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Aethlon Medical (AEMD-NASDAQ)

SeaStar Collaboration Is Intriguing, More Evidence of Exosomes' Role in Cancer Progression

We are maintaining our sum-of-the-parts valuation methodology in which we place a value of $90M for Hemopurifier in virus, pathogen, bioterror and cancer applications and value ESI at $30M. Sum-of-the-parts values AEMD at approximately $120M or ~$6.25/share.

Current Price (07/10/19)	$0.35
Valuation	**$6.25**

OUTLOOK

The major recent highlight on the operational front was the announcement of a collaboration with SeaStar Medical, Inc. Their 'CLR 2.0 Hemofilter' is a blood filter which is FDA 510(k)-cleared for use in patients with acute kidney injury, pulmonary edema and congestive heart failure. While Aethlon has yet to provide specifics in terms of exactly what the duo will pursue in terms of product development, they did note on the Q4 call that their focus, at least initially, will likely be on the development of a joint product which includes a combination of each parties' technologies for one or more (not-yet-specified) critical care applications. But it also sounds as if there's potentially lots of different optionality in terms of cross-application of each's technologies towards individual pursuits either related to the Hemopurifier and CLR 2.0 Hemofilter or development of novel products. We think it is mostly a blank slate at this point and look forward to hearing updates on their plans for leveraging their joint technologies and other resources. Meanwhile, there is no shortage of new evidence supporting the role of exosomes in the progression of cancer. As this describes the basis for Aethlon's pursuit of the Hemopurifier in a potential cancer indication, a growing database of evidence can have important contextual implications including potentially influencing key opinion leaders and regulators alike.

SUMMARY DATA

52-Week High	**$1.74**
52-Week Low	**$0.30**
One-Year Return (%)	**-70.68**
Beta	**1.29**
Average Daily Volume (sh)	**268,549**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**15**
Insider Ownership (%)	**7**
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 2020 Estimate	**N/A**
P/E using 2021 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)
2018	0.0 A	0.0 A	0.1 A	0.1 A	0.2 A
2019	0.2 A	0.0 A	0.0 A	0.1 A	0.2 A
2020	0.0 E	0.2 E	0.2 E	0.2 E	0.6 E
2021					1.1 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2018	-$0.21 A	-$0.14 A	-$0.08 A	-$0.08 A	-$0.46 A
2019	-$0.06 A	-$0.08 A	-$0.11 A	-$0.09 A	-$0.34 A
2020	-$0.08 E	-$0.07 E	-$0.06 E	-$0.06 E	-$0.27 E
2021					-$0.20 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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Fiscal Q4 2019 Financials, Operational Update

Aethlon reported financial results for their fiscal fourth quarter ending March 31, 2019 and provided a business update. Revenue of $80k was recorded in the quarter, representing the initial payment under AEMD's ongoing NCI grant (*The Hemopurifier Device for Targeted Removal of Breast Cancer Exosomes from the Blood Circulation*), which was awarded in September 2018 and will pay a total of $298.4k through ~August 2019. This revenue relates to a completed milestone, "to evaluate Hemopurifier-mediated capture of breast cancer exosomes". We assume the remainder of the contract is recognized as revenue by Q2'20 (ending September 30, 2019).

Operating expenses were up 24% from Q4'18 but down 15%, or ~$293, sequentially. For the full year, operating expenses were $6.2M, an increase of $1.3M, or 25%, from 2018. Much of the yoy increase is explained by separation-related accruals related to the departure of (prior CEO,) Jim Joyce.

Cash used in operating activities was $1.4M and $4.3M ($1.2M and $4.7M, ex-changes in working capital) in the three and twelve months ending March 31, 2019 as compared to $1.0M and $3.9M ($915k and $3.6M, ex-changes in working capital) in the comparable prior year periods.

Relative to the operational update…

The major recent highlight on the operational front was the announcement, made concurrent with the company's fiscal Q4'19 earnings release, of a **collaboration with SeaStar Medical, Inc**. SeaStar, which was formed approximately one year ago when CytoPherx acquired Immunocept Medical Products (and subsequently changed their name to SeaStar), is led by Dr. Charles Fisher, who is also a Director on Aethlon's Board. SeaStar's 'CLR 2.0 Hemofilter' is a blood filter which is FDA 510(k)-cleared for use in patients with acute kidney injury, pulmonary edema and congestive heart failure.

Aethlon's press release announcing the relationship notes that CLR 2.0 is currently marketed for organ preservation in the solid organ transplant market. Similar to the Hemopurifier, CLR 2.0 cartridges are compatible with standard, hospital-based CRRT (continuous renal replacement therapy) equipment. In terms of the extent and depth pf SeaStar's extracorporeal blood filtration related IP, this PR announcing CytoPerx's acquisition of Immunocept mentions that, "there are 62 issued and pending U.S. patents covering nearly everything that can be done with hollow fiber membranes in the acute inflammation and multi-organ failure therapeutic space."

While Aethlon has yet to provide specifics in terms of exactly what the duo will pursue in terms of product development, the press release does note that, "…the companies plan to jointly develop complete treatment solutions that will allow deployment into multiple inpatient and outpatient treatment settings in any clinical indication where combined use of the Hemopurifier and CPCs may improve or expand indications for use, including but not limited to infectious disease, oncology and organ preservation and transplant." Much of the appeal of working together appears related to the potential complementariness of the two technologies' targeted indications – for example, Hemopurifier's ability to capture exosomes and clear viruses may have real utility in (CLR 2.0's) an organ transplantation indication.

Aethlon did not provide much more in the way of specifics on the Q4'19 earnings call but did say that their focus, at least initially, will likely be on the development of a joint product which includes a combination of each parties' technologies for one or more (not-yet-specified) critical care applications. But it also sounds as if there's potentially lots of different optionality in terms of cross-application of each's technologies towards individual pursuits either related to the Hemopurifier and CLR 2.0 Hemofilter or development of novel products. We think it is mostly a blank slate at this point and look forward to hearing updates on their plans for leveraging their joint technologies and other resources.

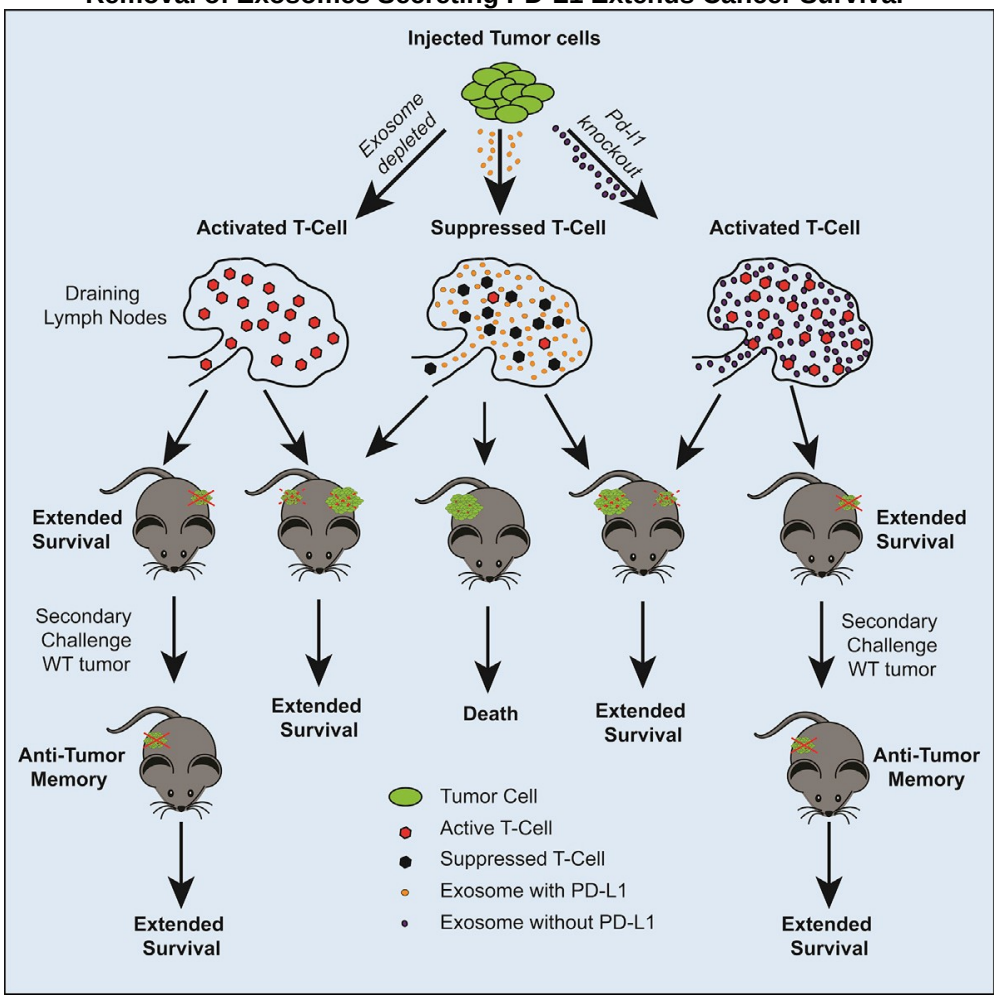
Hemopurifier cancer-related pursuit

While management did not offer details in terms of their interaction with FDA regarding the Breakthrough Device designation for the Hemopurifier in the treatment of cancer, they did indicate that communication with the agency has been ongoing and that progress towards commencement of eventual clinical studies is being made. Management also noted that they hope to have more to talk about relative to this in the coming months.

Encouragingly, there is no shortage of new evidence supporting the role of exosomes in the progression of cancer and, similarly, that removing tumor-derived exosomes from circulation may 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, a growing database of evidence can have important contextual implications including potentially influencing key opinion leaders and regulators alike.

Among the new evidence supporting the targeting of tumor-derived exosomes is a paper published in April 2019 in the journal Cell. The article*, Suppression of Exosomal PD-L1 Induces Systemic Anti-tumor Immunity and Memory*, cites that when PD-L1 (a membrane-bound ligand on the cell surface of many cells that is upregulated with inflammation and oncogenic lesion) on cancer cells binds to T cells (specifically to the T cells' PD-1 receptor), it suppresses the T cells' ability to fight the tumor. As tumor-derived exosomes secrete PD-L1 (which suppress T cells' cancer-killing ability), removal of exosomal PD-L1 inhibits cancer growth.

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



Refresher on Cancer Breakthrough Device Designation

In November 2018 AEMD announced that they had received Breakthrough Device designation from FDA for their Hemopurifier in the treatment of cancer. The proposed indications under this Breakthrough Device designation includes "The Hemopurifier is a single-use device indicated for 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."

This is the second such designation for their flagship device, the first of which came in September 2017 when FDA approved AEMD's application seeking Expedited Access Pathway designation for their Hemopurifier with the following proposed indications for use; "The Hemopurifier is a single-use device indicated for the treatment of life-threatening highly glycosylated viruses that are not addressed with an approved treatment."

As we first mentioned in our November 27th investor Note, this could be somewhat of a game-changer, in our opinion as while the highly glycosylated virus program had substantial potential, there remains an overarching

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

question of just exactly what a viable regulatory program would encompass (we have covered this topic in detail in prior reports).

While cancer is just as impossible to effectively control and treat as are the deadly viruses that would fall under the purview of the initial Breakthrough program, it is obviously relatively widely prevalent and more 'chronic' as compared to infection from highly virulent viruses (which, if exposed, could result in death in relatively short period of time). This makes cancer a much more practical target to build a clinical and regulatory program around. And with Hemopurifier already having shown substantive efficacy in reducing or eliminating circulating tumor derived exosomes from the blood, it is possible that a cancer pursuit could be relatively fast-moving. See our Refresher on cancer-related programs that AEMD has or is currently pursuing below.

Next steps in cancer…

As the title of the proposed indications indicate, the Breakthrough Device designation (BDD) relegates use of the Hemopurifier under a formal clinical program to cancers in which exosomes have been shown to "participate in the development or severity of the disease", which have metastasized and which have failed to respond to standard of care. In addition, AEMD's device will be used as an adjunct to standard of care.

While management did not provide specifics in terms of anticipated next steps under a cancer-related clinical development program, we think it's a reasonable assumption that they will look to put the pieces together for an eventual petition to FDA to conduct formal U.S.-based clinical studies. And while we have no insight into the incremental milestones that Aethlon will be focused on or specifics in terms of their near-term goals, we do think that there is reason to believe that a cancer indication for the Hemopurifier is an eventual realistic outcome.

Already-completed clinical studies should provide at least some support for the safety of the device, while preclinical studies support Hemopurifiers' ability to capture exosomes. And there is a growing body of evidence that, yes, exosomes do play a role in cancer progression. And as it relates to a question of Hemopurifiers' safety, the fact that the BDD indication is for metastasized cancers and for which standard of care has failed (i.e. patients which 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 certainly 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. For these reasons, we believe eventual FDA approval to conduct clinical studies in a related cancer indication is a very realistic assumption.

We also note that AEMD had previously been aggressive in pursuing cancer as a potential target and in collaboration with the University of Pittsburgh Hillman Cancer Center, had submitted a proposal for grant funding to NCI for a n=50 human trial in hand and neck cancer. The goal is to determine if tumor-derived exosome capture via Hemopurifier can enhance efficacy of Bristol-Myers' Opdivo (nivolumab), a checkpoint inhibitor which currently generates $6B in annualized revenue. While funding was not approved following the initial submission, AEMD indicated on the Q2 '19 call (November 2018) that an amended filing could be in the works. If eventually funded, AEMD's prior CEO, Jim Joyce, noted at the time that he believed that this human study could form the basis of a clinical study protocol for an eventual IDE submission to FDA. As we noted in our Q2 update (Nov 9th *Pivot Towards Cancer Makes Sense. FDA Filing For Breakthrough Device in Cancer*), we believed that eventual approval of an IDE for such a study protocol could represent the first significant step towards a possible regulatory program positioning Hemopurifier as an adjunct to already established cancer therapies. That could open up new opportunities for AEMD in relation to development of Hemopurifier, potentially including collaborations with the likes of Bristol-Myers. While too early to speculate on chances of such an opportunity materializing, given the potential upside to AEMD, it is something that we will be closely watching. It is not clear whether AEMD is still/may still pursue re-submittal of this grant application.

We hope to know more about the company's specific plans, including near-term goals towards pursuit of U.S. clinical studies. We also think that, in the meantime, AEMD may apply to FDA for Expanded Access / Compassionate Use of Hemopurifier in an oncology setting. While Expanded Access, if granted, would not be a substitute for clinical studies, it could offer the opportunity for initial human use/experience in cancer and potentially provide some relevant value in further supporting the use of the device for this application. As a reminder, the Hemopurifier was previously granted Expanded Access for the treatment of Ebola.

Hemopurifier Cancer programs

Cancer as a target of Hemopurifier has gained a lot of traction as of late. Part of the reason relates to recent NCI grants – but also relates to the growing body of evidence surrounding exosomes' role in cancer progression. As it

relates to the NCI grants, AEMD recently successfully completed a phase I contract evaluating Hemopurifier in the removal of melanoma-derived exosomes and is expected to submit for a subsequent phase II contract. Continued successful completion should significantly bolster the already compelling evidence demonstrating the potential of Hemopurifier to reduce circulating exosomes from the blood and cancer metastasis.

In fiscal Q1 '19 AEMD received final payment from the phase I grant funded by the National Cancer Institute. The contract, dubbed "Device Strategy for Selective Isolation of Oncosomes and Non-Malignant Exosomes", paid $299k over nine months. The University of Pittsburgh and Massachusetts General Hospital worked under AEMD to complete the contract. Deliverables included demonstrating the ability of Hemopurifier to capture melanoma exosomes from plasma and to isolate tumor-derived exosomes from non-malignant exosomes. A follow-on phase II contract, worth approximately $1.5M over two years, could follow. AEMD noted on the fiscal Q2 2019 call in November 2018 that they were preparing the submission and, at the time, had expected to make the filing later that same month (it is currently unclear whether that submission had been made).

And, in September 2018 AEMD was awarded another NCI contract. Titled, "The Hemopurifier device for targeted removal of breast cancer exosomes from the blood circulation", the award will pay $298k over 12 months. The work is also being done in conjunction with the University of Pittsburgh and Massachusetts General Hospital. Initial payment, in the amount of $50k, was received under this contract in January 2019 and initial revenue of $80k was recognized in fiscal Q4'19 (ending 3/31/19). Then, in late-October 2019 AEMD received notification of a U.S. DoD Army Breakthrough Award. Titled "Isolation of triple negative breast cancer exosomes using the Hemopurifier", AEMD noted on the November call that they were in the contracting process.

AEMD could also have initial data from an investigator-initiated study conducted at UC Irvine in a program titled, "Plasma exosome concentration in cancer patients undergoing treatment" which is evaluating the ability of Hemopurifer in the in-vitro capture of tumor-derived exosomes. The study, which was conducted in 2018, enrolled 17 subjects (data includes 120 samples) across four different cancer types (breast cancer, esophageal cancer and ovarian cancer). Management's comments on the Q1 '19 call in August indicated that initial results are promising.

We also note that AEMD had previously been aggressive in pursuing cancer as a potential target and in collaboration with the University of Pittsburgh Hillman Cancer Center, had submitted a proposal for grant funding to NCI for a n=50 human trial in hand and neck cancer. The goal is to determine if tumor-derived exosome capture via Hemopurifier can enhance efficacy of Bristol-Myers' Opdivo (nivolumab), a checkpoint inhibitor which currently generates $6B in annualized revenue. While funding was not approved following the initial submission, AEMD indicated on the Q2 '19 call (November 2018) that an amended filing could be in the works. If eventually funded, AEMD's prior CEO, Jim Joyce, noted at the time that he believed that this human study could form the basis of a clinical study protocol for an eventual IDE submission to FDA. As we noted in our Q2 update (Nov 9th *Pivot Towards Cancer Makes Sense. FDA Filing For Breakthrough Device in Cancer*), we believed that eventual approval of an IDE for such a study protocol could represent the first significant step towards a possible regulatory program positioning Hemopurifier as an adjunct to already established cancer therapies. That could open up new opportunities for AEMD in relation to development of Hemopurifier, potentially including collaborations with the likes of Bristol-Myers. While too early to speculate on chances of such an opportunity materializing, given the potential upside to AEMD, it is something that we will be closely watching. It is not clear whether AEMD is still/may still pursue re-submittal of this grant application.

On the ESI side of the business…
In March 2018 AEMD announced initiation of their CTE/TauSome study at the first (and primary) site, Translational Genomics Research Institute in Arizona. Enrollment, which included nine former NFL players on just the first day, stood at 20 as of the day of the Q1 call (Aug 8th) and was at 41 as of the Q2 call (Nov 6th). Management did not provide an enrollment update on the Q3 or Q4 calls but has noted that the study continues as does patient enrollment. AEMD has been active in both promoting awareness of the study as well as in encouraging enrollment. A newly formed NFL 'Player's Council' could further aid in that regard. And, in May 2019 AEMD announced a collaboration with Prostate On-Site Project, host of the Jerry Colangelo Sports Legends Gold Classic in Phoenix, to encourage participation in the study.

DEVELOPMENT BACKGROUND

EAP/Breakthrough Designation, Broad-Spectrum Indication for Treatment of Life-Threatening Diseases
While we think the viral BDD offers potential opportunity over the longer-term and possible use under Expanded Access, we think given the BDD for cancer, that AEMD's resources and attention will be largely focused on an

oncology program. As such, we will keep our commentary brief as it relates to use of Hemouprifier in glycosylated viruses.

In September 2017 FDA approved AEMD's application seeking Expedited Access Pathway designation for their Hemopurifier with the following proposed indications for use; "The Hemopurifier is a single-use device indicated for the treatment of life-threatening highly glycosylated viruses that are not addressed with an approved treatment." This implies a fairly broad indication given its non-specificity to a particular virus, disease or condition as well as the fact that many of the highly glycosylated viruses lack an effective therapy.

As a refresher, viruses use glycosylation as a means to avoid detection by the body's immune system. Highly glycosylated viruses, such as HIV, HCV, Ebola, West Nile and pandemic flu strains (among a host of others) have proven to be particularly resilient and difficult to treat. Aethlon also recently began an in vitro study to demonstrate capture of the (current) H3N3 flu strain. The filter within the Hemopurifier contains galanthus nivalis agglutinin (GNA) which binds to the glycan shield of these viruses, thereby removing it from the bloodstream prior to the toxins infecting other cells or organs.

In October 2017 FDA issued new draft guidance for their (previously proposed) 'Breakthrough Device' program. This program was borne out of the agency's 21st Century Cures Act and will supersede the Expedited Access Pathway as well as the Priority Review Program. Similar to those programs, the Breakthrough Device program is aimed at facilitating development and expediting review of those devices that provide for more effective treatment of life-threatening illnesses and conditions.

AEMD had also been considering a potential supplement to their existing compassionate use IDE that was previously approved by FDA for use of Hemopurifier in the treatment of Ebola. Management noted on a prior earnings call that the supplement would be for other life-threatening viruses that Hemopurifier has already demonstrated (in, at least, in-vitro studies) the ability to capture. In addition to Ebola, other viruses and pathogens that Hemopurifier has shown utility in capturing include Zika, Chikungunya, Dengue virus, H1N1 swine flu, H5N1 bird flu virus, the reconstructed Spanish flu of 1918 virus, West Nile virus and MERS.

Relative to ESI, Aethlon is looking to build on the success of their findings as part of the DETECT study (see Appendix for details) and recently initiated what is eventually expected to be the largest study in NFL players in the detection of CTE in living individuals. As a reminder, Aethlon's majority-owned subsidiary Exosome Sciences has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. Results from DETECT (see below for more details), presented in April 2015, showed that the NFL players had significantly higher levels of TauSome (tau) in their blood/plasma than those of the controls (subsequent to release of these preliminary results, additional analysis (per the company's comments) showed that TauSome levels were approximately 9 times higher, on average, in the NFL group as compared to control subjects). Tau levels were also correlated to performance on cognition tests, with higher tau levels corresponding to poorer test performance. Investigators concluded that TauSome levels in blood plasma may be an accurate biomarker for CTE.

The goal of AEMD's new study, announced in January 2017, is to further validate TauSome as an accurate, non-invasive, reliable biomarker for the diagnosis of CTE in living individuals. While initiation of the study took longer than initially anticipated, in March 2018 AEMD announced commencement at their first (and primary) site, Translational Genomics Research Institute (TGen) in Arizona. Enrollment, which included nine former NFL players on just the first day, stood at 41 as of early November 2018.

This and other studies should provide additional data points and provide more insight into the potential future utility of the diagnostic for CTE – and potentially other conditions such as Alzheimer's disease. While the DETECT study included 78 former NFL players (and 16 controls), ESI's new study is expected to enroll up to 200 participants, many of which are expected to be former NFL players, at several U.S. sites – at full enrollment it could be the largest study in NFL players at risk of CTE. The study is also expected to assess the potential correlation of Tausome levels in NFL players with that of Alzheimer's patients - with the potential future goal of leveraging this biomarker (as a companion diagnostic) and study data to support enrollment of NFL players in clinical studies evaluating novel anti-tau drugs which are currently aimed mostly at Alzheimer's patients. Interestingly, additional analysis done subsequent to publishing of the preliminary DETECT data, found that when looking at Alzheimer's patients, they found tau levels in those patients were 10 times higher, on average, as compared to the control subjects in DETECT.

Success in DETECT was a major milestone, in our opinion, but this larger, follow-on study should provide more definitive information relative TauSome's place in the detection of CTE (as well as potentially its relationship to other

diseases such as Alzheimer's) – a goal that has escaped the clinical community so far and one that would be a major breakthrough and likely be instrumental in helping to shape the diagnosis, treatment and monitoring of the disease. As such, we look forward to updates on the progress of both the Hemopurifier and ESI related programs.

We also think there are reasons to be optimistic that additional opportunities may present themselves to ESI (and, maybe, the Hemopurifer programs) as it relates to Alzheimer's - which continues to garner more investor and philanthropic interest and which more and more is learned about every day. Relative to funding – this recently includes a $30M 'venture philanthropy' accelerator for Alzheimer's diagnostics backed by Bill Gates and Leonard Lauder. The fund is focused on identifying and developing biomarkers and diagnostics for early detection of Alzheimer's disease. Recent research is also revealing more about the potential role of exosomes in Alzheimer's – this includes a study[2] published in Acta Neuropathologica in June 2018 which showed exosomes in the brains of subjects with Alzheimer's contained increased levels of amyloid-beta oligomers (which are believed to play a key role in the pathogenesis of Alzheimer's) and these exosomes can act as vehicles for spreading these toxic substances.

Outlook Valuation

Given the difficulty in designing clinical studies around highly virulent viruses, we think the BDD for cancer could be a game-changer for Aethlon. While cancer is just as impossible to effectively control and treat as are the deadly viruses that would fall under the purview of the initial Breakthrough program, it is obviously relatively widely prevalent and more chronic as compared to infection from highly virulent viruses (which, if exposed, could result in death in relatively short period of time). This makes cancer a much more practical target to build a clinical and regulatory program around. 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, it is possible that a cancer pursuit could be relatively fast-moving.

We think that there is reason to believe that a cancer indication for the Hemopurifier is an eventual realistic outcome. Already-completed clinical studies should provide at least some support for the safety of the device, while preclinical studies support Hemopurifiers' 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 which 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 certainly 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. And, encouragingly, there is no shortage of new evidence supporting the role of exosomes in the progression of cancer and, similarly, that removing tumor-derived exosomes from circulation may 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, a growing database of evidence can have important consequences including potentially influencing key opinion leaders and regulators alike. For these reasons, we believe eventual FDA approval to conduct clinical studies in a related cancer indication is a very realistic assumption.

Relative to ESI, the new, larger CTE study should provide more definitive information relative TauSome's place in the detection of CTE (as well as potentially its relationship to other diseases such as Alzheimer's) – a goal that has escaped the clinical community so far and one that would be a major breakthrough and likely be instrumental in helping to shape the diagnosis, treatment and monitoring of the disease.

We are maintaining our sum-of-the-parts valuation methodology in which we place a value of $90M for Hemopurifier in virus, pathogen, bioterror and cancer applications and value ESI at $30M. Sum-of-the-parts values AEMD at approximately $120M or ~$6.25/share. We think development progress of Hemopurifier, potentially including agreement on design of clinical studies and IDE approval to conduct U.S.-based clinical studies, along with precursors to these possible events, could be valuation catalysts. We also note that while it is too early to gauge the potential value of the AEMD / SeaStar collaboration, that progress towards a joint product development program (or related synergies with AEMD's current individual pursuits) could offer value-creation and/or value-enhancement opportunity.

[2] Sinha, M. et al. Alzheimer's disease pathology propagation by exosomes containing toxic amyloid-beta oligomers. Acta Neuropathol. 2018; 136(1): 41–56.

PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

	2017 A	2018 A	Q1 A	Q2 A	Q3 A	Q4 A	2019 A	Q1 E	Q2 E	Q3 E	Q4 E	2020 E	2021 E
Revenue	$392.1	$149.6	$149.6	$0.0	$0.0	$80.0	$229.6	$0.0	$218.4	$187.5	$187.5	$593.4	$1,125.0
YOY Growth	*-55.8%*	*3128.2%*	-	-	-	*6.9%*	*53.5%*	*-100.0%*	*#DIV/0!*	*#DIV/0!*	*134.4%*	*158.4%*	*89.6%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$392.1	$149.6	$149.6	$0.0	$0.0	$80.0	$229.6	$0.0	$218.4	$187.5	$187.5	$593.4	$1,125.0
Gross Margin	*100.0%*	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$5,817.4	$4,402.1	$1,052.1	$1,139.2	$1,720.0	$1,430.7	$5,342.0	$1,291.0	$1,329.0	$1,383.0	$1,448.0	$5,451.0	$5,527.0
% SG&A	*1483.8%*	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$673.0	$578.6	$194.8	$207.8	$243.8	$240.2	$886.6	$258.0	$262.0	$244.0	$278.0	$1,042.0	$1,147.0
% R&D	*171.7%*	-	-	-	-	-	-	-	-	-	-	-	-
Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6,098.4)	($4,831.1)	($1,097.3)	($1,347.0)	($1,963.9)	($1,590.9)	($5,999.1)	($1,549.0)	($1,372.6)	($1,439.5)	($1,538.5)	($5,899.6)	($5,549.0)
Operating Margin	*-1555.4%*	-	-	-	-	-	-	-	-	-	-	-	-
Other Expense, total	$1,208.4	$868.7	$55.1	$55.1	$55.1	$55.2	$220.5	$53.5	$0.0	$0.0	$0.0	$53.5	$0.0
Pre-Tax Income	($7,306.7)	($5,699.8)	($1,152.4)	($1,402.1)	($2,019.0)	($1,646.1)	($6,219.5)	($1,602.5)	($1,372.6)	($1,439.5)	($1,538.5)	($5,953.1)	($5,549.0)
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($7,276.1)	($5,679.6)	($1,146.2)	($1,393.4)	($2,013.0)	($1,642.1)	($6,194.8)	($1,596.1)	($1,367.1)	($1,433.7)	($1,532.3)	($5,929.3)	($5,526.8)
Net Margin	*-1855.8%*	*-3795.9%*	-	-	-	-	*0.0%*	-	-	-	-	*-999.2%*	*-491.3%*
EPS	($0.94)	($0.46)	($0.06)	($0.08)	($0.11)	($0.09)	($0.34)	($0.08)	($0.07)	($0.06)	($0.06)	($0.27)	($0.20)
YOY Growth	*42.2%*	*65.1%*	-	-	-	-	*0.0%*	-	-	-	-	*79.3%*	*-9.3%*
Diluted Shares O/S	7,764	12,317	17,755	17,789	18,050	18,905	18,125	19,062	19,120	24,074	26,452	22,177	28,000

Brian Marckx, CFA

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Appendix

U.S. Feasibility Study HCV Capture Data Announced at BIO International Convention
During a presentation at the 2017 BIO International Convention in San Diego on June 21st management announced HCV capture data from their recently completed U.S. feasibility study. As a reminder, eight patients with ESRD and infected with HCV were enrolled in the single-arm study, which was conducted at DaVita MedCenter in Houston. Subjects received Hemopurifier treatment 3x/week for two consecutive weeks. Data related to vital signs, blood work, hematology and liver function were collected during the weeks of Hemopurifier treatment as well as one week prior. So while this was primarily a safety study, efficacy-related data including viral load reductions and measurement of total virus captured were also collected and are expected to be included in the final report submission to FDA.

Relative to the primary endpoint (i.e. safety), Aethlon announced earlier that Hemopurifier treatment was well-tolerated and that there were no device-related adverse events reported. Given that safety was the main objective of the study and these patients (i.e. those with ESRD and HCV) were of highly compromised health, the positive safety outcome is significant not only in terms of the event-profile of the device, but also as solid support in petitioning FDA for follow-on clinical trials as well as for (potentially immediate) consideration under PHEMCE's broad-spectrum countermeasure program mandate.

As it relates to the (secondary) efficacy measures, the BIO presentation gave us the first glimpse on viral capture during the feasibility study. Capture data that was presented relates to measurements taken following two (of the six total) Hemopurifier treatments. Data was available from 13 cartridges related to seven patients (two cartridges from six patients and one cartridge from one patient). As the slides from the presentation (below) show, virus capture ranged from a low of 589k I.U. (patient six, cartridge two) to a high of 1.62B (patient one, cartridge two). Average capture per cartridge was 154.4M. Management noted during the presentation that the study researchers mistakenly (i.e. violated study protocol) thoroughly saline-washed the cartridges at the treatment site following Hemopurifier treatment (and prior to measuring capture data) which could have had the effect of reducing the capture yields.

While its difficult to judge the clinical significance of this data, it does clearly show that the Hemopurifier is capturing the HCV virus (which may have been even greater if not for the saline-wash issue). This adds to the considerable prior evidence of Hemopurifier's ability to capture target substances including human studies in HIV and Ebola (as well as earlier human studies in HCV) and in vitro studies in a host of other viruses.

Values measured post 500 ml/min high pressure saline wash

DaVita Med Center Dialysis Virus Capture Study
Houston, Texas USA / HCV-Infected ESRD Subjects / 4-Hour Treatment

Patient Cartridge Code	IU Capture Value	Total Virus Capture
01-V1*	N/A	N/A
01-V2	1.62×10^9	1,620,000,000
02-V1	3.99×10^6	3,990,000
02-V2	1.18×10^7	11,800,000
03-V1	1.38×10^7	13,800,000
03-V2	1.29×10^7	12,900,000
04-V1	1.24×10^8	124,000,000
04-V2	6.38×10^7	63,800,000
05-V1	4.19×10^7	41,900,000
05-V2	7.10×10^6	7,100,000
06-V1	1.71×10^6	1,710,000
06-V2	5.89×10^5	589,000
07-V1	2.84×10^6	2,840,000
07-V2	1.03×10^8	103,000,000
	Average Virus Capture	154,418,000

* Assay protocol deviation / improper storage and loss of elution fluid

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CTE Study Refresher…

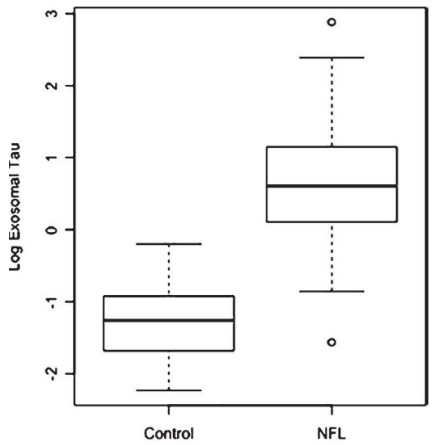
As a reminder, Aethlon's majority-owned subsidiary Exosome Sciences (ESI) has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. ESI has used what they learned in how to isolate certain brain-specific biomarkers to evaluate blood/plasma samples collected by participants (former NFL players and a control group) enrolled in BU's DETECT study. The study is the first on CTE funded by the NIH.

In April 2015 investigators presented initial findings of DETECT at the annual Traumatic Brain Injury Conference held in Washington, DC. Results were from 78 former NFL players and 16 controls and showed that the NFL players had significantly higher levels of tausome (tau) in their blood/plasma than those of the controls (subsequent to release of these preliminary results, additional analysis (per the company's comments) showed that TauSome levels were approximately 9 times higher, on average, in the NFL group as compared to control subjects). Tau levels were also correlated to performance on cognition tests, with higher tau levels corresponding to poorer test performance.

A manuscript of the preliminary results were published in the online version of the Journal of Alzheimer's Disease in early 2016. Inclusion criteria for the NFL group included age 40-69, a minimum of 12 years of tackle football including a minimum of 2 years in NFL at position associated with extensive head impacts and a self-report of having symptoms associated with CTE including changes in cognition, behavior and mood. Inclusion criteria for control included male age 40-69, minimum of 4 years in non-contact sports including 2 at college level or higher.

The publication provided additional details of the results which included (all charts and graphics[3]);

- Total plasma exosomes did not differ between the NFL and control groups and NFL did have significantly higher ($p<0.0001$) plasma exosomal tau (results in figure below are unadjusted for age). Per management's comments, additional analysis done subsequent to this preliminary data found that tau levels were approximately nine times higher in the NFL group as compared to the control group



- Plasma exosome levels were still statistically significantly higher ($p<0.0001$) in the NFL group than in control after adjusting for age and body mass (BMI)

Parameter estimates of ANCOVA for exosomal tau

Predictor	Estimate	Standard Error	*t*-test	*p*-value
Difference of control minus NFL exosomal tau levels	–1.93	0.24	–8.05	<0.0001
Age	0.01	0.01	1.20	0.2351
Body Mass Index	0.01	0.02	0.34	0.7319

[3] Preliminary Study of Plasma Exosomal Tau as a Potential Biomarker for Chronic Traumatic Encephalopathy. Stern, Robert A. et al. Journal of Alzheimer's Disease, vol. Preprint, no. Preprint, pp. 1-11, 2016

- The diagnostic demonstrated 82% sensitivity with 100% specificity, 100% positive predictive value and 53% negative predictive value. In other words, all of the elevated tau results came from NFL players, although not all NFL players showed elevated tau levels

- In the NFL cohort, tau levels were statistically significantly inversely correlated to performance on cognition tests (Wechsler Adult Intelligence Scale Digital Symbol and Neuropsychological Assessment Battery List Learning)

- While exosomal tau was statistically correlated to cognition, it was not correlated to any of the mood or behavioral measures

Relationship between log exosomal tau and measures of cognition, mood, and behavior from mixed effects regression analysis adjusted for age and education as well as for associations of multiple tests per subject and correlations of tests within the same domain for the NFL group only

Domain and Measure	Partial Correlation	Beta Estimate	Standard Error	t-test	p-value
Psychomotor Speed					
Wechsler Adult Intelligence Scale-Revised [78] Digit Symbol Test, Raw Score	–0.33	–3.01	1.16	–2.60	0.0093
Trail Making Test [79] Part A, T-Score	–0.18	–2.03	1.52	–1.33	0.1826
Executive Functioning					
Trail Making Test [79] Part B, T-Score	–0.03	–0.11	2.15	–0.05	0.9589
Wisconsin Card Sorting Test [80] Percent Errors, T-score	–0.09	–0.74	1.28	–0.58	0.5605
Rey-Osterreith Complex Figure –Boston Qualitative Scoring System (BQSS) [81] Organization Score, T-score	0.09	1.69	2.06	0.82	0.4117
Behavior Rating Inventory of Executive Function–Adult Version (BRIEF-A) [82] Metacognition Index, T-score	0.01	0.34	1.75	0.20	0.8434
Learning and Memory					
BQSS [81] Immediate Presence & Accuracy, T-score	–0.14	–1.14	1.32	–0.86	0.3879
BQSS [81] Delayed Presence & Accuracy, T-score	–0.19	–1.74	1.44	–1.21	0.2258
Neuropsychological Assessment Battery (NAB) [83] List Learning Test List A Immediate Recall, T-score	–0.31	–2.84	1.14	–2.50	0.0126
NAB [83] List Learning Test List A Short Delay Recall, T-score	–0.29	–3.41	1.63	–2.09	0.0365
NAB [83] List Learning Test List A Long Delay Recall, T-score	–0.30	–4.35	1.78	–2.44	0.0147
Visuospatial Skills					
NAB [83] Map Reading Test, T-score	0.11	1.38	1.25	1.10	0.2709
Language					
NAB [83] Naming Test, T-Score	–0.12	–1.41	1.46	–0.97	0.3336
Mood					

Key Takeaways:

- ESI's tau diagnostic demonstrated
    - o exosome tau was significantly higher (~9x) in NFL players than in control
    - o exosome tau was significantly higher (~10x) in Alzheimer's patients than in control
    - o exosome tau was significantly correlated to performance on cognition tests. Higher levels of tau correlated to poorer test performance on memory and psychomotor speed tests

- Exosome tau was not correlated to mood or behavior measures

- Highest levels of tau were found only in NFL players although not all NFL players had high levels of tau
- Confirmation that the diagnostic can accurately identify individuals with CTE would require neuropathological examination of the brain

Relative to the lack of association between tau levels and mood/behavior test results, the investigators noted that there is evidence suggesting tau is a better indicator of cognitive function than it is of mood/behavior and that CTE-related cognitive functionality impairments have been reported to be more prevalent in later stage of the disease as compared to mood/behavior changes. In addition, they note "It is possible that the mood and behavioral features may have multiple potential etiologies, in addition to CTE-associated tau degeneration, whereas the cognitive changes are more consistently due to the tau degeneration."

Relative to the fact that not all NFL players had high levels of tau – the investigators indicated that this was not a surprise as it should be expected that not all NFL players, even those in the study (i.e. – which have at least some symptoms), would have CTE.

While the investigators concluded that these findings suggest exosomal tau in plasma may be an accurate biomarker for CTE, additional research needs to be done. They note some limitations of the study including that;
- confirmation of association between exosome tau and CTE would require a neuropathological exam
- the study did not include markers for where the tau originated so there was not complete confidence that these were all brain-derived exosomes (tau is also present in other areas of the body besides the brain)
- and if these were brain-derived exosomes, the study was also not powered to differentiate between where in the brain they came from (i.e. – neuronal vs, non-neuronal, which may have implications)
- small sample size of the study (particularly control)
- lack of an additional biomarker for CTE

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