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Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

Establishing the Infrastructure To Support Expanding Opportunities

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 first patient in AEMD's EFS was treated in December 2020. Reflecting the critical need for new breakthroughs in oncology treatments, this study could be an important catalyst. Depending on the clinical results, AEMD's opportunities could multiply.

OUTLOOK

With two Early Feasibility Studies of its lead product, the Hemopurifier, moving forward, AEMD potentially has expanded the commercial opportunity for the device and shortened the path to approval. Aethlon has expanded its executive team in order to support the many opportunities the company has in front of it. Oncology represents a potentially enormous commercial market, as 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 (1/27/21)	$2.42
Valuation	**$8.00**

SUMMARY DATA

52-Week High	**$4.34**
52-Week Low	**$1.18**
One-Year Return (%)	**-28.61**
Beta	**0.68**
Average Daily Volume (sh)	**1,941,387**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$28**
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	0.0 E	0.5 E	0.5 E
2022					0.5 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	-$0.15 E	-$0.11 E	-$0.55 E
2022					-$0.43 E

Quarters might not add to annual reflecting rounding

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KEY POINTS

What's New?

- Earlier this month, Aethlon 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 has commenced a clinical 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. Depending on the results of the EFS, AEMD's opportunities could multiply.

- The revenue trajectory of Keytruda also shows the potential that a successful therapeutic treatment might have. 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.

- Moreover, there are also other diseases that are exosome dependent that could benefit from the Hemopurifier. In addition, COVID-19 could represent another opportunity and path to approval for the Hemopurifier.

Management team with vast healthcare experience

SETTING UP INTERNAL INFRASTRUCTURE TO SUPPORT OPPORTUNITIES

Management team with vast healthcare experience

Earlier this month, Aethlon Medical (NASDAQ: AEMD) expanded its executive team in order to support 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 October 2020. In the aggregate, this management team has more than a century of healthcare experience.

In August 2020, the National Institute for Dental and Craniofacial Research (NIDCR) awarded AEMD a grant for studies in head and neck cancer that will be a collaborative project between Aethlon and the UPMC Hillman Cancer Center at the University of Pittsburgh. The grant, valued at up to $3.5 million over five years for multi-institution studies, will profile the biomarkers of exosomes in patients with recurrent and metastatic head and neck cancer and will explore 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. Depending on the results of the EFS, AEMD's opportunities could multiply. The company's EFS is important from several aspects. The Hemopurifier has previously been tested in human subjects – with no instances of serious safety concerns – but the totality of clinical experience to-date has been relatively modest and in disease areas (hepatitis C virus) that would likely not have nearly the commercial opportunity as would oncological applications. Nevertheless, prior studies have provided proof-of-concept of the Hemopurifier's safety profile and efficacy.

The HemoPurifier, AEMD's lead product, is an extracorporeal (i.e. outside of the body) blood filtration device that is designed to selectively remove harmful particles from the circulatory system. Called the Aethlon Hemopurifier®, the name of the device itself suggests its primary goal, as hemo relates to blood and the hemopurifier is designed to purify, or remove the harmful elements from blood.

The Aethlon Hemopurifier 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. Importantly, the Hemopurifier captures only harmful agents and minimizes the loss of essential blood components.

Previous clinical testing has shown that the Hemopurifier can successfully and safely remove viral toxins from the blood and preclinical testing has demonstrated its ability to remove tumor-derived exosomes. Nevertheless, the Early Feasibility Study (EFS) will be the first real world-type evaluation of whether it could have utility in the treatment of cancer. Moreover, unlike HCV, which new drugs have turned into a highly treatable and even curable disease, cancer cures (with some rare exceptions) remain elusive. Treatment of metastatic disease is largely related to one or more of a combination of investigational (drugs, immunotherapy, radiation) therapies and focused on marginal life extension (often with poor quality of life) and palliative care.

Potential Opportunity As New Cancer Treatment

Keytruda has shown to be a revolutionary drug in the treatment of cancer. Keytruda has produced significant improvements in patients that respond well to its treatment but that group represents about 30%-35% of total patients treated with Keytruda, according to management, implying the potential to improve overall treatment response.

The revenue trajectory of Keytruda also shows the potential that a successful therapeutic treatment might have. 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 has been successfully used to treat 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]

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. Which, given the approximate $12k per month cost of Keytruda treatment, means this indication alone (and just in the U.S.) represents an estimated annual market of more than $9 billion.

Critical Need For New Breakthroughs in Cancer Treatments

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.

[1] BioSpace, Oct 4, 2019. Alex Keown

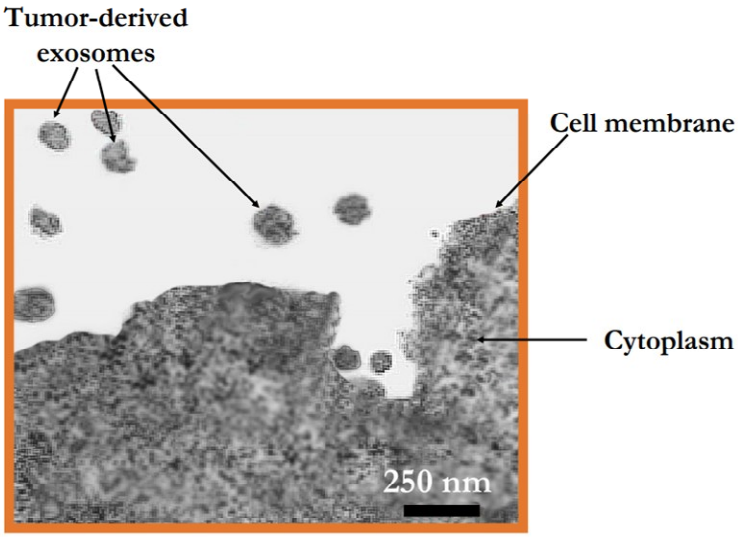
AEMD's EFS study, while small and not necessarily powered for conclusive efficacy, might still provide some insight into the potential utility of the Hemopurifier in additive cancer therapy and potentially extending cancer survival rates through the removal of exosomes.[2]

There Are Other Diseases That Are Exosome Dependent …

…and could benefit from the 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 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.

Exosomes: Nanosized Particles Rleased by Tumors



Source: aethlonmedical.com

A targeted application of the Hemopurifier is for the removal of exosomes as a treatment of cancer. Exosomes are nanosized particles released by cancer cells that promote the growth and spread of tumors, suppress the immune system and constrain the benefit of leading cancer therapies, in turn contributing to spreading metastasis. 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.

COVID-19 *Could Represent Another Opportunity & Path To Approval for Hemopurifier*

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.

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

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.

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.

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 E	4Q21 E	2021 E
Year ends March 31								
Revenue	$149.6	$229.6	$650.2	$0.0	$0.0	$0.0	$520.1	$520.1
YOY Growth		*53.5%*	*183.2%*	*-100.0%*	*-100.0%*	*-100.0%*	*-100.0%*	*-100%*
Cost of Goods Sold	$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	$0.0	$520.1	$520.1
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*NM*	*NM*	*NM*	*NM*	*NM*
SG&A	$4,394.7	$5,332.6	$5,653.2	$1,033.3	$1,262.5	$1,275.1	$1,287.9	$4,858.7
SG&A %of Prod Sales	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
R&D	$586.0	$896.0	$927.0	$377.2	$508.9	$514.0	$519.1	$1,919.2
R&D %Tot Sales	*391.7%*	*390.2%*	*142.6%*	*NM*	*NM*	*NM*	*NM*	*NM*
Operating Income	($4,831.1)	($5,999.0)	($5,930.0)	($1,410.4)	($1,771.4)	($1,789.1)	($1,286.8)	($6,257.8)
Operating Margin	-	-						
Total Other Expense	$868.7	$220.5	$450.1	$0.7	$0.0	$0.0	$0.0	$0.7
Pre-Tax Income	($5,699.8)	($6,219.5)	($6,380.1)	($1,411.1)	($1,771.4)	($1,789.1)	($1,286.8)	($6,258.5)
Taxes (benefit)	$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%*
Minority interest	($20.3)	($24.8)	($6.1)	($0.9)	($0.8)	($0.8)	($0.8)	($3.4)
Net Income	($5,679.6)	($6,194.8)	($6,374.0)	($1,410.3)	($1,770.6)	($1,788.3)	($1,286.0)	($6,255.1)
Net Margin			*-980.3%*					
EPS	($6.92)	($5.13)	($1.87)	($0.15)	($0.15)	($0.15)	($0.11)	($0.55)
Diluted Shares O/S	821	1,208	3,415	9,633	12,071	12,071	12,071	11,461

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

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HISTORICAL STOCK PRICE



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