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Aethlon Medical (AEMD-NASDAQ)

Advancing The Hemopurifier in Two Feasibility Studies

We are encouraged by the company's pipeline to study the Hemopurifier in two early feasibility studies around the treatment of patients with head and neck cancer and, separately, those with COVID-19. We believe receipt in August 2020 of an NIDCR grant for collaborative (with the University of Pittsburgh) multi-institution studies in head and neck cancer validates the potential of the Hemopurifier.

OUTLOOK

With Breakthrough Device designation and the FDA's approval of AEMD's IDE application to initiate an Early Feasibility Study of its lead product, the Hemopurifier, in patients with head and neck cancer in combination with Keytruda, we believe that AEMD potentially has expanded the commercial opportunity for the device and shortened the path to approval.

COVID-19 potentially represents a new opportunity to provide additional proof-of-concept and validate the Hemopurifier against other deadly diseases, as well.

Current Price (10/12/20)	$1.48
Valuation	**$8.00**

SUMMARY DATA

52-Week High	**$6.89**
52-Week Low	**$0.76**
One-Year Return (%)	**-64.94**
Beta	**0.35**
Average Daily Volume (sh)	**334,044**
Shares Outstanding (mil)	**12**
Market Capitalization ($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				0.5 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	-$0.12 E	-$0.12 E	-$0.08 E	-$0.45 E
2022					-$0.43 E

Quarters might not add to annual reflecting rounding

Disclosures on page 13

KEY POINTS

- Aethlon Medical is developing products to diagnose and treat diseases, initially in oncology and viral diseases that are life-threatening and not addressed with already approved treatments. The company's lead product is the Hemopurifier®, a proprietary cartridge that uses existing hospital or clinic treatment equipment to remove harmful elements from a patient's blood and return cleansed blood back into the circulatory system.

- The Hemopurifier has received FDA "Breakthrough Device" designation for the treatment of two indications – patients with: 1) advanced or metastatic cancer that are unresponsive to or intolerant of standard of care therapy and/or where exosomes have been shown to contribute to the disease development and/or severity; and 2) life-threatening viruses that approved therapies do not address.

- The FDA has approved AEMD's 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 plans to enroll 10-12 subjects at the UPMC Hillman Cancer Center in Pittsburgh. The primary endpoint of the study will be safety. Secondary endpoints include measures of 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.**

- 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 a new feasibility study. AEMD intends to enroll up to 40 COVID-19 ICU patients at up to 20 domestic centers. Endpoints will include safety, reduction in circulating virus and clinical outcomes.

- In August 2020, the National Institute for Dental and Craniofacial Research (NIDCR) awarded a grant to Aethlon and the University of Pittsburgh for collaborative multi-institution studies in head and neck cancer. The grant, valued at up to $3.5 million over five years, will profile the biomarkers of exosomes in patients with recurrent and metastatic head and neck cancer and study the impact of clinical depletion of exosomes using the Hemopurifier.

- The company is well-capitalized, with $15.7 million in cash, up from $9.6 million at the end of fiscal 2020 (AEMD's fiscal year ends March) and no debt as of June 2020. The company has also been adept at leveraging non-dilutive government funding from the NCI to supplement its R&D spending.

COMPANY BACKGROUND

San Diego, California-based Aethlon Medical Inc. (NASDAQ: AEMD) is 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. The company'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.

Specifically, 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.

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.

The Hemopurifier As An Adjunct Treatment With Keytruda

The FDA has approved AEMD's 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 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.*

Aethlon has demonstrated the Hemopurifier's ability to capture exosomes underlying several forms of cancer, including breast, ovarian and melanoma, in laboratory experiments. This will give the company the opportunity to expand studies of the Hemopurifier's efficacy in isolating and capturing exosomes in human trials in additional cancers.

Other potential applications of the Hemopurifier (see Appendix) 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.

Exosome Sciences, Inc.

Separately, AEMD's majority-owned (80%) subsidiary Exosome Sciences, Inc. (ESI) is focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening diseases. Through ESI, AEMD is developing exosome-based biomarkers in patients who have or are at risk for various cancers.

EIS was created in 2009 as a result of Aethlon's research related to the development of the Hemopurifier. In order to test the device's effectiveness, Aethlon needed a high-sensitivity tool to measure the presence and changes of exosome levels in the body. EIS developed an Enzyme Linked Lectin Specific Assay (ELLSA) that can identify and quantify the presence of exosomes in bodily fluids including blood that are present with HIV, tuberculosis and a variety of cancers, including ovarian, melanoma, breast, lymphoma, and colorectal.

ESI formed a collaboration with Newport Beach, California-based Hoag Hospital in September 2019 to jointly identify and characterize potential early disease markers for cancer diagnostics, progression and treatment resistance.

THE HEMOPURIFIER

The company's flagship product, 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,

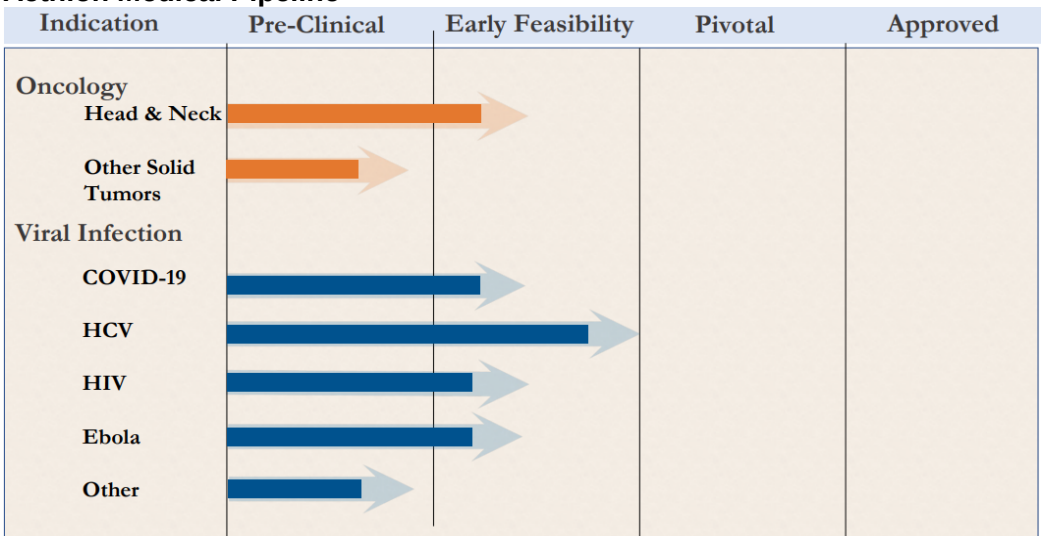
removes the virus and harmful viral glycoproteins from the body while allowing for healthy cells to pass through and back into the circulatory system. The Hemopurifier pores are 200 nanometers so any particles smaller than 200 nanometers will flow through.

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 nucleaic 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.

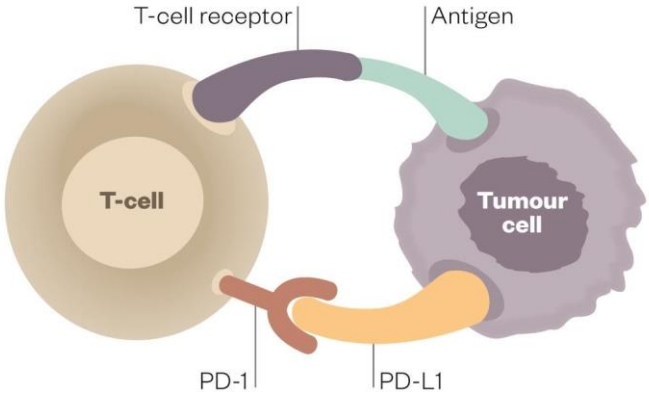
The EFS – analogous to a Phase 1 safety-oriented study – will use the Hemopurifier in conjunction with pembrolizumab in patients with advanced head and neck cancer. Pembrolizumab, marketed by Merck (MRK) as Keytruda, is a next-gen cancer therapy used in immunotherapy against a variety of advanced cancers. A humanized antibody that was initially approved by the FDA in 2014, pembrolizumab is one of a new class of drugs known as checkpoint inhibitors that work 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).

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

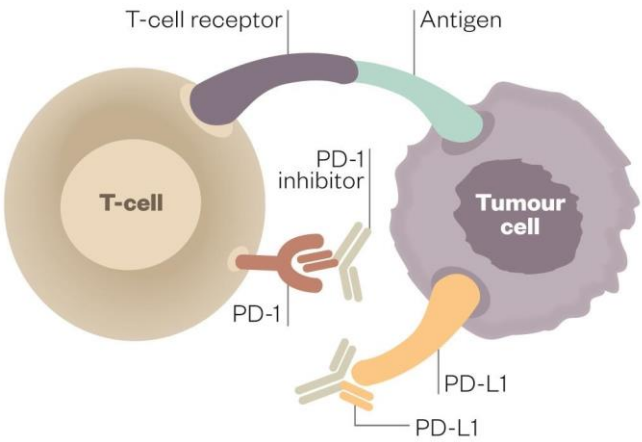
('programmed death-ligand 1'), a protein on the healthy cell that alerts the immune cell not to attack it. PD-L1 is also found on some cancer cells, however, which use it as a defense mechanism by tricking T cells into not destroying it.

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.

Tumor Uses PD-L1 as Defense Mechanism



PD-1 Inhibitor Blocks Tumor's Defense Mechanism



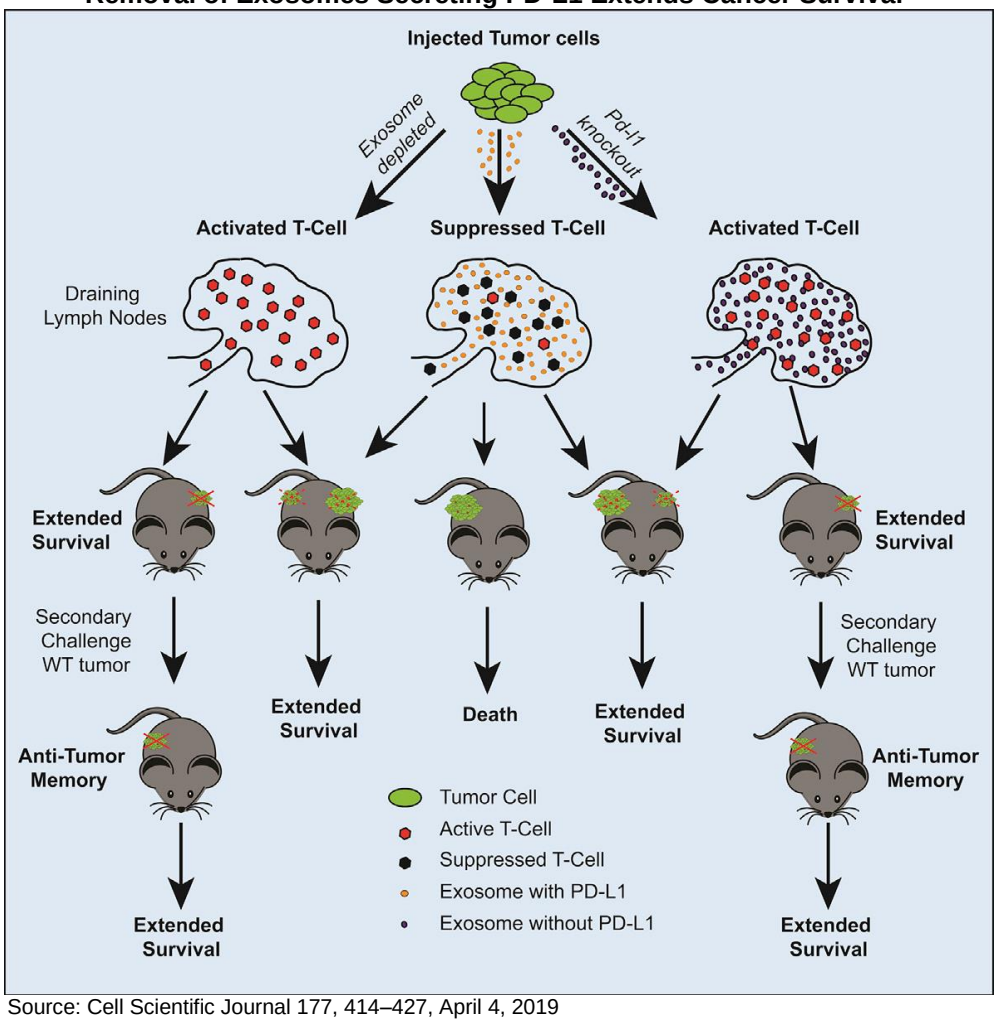
Source: The Pharmaceutical Journal, Nov 2014. Malini Guha

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.

Removal of Exosomes Secreting PD-L1 Extends Cancer Survival[1]



Source: Cell Scientific Journal 177, 414–427, April 4, 2019

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.[2]

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.

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

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

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.

Early Feasibility Study

The design of the Early Feasibility Study is consistent with the indication granted to Hemopurifier under the FDA's Breakthrough Device designation awarded in November 2018 and relates to "the treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease. Therapy with the Hemopurifier device should be an adjunct to standard of care for cancer."

IDE approval is a major milestone in our opinion. 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. 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.

New SARS-CoV-2/COVID-19 Feasibility Study

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 a new feasibility study. AEMD intends to enroll up to 40 COVID-19 ICU patients at up to 20 domestic centers. Endpoints will include safety, reduction in circulating virus and clinical outcomes.

The Hemopurifier has previously been tested in patients with hepatitis C virus (HCV) infection and in one patient with Ebola virus infection. 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. 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.

GROWING IP PORTFOLIO

The company has five U.S. patents and 33 international patents and 17 patent pending applications worldwide related to the Hemopurifier and other technologies, as noted.

Earlier this year, the company received European Patent No. 1,993,600 entitled "Extracorporeal Removal of Microvesicular Particles." The '600 patent embodies Aethlon's Hemopurifier® technology designed for the depletion of immune suppressive, and potentially cancer-promoting, exosomes from the circulatory system.

FINANCIAL REVIEW

Fiscal 1Q FY 2021 Financials, Operational Update:

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 1Q FY 2021. While the company invoiced the NCI for $206,729, under the milestone revenue recognition method AEMD uses, it was recorded as deferred revenue because the necessary milestones were not achieved during the quarter. This compares to $30,000 in government contract revenue recognized in 1Q FY 2020.

With operating expenses of $1.4 million in 1Q 2021, AEMD reported an operating loss of ($1.4) million and net loss of ($1.4) million and loss / share of ($0.15). This compares to a loss/share of ($1.63) recorded in 1Q 2020.

Cash

The company is well-capitalized, with $15.7 million in cash as of June 2020, up from $9.6 million at the end of fiscal 2020 (AEMD's fiscal year ends March), and no debt. Cash used in operating activities was $1.1 million compared to $1.2 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 studies discussed above. 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[3] 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.

MANAGEMENT

CEO Timothy Rodell, M.D., FCCP, joined the company in December 2018 as Interim CEO and was appointed CEO in February 2020. Prior to AEMD, he was CEO of GlobeImmune, Inc. from 2002 until 2016, when that

[3] For NIH/NCI Topic 359, entitled "*A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring*."

company was acquired. He has extensive experience in the biopharma industry, with more than 30 years in executive positions over the course of his career. He also was CEO at RxKinetix, Inc. and held senior positions at OXIS International, Inc. and Cortech, Inc.

CFO James Frakes joined Aethlon Medical in January 2008, with nearly 20 years of CFO level experience.

Earlier this year, the company hired a new VP of Manufacturing and Product Development. Thomas Taccini joined the company in May of 2020. He has more than 35 years of industry experience.

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 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.

RISKS

Risks to AEMD 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 commercialization timelines.
- The company might not obtain non-dilutive financing as easily as it has in the past.
- Clinical results might not support the further advancement of the Hemopurifier, although the company has fairly extensive data from prior studies suggesting this is unlikely.

FINANCIAL MODEL

Aethlon Medical Inc.

AEMD ($000s)	2018 A	2019 A	2020 A	1Q21 A	2Q21 E	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	$1,043.6	$1,054.0	$1,064.6	$4,195.4
SG&A %of Prod Sales	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*	*NM*
R&D	$586.0	$896.0	$927.0	$377.2	$380.9	$384.7	$388.6	$1,531.4
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)	($1,424.5)	($1,438.8)	($933.0)	($5,206.7)
Operating Margin	-	-						
Total Other Expense	$868.7	$220.5	$450.1	$0.7	$0.7	$0.7	$0.8	$3.0
Pre-Tax Income	($5,699.8)	($6,219.5)	($6,380.1)	($1,411.1)	($1,425.3)	($1,439.5)	($933.8)	($5,209.7)
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)	($0.9)	($0.9)	($0.9)	($3.5)
Net Income	($5,679.6)	($6,194.8)	($6,374.0)	($1,410.3)	($1,424.4)	($1,438.6)	($932.9)	($5,206.2)
Net Margin			*-980.3%*					
EPS	($6.92)	($5.13)	($1.87)	($0.15)	($0.12)	($0.12)	($0.08)	($0.45)
Diluted Shares O/S	821	1,208	3,415	9,633	12,070	12,071	12,071	11,461

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

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, with certain ones 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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