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Aethlon Medical (AEMD-NASDAQ)

Company Provides Update on Studies and Business Outlook

Aethlon provided an updated outlook on the two clinical studies underway. One study is 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 other study is designed to evaluate the Hemopurifier in the treatment of patients with severe life-threatening symptoms as a result of COVID-19.

OUTLOOK

With two Early Feasibility Studies (EFS) of its lead product, the Hemopurifier, moving forward, 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 (2/10/21)	$3.08
Valuation	**$8.00**

SUMMARY DATA

52-Week High	**$3.73**
52-Week Low	**$1.18**
One-Year Return (%)	**19.38**
Beta	**0.64**
Average Daily Volume (sh)	**2,090,074**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$36**
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

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KEY POINTS

What's New?

- Aethlon reported 3Q FY2021 results last night and provided an updated outlook on the two clinical studies underway. One, of patients with head and neck cancer, is exploring the impact of clinical depletion of exosomes using the Aethlon Hemopurifier along with standard of care treatment, Keytruda.

- The first patient was treated in December 2020, with no adverse safety consequences. The company is optimistic that enrollments will continue with little-to-no delay from the surge in COVID-19 cases. We would expect the company to release data from the study, following enrollment and treatment of all 10-12 participants, fairly shortly after the study is completed.

- The revenue trajectory of Keytruda shows the potential that a successful cancer therapeutic treatment could have and that there are multiple cancers that could benefit from 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.

- Aethlon has expanded its executive team in order to support the many opportunities the company has in front of it, hiring two key executives. The addition of these senior team members follows the October 2020 appointment of Charles J. Fisher, Jr., M.D. as AEMD's CEO.

- AEMD ended the quarter with about $12.1 million in cash, which – along with government funding for research studies – will enable it to continue to advance and build inventory of the Hemopurifier for these two studies.

COMPANY PROVIDES UPDATE ON STUDIES & OUTLOOK

Aethlon Medical (NASDAQ: AEMD) reported 3Q FY2021 results last night and provided an updated outlook on the two clinical studies underway. One is an oncology study of patients with head and neck cancer that is exploring the impact of the Aethlon Hemopurifier® with standard of care treatment, Keytruda. If the clinical study indicates that the depletion of exosomes using the Hemopurifier can boost the percentage of patients who respond favorably to Keytruda® it could have significant implications. Keytruda improves the outcome in about 30% to 35% of head and neck cancer patients, but unfortunately the treatment does not produce positive outcomes in the majority of treated patients.

AEMD believes that lowering the presence of immune suppressive exosomes from the patient's circulatory system prior to Keytruda treatment could improve patient outcomes. Thus, if clearance of exosomes using the Hemopurfier prior to the patient receiving Keytruda treatment can boost the number of patients who respond positively to the Keytruda treatment, it could open the door to the Hemopurifier as a standard of care treatment for cancer patients along with Keytruda.

The primary endpoint of the study is safety. The secondary endpoint is exosome depletion. If the study indicates that the Hemopurifier can 1) successfully clear exosomes in the clinical trial; and 2) that exosome depletion appears to have a positive impact on the ability to boost the percent of patients that respond positively to Keytruda, that has significant consequences, we believe, for the Hemopurifier and for Aethlon Medical. The field of cancer needs novel breakthrough treatment therapies to improve patient outcomes, which we believe is illustrated by how commercially successful Keytruda has been.

The revenue trajectory of Keytruda shows the potential that a successful therapeutic treatment might have and there are also other diseases that are exosome dependent that could benefit from the Hemopurifier. Keytruda generated $11.1 billion in revenue in 2019, up about 55% from $7.2 billion in 2018, and is Merck's most important product. Analysts are predicting that it could reach over $22 billion in revenue by 2025 and become the best-selling drug of all time.

Keytruda, which has been used to treat 25+ different types of cancer, illustrates the potential to use the Hemopurifier to treat a range of cancers

Moreover, depending on the results of the EFS, AEMD's opportunities could multiply. Again, Keytruda provides an important illustration of the potential use of the hemopurifier if the data of the ongoing EFS supports further research. Keytruda has been successfully used to treat more than 25 different types of cancer, has regulatory approval in more than 22 oncological indications (including non-small cell lung cancer, head and neck cancer, melanoma, cervical cancer and many more) and has been used in over 1,000 clinical trials.[1] In fact, Keytruda recently received endorsement for expanded approval in the EU to treat certain patients with relapsed or refractory Classical Hodgkin lymphoma.

As such, cancer not only represents a potentially enormous commercial market but the (unfortunate) terminality and incidence of metastatic disease means that development-related opportunities (potentially including non-dilutive funding, partnerships, clinical trials, regulatory-related resources, etc...) are likely more abundant than those available to study and commercialize other diseases. In addition, the finality of terminal diseases means that demonstration of 'effectiveness' (as well as 'acceptable safety') may be comparably less onerous than in less serious conditions or those with currently available treatment options. Moreover, as side effects of some cancer drugs can be particularly challenging to manage and cope with, 'effectiveness' might also be defined (for example) as an improvement to quality of life.

These reasons underscore why we view FDA approval of the IDE as such a significant event. If all goes well, it will also eventually prove to represent a development and commercial inflection in focus for AEMD. In the meantime, the FDA's regulatory framework for clinical evaluation of novel therapeutics should provide ample opportunity over time to help judge the potential utility of the Hemopurifier in the treatment of cancer – and, by extension, regular and multiple opportunities for inflection in the market value of AEMD.

AEMD's EFS study, while small and not necessarily powered for conclusive efficacy, might still provide some insight into the potential utility of the Hemopurifier in additive cancer therapy and potentially extending cancer survival rates through the removal of exosomes.[2] We note that the Hemopurifier has received FDA "Breakthrough Device" designation (BDD) for the treatment of:

- Cancer types where exosomes have been shown to contribute to the disease development and/or severity and/or patients with advanced or metastatic cancer who are unresponsive to or intolerant of standard of care therapy;

- Life-threatening viruses that are not addressed by approved therapies.

The first patient was treated in December 2020, with no adverse safety consequences. The company is optimistic that enrollments will continue with little-to-no delay from the surge in COVID-19 cases. The University of Pittsburgh Medical Center, where the study is being conducted, continues to interview candidates for enrollment. We would expect the company to release data from the study, following enrollment and treatment of all 10-12 participants, fairly shortly after the study is completed.

POTENTIAL FOR TREATMENT OF INFECTIOUS DISEASES INCLUDING COVID-19

COVID-19 & Other Exosome-Dependent Infectious Diseases Could Represent Another Opportunity & Path To Approval for Hemopurifier

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

[1] BioSpace, Oct 4, 2019. Alex Keown
[2] Poggio et al., *Suppression of Exosomal PD-L1 Induces Systemic Anti-tumor Immunity and Memory* 2019, Cell 177, 414–427

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 ongoing coronavirus outbreak could represent a new potential opportunity for AEMD and the Hemopurifier. The FDA also has 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. AEMD intends to enroll up to 40 COVID-19 ICU patients at up to 20 domestic centers in an open study. AEMD is In the process of enrolling centers to participate in the study.

Endpoints will include safety, reduction in circulating virus and clinical outcomes.

Primary Outcome Measures:

- Safety and tolerability
- Incidence of device related adverse and/or serious adverse events

Secondary Outcome Measures:

- Length of stay in the ICU
- In-hospital mortality
- Days free of dependence on ventilator
- Evaluation of SARS-CoV-2 RNA levels & viral particle load post-Hemopurifier treatment

The EFS differentiates the Hemopurifier from other COVID-19 treatments being used in either FDA EUA or other situations in that the patient population will be those patients already in the ICU and so with severe symptoms. AEMD expects to generate substantial data from the EFS.

Separately, AEMD also recently treated one COVID-19 patient under an emergency use single patient pathway (sometimes referred to as compassionate use) that allows for the use of an investigational product in patients who essentially have no other treatment options. Over a nine-day period, the patient successfully received eight Hemopurifier treatments of six hours each, confirming that the Hemopurifier can be used to treat COVID-19 patients.

Hemopurifier Has Demonstrated Ability To Clear Other Coronavirus Diseases and 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.

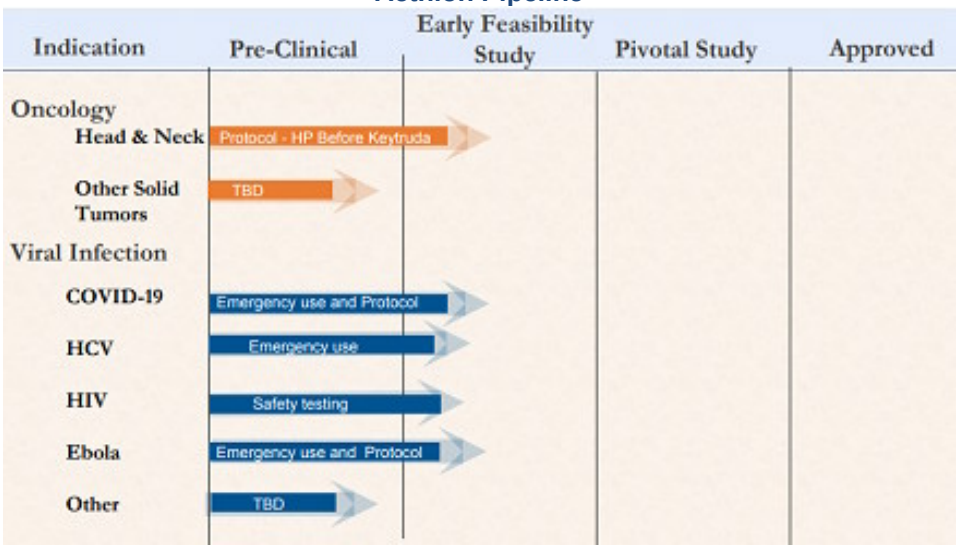
COMPANY EXPANDED EXECUTIVE TEAM TO SUPPORT OPPORTUNITIES

Management team with vast healthcare experience

With several potential opportunities on the horizon, as illustrated in the company's pipeline below, AEMD has expanded its executive team over the past several months to support its clinical studies and the many opportunities the company has in front of it. AEMD made two key appointments. Guy Cipriani was named SVP and Chief Business Officer. He will be responsible for business development and partnerships and involved in fundraising and corporate development. Steven LaRosa, M.D., has become AEMD's Chief Medical Officer, with responsibility for the clinical development of the Hemopurifier®. Both have significant industry experience.

The company's CEO Charles J. Fisher, Jr., M.D. also recently joined AEMD as CEO, coming on board in that role in late 2020. Reflecting his experience, he took the helm to help the company accelerate the progression of clinical studies towards potential commercialization. His prior experience includes a role as professor and Head of Critical Care Medicine at The Cleveland Clinic Foundation, as well as various professor, division chief and / or director positions at other facilities, including UC Davis Medical Center and Case Western Reserve University. He has also held executive roles at Eli Lilly & Co and Abbott Laboratories. In the aggregate, this management team has more than a century of healthcare experience.

Aethlon Pipeline



Source: Company reports

Largely reflecting the expanded executive team, the company registered 3Q FY21 consolidated operating expense of roughly $3.1 million compared to about $1.3 million in the prior FY 3Q. Payroll and related expenses more than doubled, which included severance costs of roughly $0.6 million related to the CEO transition. We have adjusted our estimates as a result of 3Q FY21 actual results. The company ended the quarter with about $12.1 million in cash, which – along with government funding for research studies – will enable it to continue to advance and build inventory of the Hemopurifier for these two studies.

VALUATION

Given the unfortunate prevalence of the disease 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. Already-completed clinical studies could provide at least some support for the safety of the device, while preclinical studies support Hemopurifier's ability to capture exosomes.

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, while highly virulent viruses likely represent a much more challenging target, given the difficulty in designing appropriate clinical trials, 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.

Specific to head and neck cancer (i.e. the subject of AETH's EFS study), Keytruda is the only checkpoint inhibitor that has FDA approval as a first-line treatment for this indication (Bristol-Myers' Opdivio is FDA approved for patients that fail chemotherapy), which FDA granted in June of this year. An estimated 65k people in the U.S. are diagnosed each year with head and neck cancer. Given the approximate $12k per month cost of Keytruda treatment, this means this indication alone (and just in the U.S.) represents an estimated annual market of more than $9 billion.

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 ESI at about $30 million (as a reminder, AEMD recently announced a collaboration between ESI and Hoag Memorial Hospital focused on learning more about exosomes in cancer).

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 price target is based on the company's current preliminary development state and could change with achievement of certain milestones.

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
Year ends March 31									
Revenue	$149.6	$229.6	$650.2	$0.0	$0.0	$624.9	$520.1	$1,145.0	$1,168.0
YOY Growth		*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
Gross Margin	*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
SG&A %of Prod Sales	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
R&D	$586.0	$896.0	$927.0	$377.2	$508.9	$461.2	$465.8	$1,813.0	$2,300.04
R&D %Tot Sales	*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)
Operating Margin	-	-							
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
Tax Rate	*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)
Net Margin			*-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*

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HISTORICAL STOCK PRICE



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