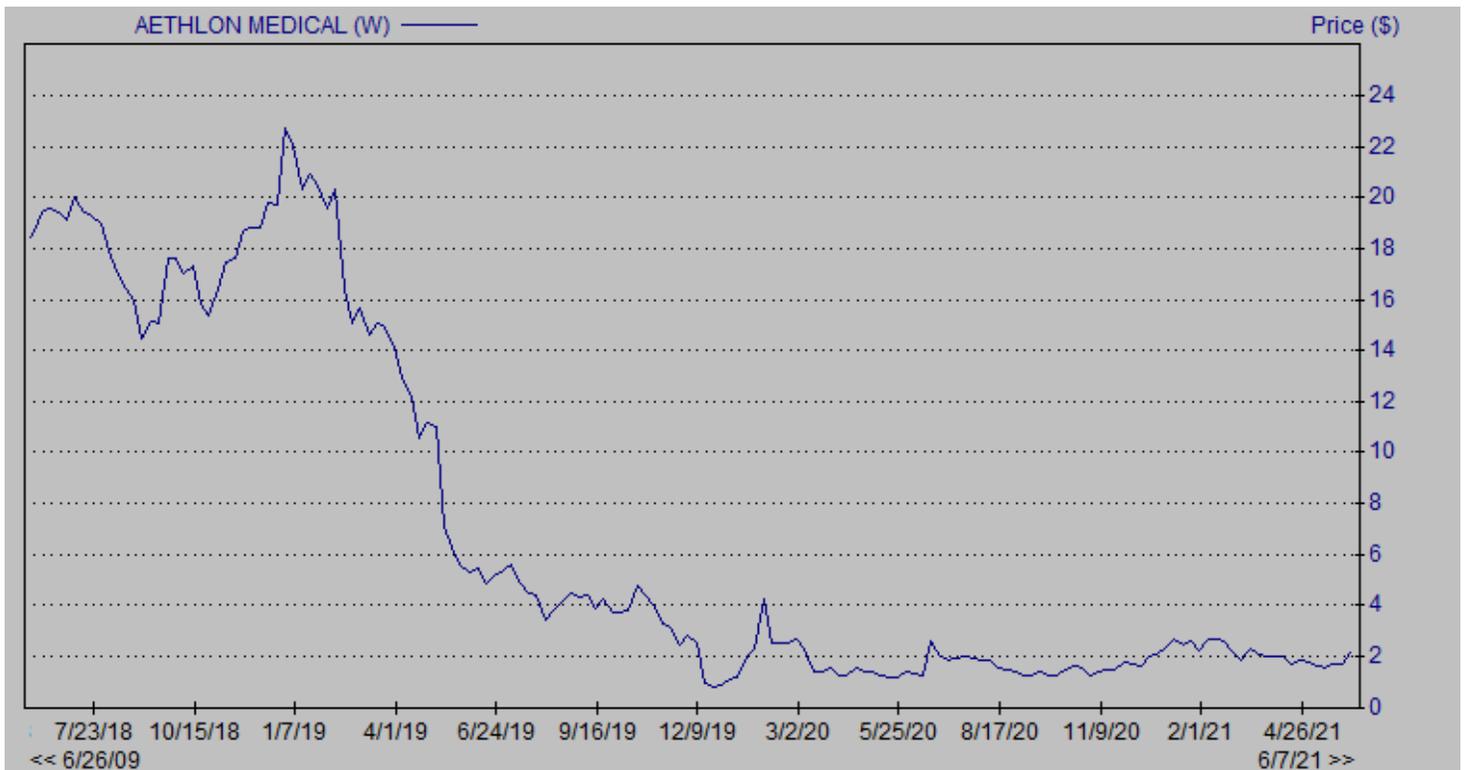
FINANCIAL MODEL

Aethlon Medical Inc.

AEMD (\$000s)	2018 A	2019 A	2020 A	1Q21 A	2Q21 A	3Q21 A	4Q21 E	2021 E	2022 E
<i>Year ends March 31</i>									
Revenue	\$149.6	\$229.6	\$650.2	\$0.0	\$0.0	\$624.9	\$520.1	\$1,145.0	\$1,168.0
<i>YOY Growth</i>		53.5%	183.2%	-100.0%	-100.0%	51.1%	151.6%	76%	2%
Cost of Goods Sold	\$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	\$0.0	\$0.0	\$624.9	\$520.1	\$1,145.0	\$2,290.1
<i>Gross Margin</i>	100.0%	100.0%	100.0%	NM	NM	NM	NM	NM	NM
OpEx	\$4,394.7	\$5,332.6	\$5,653.2	\$1,033.3	\$1,262.5	\$2,607.3	\$2,633.4	\$7,536.4	\$10,533.42
<i>SG&A %of Prod Sales</i>	NM								
R&D	\$586.0	\$896.0	\$927.0	\$377.2	\$508.9	\$461.2	\$465.8	\$1,813.0	\$2,300.04
<i>R&D %Tot Sales</i>	391.7%	390.2%	142.6%	NM	NM	NM	NM	NM	NM
Operating Income	(\$4,831.1)	(\$5,999.0)	(\$5,930.0)	(\$1,410.4)	(\$1,771.4)	(\$2,443.6)	(\$2,579.0)	(\$8,204.4)	(\$14,998.3)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-	-
Total Other Expense	\$868.7	\$220.5	\$450.1	\$0.7	\$0.0	\$0.8	\$0.8	\$2.3	\$4.0
Pre-Tax Income	(\$5,699.8)	(\$6,219.5)	(\$6,380.1)	(\$1,411.1)	(\$1,771.4)	(\$2,444.4)	(\$2,579.8)	(\$8,206.7)	(\$15,002.3)
Taxes (benefit)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Minority interest	(\$20.3)	(\$24.8)	(\$6.1)	(\$0.9)	(\$0.8)	(\$1.5)	(\$1.5)	(\$4.7)	(\$8.5)
Net Income	(\$5,679.6)	(\$6,194.8)	(\$6,374.0)	(\$1,410.3)	(\$1,770.6)	(\$2,442.9)	(\$2,578.3)	(\$8,202.0)	(\$14,993.7)
<i>Net Margin</i>			-980.3%						
EPS	(\$6.92)	(\$5.13)	(\$1.87)	(\$0.15)	(\$0.15)	(\$0.20)	(\$0.21)	(\$0.71)	(\$1.20)
Diluted Shares O/S	821	1,208	3,415	9,633	12,071	12,093	12,093	11,473	12,493

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

HISTORICAL STOCK PRICE



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