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Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

AEMD: Compassionate Use, Real-World Data, Awaiting FDA Final Guidance

AEMD continues to make substantive positive progress on several fronts. Using sum-of-the-parts valuation and based on current development progress in each respective category we place value of $90M for Hemopurifier in virus, pathogen, bioterror and cancer applications and combined value of ESI and ELLSA technology of $30M. Total company value equates to ~$120M or $6.75/share

Current Price (08/27/18)	$1.06
Valuation	**$6.75**

OUTLOOK

AEMD is evaluating a potential supplement to their existing compassionate use IDE that was previously approved by FDA for use of Hemopurifier in the treatment of Ebola. While we do not think supplemental approval is likely to generate much in the way of revenue, the opportunity to gain additional real-world human clinical experience could be of significant value. In fact, assuming supplemental use in other life-threatening targets is granted, evidence of additional 'successful/safe' clinical use under expanded access could be a significant step forward in AEMD's quest for U.S. regulatory marketing approval. As we have opined in the past, we think a viable approval pathway in the U.S., if it exists, may include aggregation of sufficient evidence of safety and clinical utility through less-traditional routes (such as Real World data). Compassionate use may play a role.

Cancer as a target of Hemopurifier seems to be gaining traction. Part of the reason relates to the recent NCI grant – but it appears that part also relates to the growing body of evidence surrounding exosomes' role in cancer progression. AEMD has had initial successes in cancer and is now more aggressively pursuing this as another potential target for Hemopurifer.

SUMMARY DATA

52-Week High	**$2.70**
52-Week Low	**$0.80**
One-Year Return (%)	**-23.57**
Beta	**1.93**
Average Daily Volume (sh)	**80,550**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$19**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
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 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Average,**
Type of Stock	**Small-Growth**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2017	0.0 A	0.4 A	0.0 A	0.0 A	0.4 A
2018	0.0 A	0.0 A	0.1 A	0.1 A	0.2 A
2019	0.2 A	0.0 E	0.0 E	0.2 E	0.3 E
2020					0.8 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2017	-$0.28 A	-$0.29 A	-$0.15 A	-$0.22 A	-$0.94 A
2018	-$0.21 A	-$0.14 A	-$0.08 A	-$0.08 A	-$0.46 A
2019	-$0.06 A	-$0.07 E	-$0.07 E	-$0.07 E	-$0.28 E
2020					-$0.35 E

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

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Fiscal Q1 2019 Financials, Operational Update

Aethlon reported financial results for their fiscal first quarter 2019 ending June 30th and provided a business update. Revenue of $150k represented the final payment from the phase I NCI cancer grant. A subsequent, phase 2 contract worth approximately $1.5M over two years, could follow – AEMD's application for which is expected to be submitted later this year. Q1 operating loss was $1.1M, down slightly from the ~$1.2M quarterly average during fiscal 2018. EPS was ($0.06), compared to our ($0.07) estimate.

Cash used in operating activities was $818k ($851k, ex-changes in working capital) – slightly lower than the $1.0M ($900k) quarterly averages during fiscal 2018. Cash balance, which was $6.1M at quarter-end, is expected to be sufficient to fund operations for at least the next 12 months.

Relative to the operational update…

Updates to several of the development programs were provided on the call, including that related to Hemopurifier under the Breakthrough Device designation, Hemopurifier's potential role in cancer therapy and updates in the ESI segment – including CTE/TauSome study enrollment status and potential new opportunities.

As is relates to the Breakthrough Device (BD) designation, while management indicated that they continue to have regular dialogue with FDA, that until the FDA Draft Guidance on the Breakthrough Devices Program is finalized, there may not be any substantive decisions made relative to what a potential approval pathway would encompass. In other words, we think this is largely on hold until FDA's final guidance is published (no timeline has been offered).

In the meantime, AEMD is evaluating 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 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. Filing of the supplemental compassionate use application could happen in the very near-term.

While, as we first noted when Hemopurifier was approved for compassionate use in Ebola, supplemental approval is not likely to generate much in the way of revenue, the opportunity to gain additional real-world human clinical experience could be of significant value. In fact, assuming supplemental use in other life-threatening targets is granted, evidence of additional 'successful/safe' clinical use under expanded access could be a significant step forward in AEMD's quest for U.S. regulatory marketing approval. Importantly, expanded access/compassionate use was designed to address the challenges associated with evaluating novel life-threatening target therapies – including instances where it is not feasible to conduct a traditional pivotal RCT – as is the case with life-threatening highly glycosylated viruses. As we have opined in the past, we think a viable approval pathway in the U.S., if it exists, may include aggregation of sufficient evidence of safety and clinical utility through less-traditional routes (such as Real World data). Compassionate use may play a role.

Hemopurifier Cancer programs

Cancer as a target of Hemopurifier seems to be gaining traction. Part of the reason relates to the recent NCI grant – but it appears that part also relates to the growing body of evidence surrounding exosomes' role in cancer progression.

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 $299,250 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. AEMD anticipates submitting an application for a phase II follow-on grant, which is expected to be worth approximately $1.5M over two years, later this year.

CAR-T therapies have been recent headline-grabbers with FDA approval of Novartis' Kymriah and Gilead/Kite's Yescarta for the treatment of aggressive non-Hodgkin lymphoma. The therapies showed extraordinary efficacy in clinical trials. CAR-T therapies involve removing cells from the body, modifying them to target particular cancers and then putting them back into the patient. Several recently published studies have focused on (non tumor-derived) exosomes' potential role in facilitating effectiveness of cancer therapeutics, including immunotherapies.

This includes the use of CAR-T cell-derived exosomes as a way to reduce certain challenges of CAR-T cells, such as adverse events (eg cytokine release syndrome) and difficulty in locating and penetrating solid cancers.[1,2] Exosomes also appear to have potential utility as a delivery vehicle for orally administered chemotherapies – including paclitaxel (which is currently only delivered I.V.).[3]

The common theme among the growing knowledge base is that exosomes almost certainly play a much more integral role in intracellular signaling and communication than had only recently been thought. Evidence indicates that both non-malignant and tumor-derived exosomes travel lymphatic circulation – ideal for a chemotherapy delivery vehicle but also in the metastasis of cancer (which also suggests that removal of tumor-derived exosomes could inhibit metastasis).

AEMD has had some initial successes in the capture of tumor-derived exosomes. In addition to the recent phase I NCI grant, years ago they had also demonstrated the ability of Hemopurifier to capture immunosuppressive exosomes derived from metastatic melanoma. They could also soon have initial data from an investigator-initiated study being conducted with UC Irvine evaluating the ability of Hemopurifer in capturing tumor-derived exosomes. The study, announced in April 2015, enrolled 17 subjects (data includes 120 samples) across four different cancer types (breast, gastric, head & neck, and ovarian. While analysis is ongoing, management's comments on the Q2 '19 indicated that initial results are promising.

AEMD has been more aggressive in pursuing cancer as a potential target and in collaboration with the University of Pittsburgh Hillman Cancer Center, recently 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' Optivo (nivolumab), a checkpoint inhibitor.

On the ESI side of the business, in March 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 likely increased shortly afterwards as the second enrollment date was scheduled for August 10th. AEMD has been active in both promoting awareness of the study as well as in encouraging enrollment. CEO Jim Joyce's (also an NFL alumni) NFL relationships and a newly formed 'Player's Council' could further aid in that regard. Additional study sites are expected to come online. We expect we will hear regular enrollment updates on future calls.

Board Appointments – recent highlights also include the appointment of key persons to AEMD's board of directors – the consummation of which satisfied NASDAQ's independent board and audit committee composition requirements. We expect the new appointments to be integral in developing strategy for AEMD which could include collaboration and/or partnering activities.

- In November 2017 Dr. Charles Fisher, Jr. joined AEMD's board and audit committee. Dr. Fisher was previously Head of the Section of Critical Care Medicine at The Cleveland Clinic Foundation and has extensive research and practical industry experience in the areas of sepsis and inflammation including leading the Xigris Global Product Team at Eli Lilly. Xigris was the only drug to receive FDA approval for the treatment of sepsis.
- In January 2018 Sabrina Martucci Johnson joined AEMD's board and audit committee. Ms. Johnson is CEO of Daré Biosciences (Zacks initiated June 2018) and was previously the COO and CFO of Cypress Biosciences, which developed the PROSORBA column (for the treatment of rheumatoid arthritis).
- In June 2018 Guy Cipriani joined AEMD's board. Currently Chief Business Officer of Microbion Corp. Mr. Cipriani has a ~20 years' experience in pharma and biotech industries.

PIPELINE REFRESHER

EAP/Breakthrough Designation, Broad-Spectrum Indication for Treatment of Life-Threatening Diseases
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."

[1] Xiang-Jun Tang, et al. Therapeutic potential of CAR-T cell-derived exosomes: a cell-free modality for targeted cancer therapy. Oncotarget. 2015 Dec 29; 6(42): 44179–44190.
[2] Yubin Zhou, et al. Recent advances in exosome-based cancer immunotherapy. J Cancer Immunol Ther. 2018 Volume 1 Issue 1
[3] Agrawal AK, et al. Milk-derived exosomes for oral delivery of paclitaxel. Nanomedicine. 2017 Jul;13(5):1627-1636. doi: 10.1016/j.nano.2017.03.001. Epub 2017 Mar 11.

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.

While management recently indicated that they continue to have regular dialogue with FDA, that until the FDA Draft Guidance on the Breakthrough Devices Program is finalized, there may not be any substantive decisions made relative to what a potential approval pathway would encompass. In other words, we think this is largely on hold until FDA's final guidance is published (no timeline has been offered).

In the meantime, AEMD is evaluating 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 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. Filing of the supplemental compassionate use application could happen in the very near-term.

FDA Validation…

42 viruses have been classified by the National Institute of Allergy and Infectious Diseases as life threatening category A, B or C pathogen threats in the United States. And of these 42, 40 are highly glycosylated viruses – only two of which are currently addressed with an approved therapy.

Given that it is not feasible to conduct randomized controlled clinical studies for targets such as highly virulent viruses or pandemic threats, there is great ambiguity in what FDA may designate as an appropriate program to sufficiently validate the safety and efficacy of Hemopurifier. However, the broad-spectrum indication, which is not specific to a particular virus, disease or condition may provide some greater optionality in that regard. The severity of these targets (in the absence of an effective alternative therapy) also leads us to believe that the FDA may be more liberal in defining a viable regulatory pathway and in applying safety/effectiveness criteria as compared to less severe, chronic conditions and viruses (such as HCV or HIV).

Safety has been demonstrated in prior clinical studies as has the ability of Hemopurifier to capture target substances. This includes human studies in HIV and Ebola (as well as earlier human studies in HCV) and in vitro studies in a host of other viruses. Most recently, results of a U.S. single-arm feasibility study (n=8) were presented at the 2017 BIO International Convention in June. The study, in which Hemopurifier was used to treat patients with ESRD and infected with HCV (i.e. very sick individuals), showed AEMD's device was well-tolerated (with no device-related adverse events reported) and successfully captured up to 1.62B I.U. of the HCV virus (see Appendix for additional information). Could capture data be included as an endpoint for clinical validation purposes? That is another question that may come out of the upcoming meeting with FDA.

But we do believe, however, that despite the highly deadly nature of these types of targets, that it is unlikely FDA approval (for any indication) is attainable without clinical trials. As we have talked about in recent updates, we think that **Real World Data** may play a part in clinical validation. In 2015 FDA approved more than eight new medical devices and expanded the label on several others through supporting RWD – this included several high-risk, implantable devices.

FDA's recent move towards greater acceptance of RWD in decision-making has to do, in part, with the idea that traditional clinical trials are too rigid in some circumstances as well as the fact that "traditional clinical trial(s) may be impractical or excessively challenging to conduct" (as AEMD's might be for highly virulent viruses). That could

mean that (for example), in lieu of a randomized clinical trial, the sponsor may be allowed to use an existing database or medical registry as the control arm for a pivotal study.

We also think expanded access could offer additional opportunity. While, as we first noted when Hemopurifier was approved for compassionate use in Ebola, supplemental approval is not likely to generate much in the way of revenue, the opportunity to gain additional real-world human clinical experience could be of significant value. In fact, assuming supplemental use in other life-threatening targets is granted, evidence of additional 'successful/safe' clinical use under expanded access could be a significant step forward in AEMD's quest for U.S. regulatory marketing approval. Importantly, expanded access/compassionate use was designed to address the challenges associated with evaluating novel life-threatening target therapies – including instances where it is not feasible to conduct a traditional pivotal RCT – as is the case with life-threatening highly glycosylated viruses. As we have opined in the past, we think a viable approval pathway in the U.S., if it exists, may include aggregation of sufficient evidence of safety and clinical utility through less-traditional routes (such as Real World data). Compassionate use may play a role.

In the meantime, inclusion in the Strategic National Stockpile as a broad-spectrum countermeasure is another pursuit. This may be a pathway that lends itself to either partial or full funding from additional government grants. As a reminder one of AEMD's primary objectives is to be able to fulfill the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) goal of developing broad-spectrum medical countermeasures (MCM). **PHEMCE** is an interagency governmental organization comprised of HHS, CDC, NIH, FDA, VA, DoD, DHS and USDA with a goal of coordinat(ing) the development, acquisition, stockpiling, and use of medical products that are needed to effectively respond to a variety of high-consequence public health emergencies, whether naturally occurring or intentional."

This could include both bioterror as well as pandemic threats. Category "A" bioterror threats and pandemic viruses would likely fall in these categories. The fact that Hemopurifier has shown utility in capturing a variety of viruses and pathogens should play in their favor – this includes the capture of Ebola, Zika, Chikungunya, Dengue virus, H1N1 swine flu, H5N1 bird flu virus, the reconstructed Spanish flu of 1918 virus, West Nile virus and MERS. Some of the validation work for these targets was done in conjunction with government agencies including the U.S. CDC. and the U.S. Army Medical Research Institute for Infectious Diseases.

While we do not yet know specifics relative to requisite deliverables for inclusion of consideration for stockpiling as a countermeasure, indications are that AEMD is coordinating a strategy with that goal in mind. We hope to hear related updates in the near future. We do believe that there are factors that may play in AEMD's favor including;

- Hemopurifier demonstrating the ability to capture a variety of viruses (i.e. broad-spectrum capability)
- Safety profile from the feasibility and previous human studies
- Lack of existing therapies (drugs or devices) to address almost all conceivable virulent threats
- Drugs, if developed, would likely have single-target utility (i.e. not broad-spectrum) and may have relatively short shelf-life as compared to Hemopurifier
- Drugs cannot be developed for unknown threats - unknown threats are one of the reasons why broad-spectrum capability is important
- Experts believe the risk of bioterror/virulent threats are on the rise and capable of killing tens of millions of people
- The greater the threat risk and consequences of a bioterror attack or pandemic outbreak, likely the lower the bar will be set for consideration of stockpiling therapies that may have countermeasure utility - particularly those that have demonstrated an acceptable safety profile. Importantly, these countermeasures would not necessarily need to be approved by the FDA

Another recent FDA-related development could have applicability to the PHEMCE goal. **In January 2018 FDA and the U.S. Department of Defense launched a joint program to "prioritize the efficient development of safe and effective medical products intended to save the lives of American military personnel."** Under the program DoD will work together to speed development and approval of medical products aimed at saving lives of American soldiers – this includes devices to treat life-threatening diseases or conditions (presumably such as Category A threats). Noteworthy, is the DoD/FDA joint memo specifically cites that this program is similar to that of Breakthrough designation. While we do not know if this joint program will apply to AEMD's PHEMCE efforts, we think it adds another possible pathway for Hemopurifier's eventual adoption by the U.S. government.

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 20 as of the day of the Q2 call (Aug 8th) and likely increased shortly afterwards as the second enrollment date was scheduled for August 10th.

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[4] 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

The company continues to make substantive positive progress on several fronts including an ongoing ability to raise capital, diligence on cash burn and operating expenses, gaining FDA EAP/Breakthrough Device designation, completion of the U.S. feasibility study and commencement of a new CTE study.

The lack of safety issues and capture capability demonstrated in the U.S. feasibility study was highly encouraging given that 'success' in that study may help guide the next step in the FDA pathway. And progress, even incremental progress, which brings Hemopurifier closer to reaching the U.S. market is additional validation of the utility of the device. But, the lack of much substantive new news over the last several months has been disappointing, as has the more recent revelation that this Breakthrough pathway is essentially on hold until FDA finalizes their guidance. Until then, AEMD will pursue supplementing their compassionate use IDE. If approved, we

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

think it could offer the opportunity to gain valuable clinical experience – which, in turn, could be a significant step forward in AEMD's quest for U.S. regulatory marketing approval.

Following publication of FDA's final Breakthrough Device guidance (whenever that happens), we will be back to eagerly awaiting feedback from AEMD's interaction with FDA regarding design/feasibility of a viable regulatory pathway for Hemopurifier under the proposed indication 'for the treatment of life-threatening highly glycosylated viruses that are not addressed with an approved treatment'. Answers to certain questions such as 'whether human studies in common viruses such as HCV or HIV (among a host of others including latent viral pathogens) may serve as further ("sufficient"?) validation of Hemopurifier's "efficacy" in other, more virulent targets' as well as what to expect in terms of potential endpoints (such as capture or viral load data or patient outcomes), indications and size of enrollment of a pivotal trial will also be of interest to us. It is also possible that compassionate use, if expanded to included other viruses, could serve as support for either design of a clinical study, or even as substantive support for an eventual regulatory filing.

We look favorably on AEMD's strategy of diversifying shots on goal relative to monetizing Hemopurifier and believe there are legitimate reasons (as outlined in the body of this report) why their device could generate strong consideration by the U.S. government as countermeasure against bioterror and pandemic threats. Updates on this potential pathway will also be of great interest to us.

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. Commencement of enrollment, while delayed, finally happened and represents an important milestone in our opinion. Near-term progress will be measured by the pace of enrollment. If all goes well, initial data read-out could happen sometime next year.

Using sum-of-the-parts valuation and based on current development progress in each respective category we place 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 ~$6.75/share

PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

	2016 A	2017 A	Q1 A	Q2 A	Q3 A	Q4 A	2018 A	Q1 A	Q2 E	Q3 E	Q4 E	2019 E	2020 E
Revenue	$886.6	$392.1	$0.0	$0.0	$74.8	$74.8	$149.6	$149.6	$0.0	$0.0	$187.5	$337.1	$750.0
YOY Growth	*16.3%*	*-55.8%*	*-100.0%*	*-100.0%*	-	-	*3128.2%*	-	-	-	-	*-13.0%*	*#DIV/0!*
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	$886.6	$392.1	$0.0	$0.0	$74.8	$74.8	$149.6	$149.6	$0.0	$0.0	$187.5	$337.1	$750.0
Gross Margin	*100.0%*	*100.0%*	-	-	-	-	-	-	-	-	-	-	-
SG&A	$4,489.4	$5,817.4	$1,002.8	$1,067.6	$1,109.2	$1,222.5	$4,402.1	$1,052.1	$1,071.0	$1,118.0	$1,266.0	$4,507.1	$6,544.0
% SG&A	*506.4%*	*1483.8%*	-	-	*1482.7%*	-	-	-	-	-	-	-	-
R&D	$782.0	$673.0	$157.5	$168.6	$129.2	$123.4	$578.6	$194.8	$102.4	$212.2	$311.0	$820.4	$2,425.0
% R&D	*88.2%*	*171.7%*	-	-	*172.7%*	-	-	-	-	-	-	-	-
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	($4,384.8)	($6,098.4)	($1,160.2)	($1,236.2)	($1,163.6)	($1,271.1)	($4,831.1)	($1,097.3)	($1,173.4)	($1,330.2)	($1,389.5)	($4,990.4)	($8,219.0)
Operating Margin	*-494.6%*	*-1555.4%*	-	-	-	-	-	-	-	-	-	-	-
Other Expense, total	$573.8	$1,208.4	$685.3	$72.4	$55.9	$55.1	$868.7	$55.1	$55.1	$55.1	$55.1	$220.4	$245.0
Pre-Tax Income	($4,958.6)	($7,306.7)	($1,845.6)	($1,308.6)	($1,219.5)	($1,326.2)	($5,699.8)	($1,152.4)	($1,228.5)	($1,385.3)	($1,444.6)	($5,210.8)	($8,464.0)
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	($4,872.4)	($7,276.1)	($1,841.8)	($1,303.9)	($1,215.0)	($1,318.9)	($5,679.6)	($1,146.2)	($1,223.6)	($1,379.8)	($1,438.8)	($5,188.4)	($8,430.1)
Net Margin	*-549.6%*	*-1855.8%*	-	-	-	-	*-3795.9%*	-	-	-	-	*0.0%*	*-1124.0%*
EPS	($0.66)	($0.94)	($0.21)	($0.14)	($0.08)	($0.08)	($0.46)	($0.06)	($0.07)	($0.07)	($0.07)	($0.28)	($0.35)
YOY Growth	*-45.8%*	*42.2%*	-	-	-	-	*65.1%*	-	-	-	-	*0.0%*	*129.0%*
Diluted Shares O/S	7,394	7,764	8,806	9,032	14,951	16,480	12,317	17,755	17,750	18,450	19,250	18,301	24,200

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

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CTE Study Refresher…

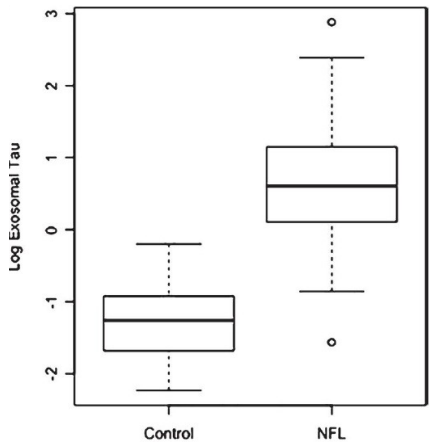
As a reminder, Aethlon's majority-owned subsidiary Exosome Sciences (ESI) has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. ESI has used what they learned in how to isolate certain brain-specific 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[5]);

- 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

[5] 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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