

# Zacks Small-Cap Research

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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)

### Oncology EFS Open For Enrollment

After receiving FDA approval of its IDE application to initiate an Early Feasibility Study (EFS) of the Hemopurifier in patients with head and neck cancer in combination with Keytruda, AEMD has commenced the clinical trial. The study is now open for enrollment of patients with advanced and/or metastatic head and neck cancer.

### OUTLOOK

AEMD has two Early Feasibility Studies of its lead product, the Hemopurifier, moving forward. One study will evaluate efficacy and safety of the Hemopurifier in patients with head and neck cancer in combination with Keytruda. The other in patients with severe COVID-19 symptoms. With these two distinct clinical trials, we believe AEMD potentially has expanded the commercial opportunity for the device and shortened the path to approval.

Current Price (10/28/20) \$1.38  
Valuation \$8.00

### SUMMARY DATA

52-Week High \$4.67  
52-Week Low \$0.76  
One-Year Return (%) -65.06  
Beta 0.35  
Average Daily Volume (sh) 591,970

Shares Outstanding (mil) 12  
Market Capitalization (\$mil) \$17  
Short Interest Ratio (days) N/A  
Institutional Ownership (%) 13  
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			0.5 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

Disclosures on page 13

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## KEY POINTS

### What's New?

- Aethlon Medical reported 2Q FY 2021 results and provided a business update, as the company pursues its development of products to diagnose and treat diseases, initially in oncology and viral diseases that are life-threatening and not addressed with already approved treatments.
- After receiving FDA approval of its IDE application to initiate an Early Feasibility Study (EFS) of the Hemopurifier in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda), AEMD has commenced this first clinical trial in patients with advanced and/or metastatic head and neck cancer. The study is now open for enrollment. AEMD plans to enroll 10-12 subjects. The primary endpoint of the study is safety, with exosome clearance an important secondary endpoint.
- The EFS will be the first real world-type evaluation of whether the Hemopurifier can successfully and safely remove viral toxins from the blood. Preclinical testing has demonstrated its ability to remove tumor-derived exosomes, which could have utility in the treatment of cancer.
- AEMD's COVID-19 EFS also is moving forward. AEMD intends to enroll up to 40 COVID-19 ICU patients at up to 20 domestic centers and is in the process of enrolling centers to participate in the study. Endpoints will include safety, reduction in circulating virus and clinical outcomes. AEMD will generate substantial data from the EFS.
- The company is well-capitalized, with \$14.5 million in cash at the end of the September quarter and no debt. Although we expect cash burn to increase as AEMD moves into the clinical studies, AEMD expects its cash balance to support operations through the next 12 months.

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## EARLY FEASIBILITY STUDIES MOVING FORWARD

San Diego, California-based Aethlon Medical Inc. (NASDAQ: AEMD), a medical technology company engaged in developing products to diagnose and treat diseases in oncology and viral diseases that are life and organ threatening and are not addressed with already approved treatments, reported 2Q FY 2021 results and provided a business update.

### Oncology EFS Open For Enrollment

After receiving FDA approval of its IDE application to initiate an Early Feasibility Study (EFS) of the Hemopurifier (see device description below) in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda), AEMD has commenced this first clinical trial in patients with advanced and/or metastatic head and neck cancer. The study is now open for enrollment.

AEMD plans to enroll 10-12 subjects at the UPMC Hillman Cancer Center in Pittsburgh. Similar to Phase 1 studies, the primary endpoint will be related to safety. The study will assess efficacy-related performance with secondary endpoints measuring exosome clearance and characterization, as well as response and survival rates. Management believes the Hemopurifier holds the potential to become an adjunct treatment along with Keytruda. *Combining Keytruda – which inhibits the spread of deadly cells – with the Hemopurifier's ability to remove tumor-derived exosomes could improve the overall treatment of patients who have progressed to severe stages of the disease.*

The primary endpoint of the study is safety, as noted, with exosome [clearance](#) an important secondary endpoint. Prior medical research and data suggest that exosomes play a key role in why some oncology patients fail to respond to treatment.

## Secondary Outcome Measures:

- Levels of exosomes
- Tumor response
- Survival

The EFS is an open study that will use the Hemopurifier in conjunction with pembrolizumab in patients with advanced head and neck cancer. The EFS will measure exosome depletion by drawing blood from enrolled patients on an hourly basis beginning immediately before and then during and after each Hemopurifier treatment and continuing until Keytruda treatment begins. Pembrolizumab, marketed by Merck (MRK) as Keytruda, is a next-gen cancer therapy used in immunotherapy against a variety of advanced cancers. Pembrolizumab, or Keytruda, is a checkpoint inhibitor that works by manipulating immune system function. In June 2019, the FDA approved Keytruda for first-line (i.e. standard of care) treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC).

### [EFS Gives AEMD Chance To Expand Studies of Hemopurifier's Efficacy in Human Trials](#)

The EFS is designed to evaluate whether pre-treatment with the Hemopurifier before Keytruda is administered is safe and leads to clearance of exosomes in the blood. Aethlon has demonstrated the Hemopurifier's ability to capture exosomes underlying several forms of cancer, including breast, ovarian and melanoma, in laboratory experiments. This EFS gives AEMD the opportunity to expand studies of the Hemopurifier's efficacy in isolating and capturing exosomes in human trials in additional cancers.

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.

And while 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, this Early Feasibility Study will be the first real world-type evaluation of whether it could have utility in the treatment of cancer.

### [Critical Need For New Breakthroughs in Cancer Treatments](#)

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.

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.

Moreover, 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.

## COVID-19 EFS Moving Forward *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.

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.

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## THE HEMOPURIFIER

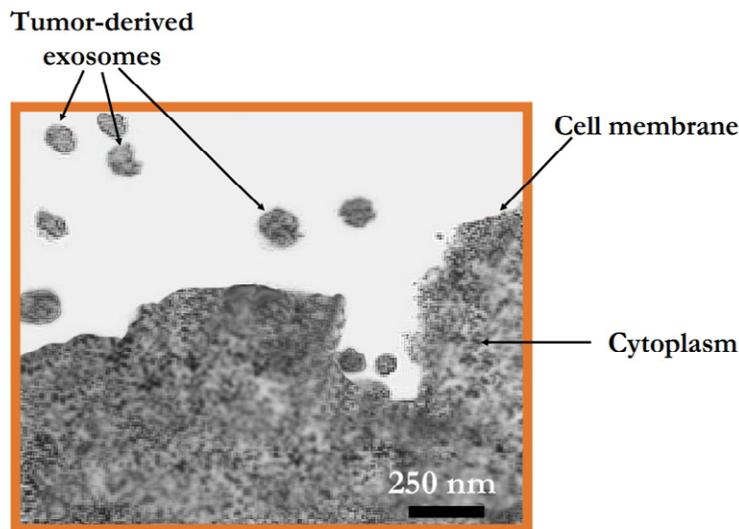
The company's lead product is the HemoPurifier, an extracorporeal (i.e. outside of the body) blood filtration device that is designed to selectively remove harmful particles from the circulatory system. Called the Aethlon Hemopurifier®, the name of the device itself suggests its primary goal, as hemo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

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 Released 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.

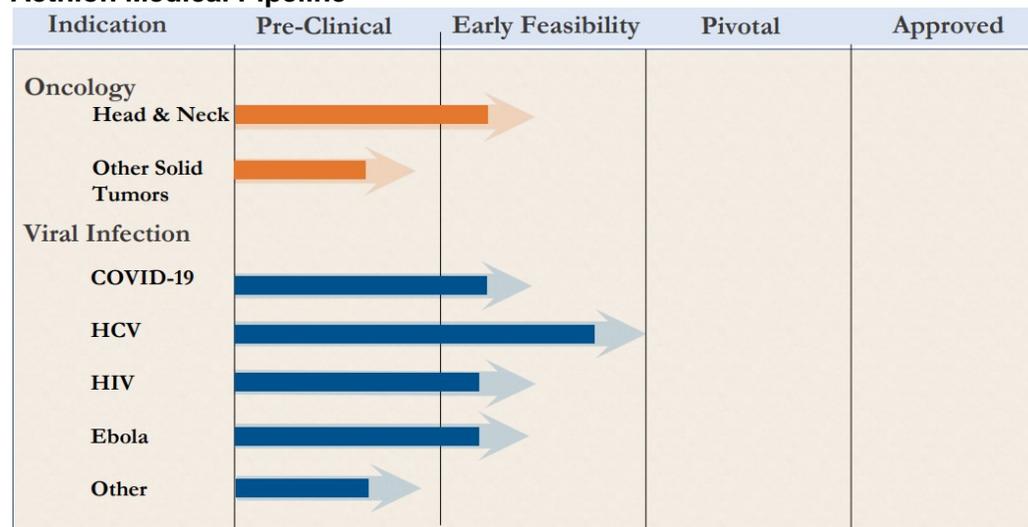
### Hemopurifier Captures Only Injurious Agents, Minimizing Loss Of Essential Blood Components

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.

As noted, the company's near-term pipeline includes the study of the Hemopurifier for treatment of patients with head and neck cancer and those with COVID-19.

### Aethlon Medical Pipeline

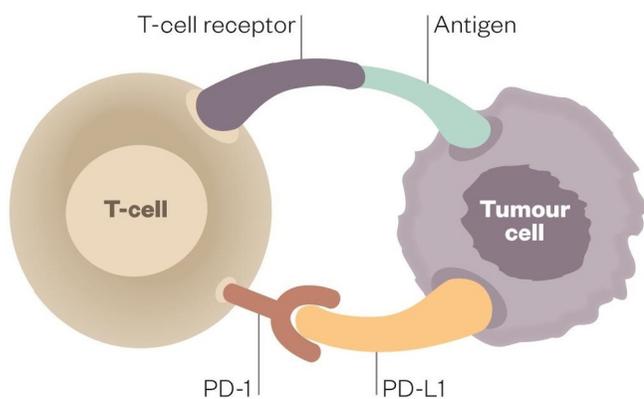


Source: <https://www.aethlonmedical.com/>

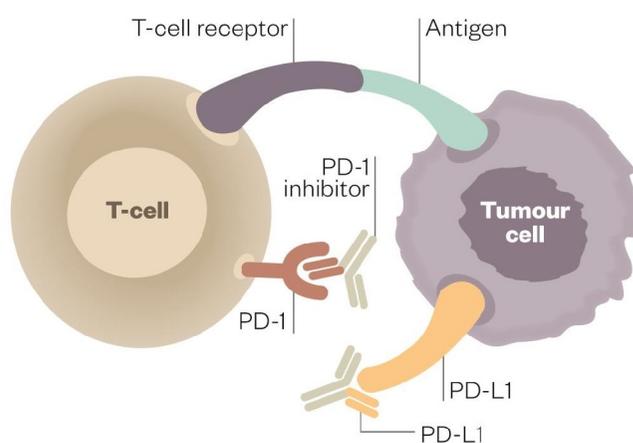
### U.S. Clinical Cancer Program

In cancer applications, the technology targets the collection of exosomes, as noted. Exosomes are small membranous particles released from cells (normal or diseased) that act as messengers between cells modulating the transport of proteins and nucleic acids. Evidence shows that exosomes secreted by some tumor (i.e. - cancer) cells are not only associated with tumor progression through the stimulation of angiogenesis (i.e. - formation of new blood vessels) but also bind to certain cancer-fighting drugs, potentially interfering with their therapeutic activity. These tumor-secreted exosomes can be found within the lesion itself, as well as in the blood. As noted, the EFS study will use the Hemopurifier in conjunction with pembrolizumab in patients with advanced head and neck cancer.

#### Tumor Uses PD-L1 as Defense Mechanism



#### PD-1 Inhibitor Blocks Tumor's Defense Mechanism



Source: The Pharmaceutical Journal, Nov 2014. Malini Guha

Pembrolizumab targets PD-1 ('programmed cell death protein 1'), a protein found on and responsible for turning T cells' immunity response on and off. When T cells encounter normal healthy cells, PD-1 attaches to PD-L1 ('programmed death-ligand 1'), a protein on the healthy cell that alerts the immune cell not to attack it. PD-L1 is

also found on some cancer cells, however, which use it as a defense mechanism by tricking T cells into not destroying it.

In cancers that overexpress PD-L1, pembrolizumab inhibits tumor growth by targeting PD-1. More specifically, pembrolizumab attaches to the PD-1 receptor, thereby blocking PD-L1 (from turning the immune response off) and exposing PD-L1 overexpressed cancer cells to attack by the body's immune system.

The hypothesis behind combining the inhibition of PD-1 (via pembrolizumab) and physical removal of tumor-derived exosomal PD-L1 (via the Hemopurifier) from the body is to evaluate whether it is more effective than PD-1 inhibition alone in fighting these unresectable tumors. As it relates to the latter, there is growing evidence to support therapeutic targeting of exosomes to fight certain solid cancers.

This includes compelling findings from a study (*Suppression of Exosomal PD-L1 Induces Systemic Anti-tumor Immunity and Memory*, April 2019) published in the journal [Cell](#) that showed that not only do exosomes play a role in cancer, but also that removal of exosomal PD-L1 inhibits tumor growth (even with tumors resistant to anti-PD-L1 antibodies) and exposure to exosomal PD-L1-deficient tumor cells may result in anti-tumor memory and immunity. Moreover, exosomal PD-L1 of some solid cancers appears to be resistant to anti-PD-L1 therapy – suggesting that effective treatment may require the direct targeting of tumor derived exosomes. Perhaps the most compelling conclusion of the study is the finding that targeting exosomal PD-L1 provides incremental benefit (i.e. suppression of tumor growth) to that of checkpoint inhibitors.

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.<sup>1</sup>

### Potential Opportunity As New Cancer Treatment

We offer some background on the success of Keytruda to treat cancer for some context of the significance of this market and the possible opportunity for AEMD. Keytruda has shown to be a revolutionary drug in the treatment of cancer. 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.<sup>2</sup>

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' Opdivo 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.

In August 2020, AEMD announced that the National Institute for Dental and Craniofacial Research (NIDCR) awarded 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.

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<sup>1</sup> Poggio et al., *Suppression of Exosomal PD-L1 Induces Systemic Anti-tumor Immunity and Memory* 2019, *Cell* 177, 414–427

<sup>2</sup> BioSpace, Oct 4, 2019. Alex Keown

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## FINANCIAL REVIEW

### Fiscal 2Q FY 2021 Financials:

Aethlon has no product revenue at this stage. Revenues reflect amounts AEMD earns from contracts and grants from the National Institutes of Health (NIH). AEMD did not record any government contract revenue in 2Q FY 2021.

Operating expenses of \$1.77 million increased from roughly \$1.70 million in 2Q FY 2020 primarily reflecting increased general and administrative expenses as AEMD added headcount to support clinical trials and inventory build-up. This was partially offset by lower professional fees reflecting lower legal and accounting fees. AEMD reported a net loss of \$1.77 million versus \$1.71 million recorded in 2Q FY 2020.

### Cash

The company is well-capitalized, with \$14.5 million in cash at the end of the September quarter, down from \$15.7 million at June 2020 and up from \$9.6 million at the end of fiscal 2020 (AEMD's fiscal year ends March). AEMD has no debt. Cash used in operating activities was \$2.3 million, in-line with \$2.3 million during the same period of 2019. This is relatively consistent with the company's average cash burn rate. Although we expect cash burn to increase as AEMD moves into the clinical studies, AEMD expects this net cash balance to support operations through the next 12 months.

The higher cash balance reflects an equity offering during 1Q FY 2021 in which AEMD raised \$7.3 million through the sale of 2.7 million shares at an average price of \$2.70 per share. The company has also been adept at leveraging government non-dilutive funding from the NCI to supplement its R&D spending. In the past two years, AEMD won or extended two contracts/grants.

- **Phase 2 Melanoma Cancer Contract:** In September of 2019, AEMD was awarded an SBIR Phase II Award contract<sup>3</sup> valued at \$1.9 million, which runs for from September 16, 2019 through September 15, 2021. Following completion of a Phase I contract, the work will focus on melanoma exosomes. Deliverables involve the design and testing of a pre-commercial prototype of the exosome isolation platform that builds on the earlier work.
- **Breast Cancer Grant:** In September 2018, AEMD received a \$298,444 grant from the National Cancer Institute (NCI). The Small Business Innovation Research, or SBIR, Phase I grant titled, "The Hemopurifier Device for Targeted Removal of Breast Cancer Exosomes from the Blood Circulation," that ran through August 31, 2019 and was extended. The subcontractors working with AEMD are the University of Pittsburgh and Massachusetts General Hospital.

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## VALUATION

As we have noted in prior reports, we think the BDD for cancer could be a game-changer for Aethlon, given the difficulty in designing clinical studies around highly virulent viruses. Cancer, difficult to control and treat effectively, is unfortunately a prevalent and chronic disease. Thus, it holds substantial potential as a target to build a clinical and regulatory program around, in our view. And with Hemopurifier already having shown substantive efficacy in reducing or eliminating circulating tumor derived exosomes from the blood, coupled with existing human safety data, a cancer pursuit could also potentially be relatively fast-moving, in our opinion.

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. Moreover, the fact that the BDD indication is for metastasized cancers and for which standard of care has failed (i.e. patients who are essentially out of options), implies a lower safety hurdle. Meanwhile, successful capture of exosomes in preclinical studies in a variety of cancers including breast, ovarian and metastatic melanoma, lends credence to the effectiveness

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<sup>3</sup> For NIH/NCI Topic 359, entitled "A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring."

of the Hemopurifier in removing exosomes from the circulation of cancer patients. And, finally, receipt and successful competition of grants from the National Cancer Institute related to this topic – that is, removal of exosomes from circulation as a cancer therapy – means that this is a pursuit that is not just of interest to Aethlon but to the U.S. government, as well. Importantly, in September 2019, AEMD announced that NCI awarded the Phase 2 (follow-on) grant related to isolation of melanoma exosomes (for diagnostic and treatment monitoring), as noted. The grant, which will pay \$1.86 million over two years, lends further validation to the potential utility of the technology in cancer treatment.

There is also no shortage of new evidence supporting 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.

And 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.

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.

## FINANCIAL MODEL

Aethlon Medical Inc.

AEMD (\$000s)	2018 A	2019 A	2020 A	1Q21 A	2Q21 A	3Q21 E	4Q21 E	2021 E
<i>Year ends March 31</i>								
Revenue	\$149.6	\$229.6	\$650.2	\$0.0	\$0.0	\$0.0	\$520.1	\$520.1
<i>YOY Growth</i>		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
<i>Gross Margin</i>	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
<i>SG&amp;A %of Prod Sales</i>	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
<i>R&amp;D %Tot Sales</i>	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)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
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
<i>Tax Rate</i>	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)
<i>Net Margin</i>			-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
<i>Source: Zacks</i>	<i>Pro forma for 10/2019 reverse stock split</i>							

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## APPENDIX: OTHER POTENTIAL HEMOPURIFIER APPLICATIONS

AEMD currently is focused on studying the efficacy of the Hemopurifier for treatment in patients with head and neck cancer and also those with SARS-CoV-2/COVID-19. Nevertheless, there are several other potential indications for the Hemopurifier.

Other potential applications of the Hemopurifier include hepatitis-C (HCV), HIV and sepsis, among others. The Hemopurifier has, in fact, been used to treat other diseases in various EFSs. The device has also been shown to capture other pathogens in vitro, including Zika virus, Lassa virus, MERS-CoV, cytomegalovirus, Epstein-Barr virus, Herpes simplex virus, Chikungunya virus, Dengue virus, West Nile virus, smallpox-related viruses, H1N1 swine flu virus, H5N1 bird flu virus, and the reconstructed Spanish flu virus. Certain applications are highlighted below

**Hepatitis-C** Hepatitis-C is a viral liver infection caused by the hepatitis C virus (HCV). It is transmitted through the direct contact of infected blood that causes swelling of the liver and is the leading cause of liver transplantation in the U.S. There are approximately three million Americans with chronic HCV and about 36k people contract the virus in the U.S. every year. Worldwide there are about 170 million people with HCV.

Symptoms vary from person-to-person with many showing no signs of the disease while others may have acute symptoms such as mild fever, headache, fatigue, nausea and muscle aches. These symptoms usually abate within a few weeks or months after becoming infected. However, the majority of people exposed to the virus develop a chronic infection - if left untreated these chronic carriers of the virus can eventually experience abdominal pain, jaundice, liver failure and even death. The goal of treatment is to remove the virus from the blood and reduce the risk of liver damage. Specifically, the goal is to rapidly reduce viral load, the extent of which is highly correlated with what is considered a clinical cure and improved patient outcomes. In small clinical trials the Hemopurifier, in combination with standard drug therapy, has shown to be able to rapidly reduce viral loads within the first few days of treatment.

**HER2 Breast Cancer** Human epidermal growth factor receptor-2 (HER2) breast cancer is a very aggressive form of the disease that accounts for approximately 30% of all breast cancers. Typical treatment for HER2 breast cancer involves the use of the monoclonal antibody Herceptin (trastuzumab), which is only effective in cancer where the HER2 receptor is overexpressed. Herceptin can be used alone or in combination with chemotherapy. While Herceptin has shown to significantly extend the lives of HER2 breast cancer patients (five year survival rate is ~ 95%) compared to legacy drugs, there's clearly a market for a product that would provide even greater efficacy (especially with no compromise to safety or patient comfort). While Herceptin is considered standard of care for HER2 breast cancer, only about one-third of patients respond to the drug. Even those that do respond typically experience only a limited duration of benefit. Aethlon hypothesizes that their Hemopurifier may be able to increase response to Herceptin through the removal of HER2 protein and tumor secreted exosomes which are binding to the cancer drug and inhibiting its efficacy.

**HIV** The application of the Hemopurifier for HIV therapy relates to effectively managing a broad range of HIV strains, including drug-resistant mutant strains. In addition to capturing HIV, the device targets the capture of envelope glycoprotein GP120 as well negative factor (Nef) protein exosomes from the blood. GP120 is a glycoprotein that is essential for virus entry into cells. GP120 was one of the first targets of HIV vaccine research and continues today - although efforts to develop such a vaccine have been hampered by certain properties of GP120 which make it difficult for antibodies to bind to it.

**Sepsis** Sepsis, more commonly known as blood poisoning, is a potentially lethal blood infection caused by pathogens. It is one of the major leading causes of deaths in intensive care unit patients. Soldiers injured in combat can be particularly prone to wound infections which can lead to sepsis, which is initially characterized by inflammation throughout the entire body, fever and vomiting. It is an especially dangerous infection as it is not only aggressive, eventually leading to loss of limbs, organ failure and death, it is also difficult to treat. As there currently are no effective methods to remove the toxins from the blood or to consistently and effectively identify the circulating pathogens, sepsis is typically treated with antibiotics that are not necessarily specific to the pathogens. As a result, antibiotic treatment protocol for sepsis often fails, contributing to its ~30% mortality rate.

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