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Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

AEMD: Breakthrough Device Status Granted, Eagerly Await FDA Meeting

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 $8.00/share

Current Price (11/08/17)	$0.84
Valuation	**$8.00**

OUTLOOK

Management noted that since receiving notice of EAP designation (in September), that they have been in contact with FDA, including with the personnel that will be working directly with them. AEMD expects to schedule an in-person meeting with FDA - which they think could happen late-2017/early-2018. Noteworthy is that management expects this meeting to be productive in terms of defining the FDA pathway for Hemopurifier. 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). We will be eager to hear results of the upcoming meeting with FDA.

SUMMARY DATA

52-Week High	**$5.17**
52-Week Low	**$0.83**
One-Year Return (%)	**-81.48**
Beta	**2.12**
Average Daily Volume (sh)	**561,759**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$13**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**12**
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 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Hmo**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2016	0.2 A	0.2 A	0.3 A	0.2 A	0.9 A
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 E	0.1 E	0.2 E
2019					0.1 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2016	-$0.18 A	-$0.16 A	-$0.16 A	-$0.16 A	-$0.66 A
2017	-$0.28 A	-$0.29 A	-$0.15 A	-$0.22 A	-$0.94 A
2018	-$0.21 A	-$0.14 A	-$0.12 E	-$0.11 E	-$0.56 E
2019					-$0.52 E

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

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Fiscal Q2 2018 Financials, Operational Update

Aethlon reported financial results for their fiscal second quarter 2018 ending September 30th and provided a business update. Operating loss was $1.2M, slightly better than our forecasted $1.4M as a result of lower than anticipated G&A and professional expenses. This compares to operating losses of $1.2M in Q1 2018 and $2.3M in Q2 2017. The significant difference from the prior year relates to lower stock-based compensation in the current-year period. Q2 2018 EPS was ($0.14), compared to our ($0.16) estimate and ($0.15) in Q1 2018 (excluding non-cash debt-extinguishment and warrant exchange expenses) and ($0.29) in Q2 2017.

Cash used in operating activities was $1.0M in Q2 and $2.1M in 1H 2018. Relative to the balance sheet, AEMD exited Q2 with $920k in cash but subsequent to quarter-end, they raised $6.0M ($5.3M net) via a secondary equity offering (5.4M shares @ $1.10/share, with 100% warrant coverage: 5yrs, $1.10 strike). AEMD expects current cash (i.e. Q2 ending balance plus offering proceeds) to be sufficient to fund operations through at least October 2018. The ATM program via HC Wainwright also remains active, although is suspended (per terms of the October financing) until early January 2018.

Relative to the operational update, highlights include award of a Phase I NCI grant, onboarding of Hemopurifier-related production capabilities, EAP/Breakthrough Device status for Hemopurifier and IRB approval to commence the new CTE study…

In October AEMD completed the initial milestone under the cancer-related Phase I grant that was awarded by NCI. We model the milestone, in the amount of approximately $75k, to be recognized as revenue in Q3. As a reminder, in September AEMD was awarded the Phase I grant funded by the National Cancer Institute. The contract, dubbed "Device Strategy for Selective Isolation of Oncosomes and Non-Malignant Exosomes" is for $299,250 and has a nine-month term. The University of Pittsburgh and Massachusetts General Hospital (researchers at Mass General were part of the tumor exosomes study discussed below) will work under AEMD to complete the contract which involves evaluation of AEMD's technology in the capture of circulating tumor-derived exosomes. Upon successful completion, **AEMD may be eligible for a Phase II grant that is expected to be worth approximately $1.5M.**

Production Capabilities Secured

Perhaps an indication of management's expectations of eventual commercialization, in October Aethlon announced a formal collaboration with iBio, Inc (IBIO), a plant-based biopharmaceuticals company, to provide (as-needed) large-scale production of the plant-derived lectin (a recombinant form of Galanthus nivalis agglutin, or GNA) housed within the Hemopurifier cartridge that captures circulating viruses from the blood.

As a reminder, Aethlon had noted during their U.S. feasibility study that they had leveraged their contract with DARPA to fund current good manufacturing practice (cGMP) systems for the production of the Hemopurifier. The DARPA grant included two manufacturing-specific milestones – the first of which AEMD completed during year-three of the contract and the other which they completed during year-four.

AEMD has noted that they completed a study with iBio, confirming their ability to produce GNA under cGMP. Per iBio's website, their CDMO development and manufacturing facility, located near Houston, is capable of growing over four million plants as "in process inventory". The large-capacity facility is also capable of meeting high production quotas which could be important, particularly in the event of high on-demand need such as, for example, if Hemopurifier was cleared for use as a countermeasure against certain pandemic outbreaks.

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

On September 12th AEMD announced that FDA approved their 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. 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.

While we had anticipated that FDA would approve the EAP pathway, confirmation of that is nonetheless a significant event given the benefits of the program. In late October 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.

Management noted that since receiving notice of EAP designation, that they have been in contact with FDA, including with the personnel that will be working directly with them. AEMD expects to schedule an in-person meeting with FDA - which they think could happen sometime near the end of 2017 or in early 2018. **Noteworthy is that (per comments on the Q2 earnings call on Nov 2nd) management expects this meeting to be productive in terms of defining the FDA pathway for Hemopurifier.** As such, we will be eager to hear results of this meeting.

FDA Validation…

Management noted on the Q2 call that 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 noted in a recent Investor Note (Oct 20th), 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.

FDA's recently appointed commissioner Dr. Scott Gottleib's remarks to The National Academy of Sciences on September 19, 2017 provide some additional insight into the regulators' thoughts towards greater application of RWD and RWE in their decision-making processes. While the full text can be found here (http://bit.ly/2yJG4ex), some of the highlights include:

- "The hierarchy of evidence is evolving as a consequence. This is the hierarchy that has long defined the reliability of clinical evidence, and puts the randomized, prospective, placebo controlled trial at the top of that pyramid. This pyramid has remained unchanged, even as our tools for collecting practical data have advanced; even as the constructs that fall underneath the fully randomized, prospective, placebo-controlled trial are expanding, and their usefulness for informing our decisions becoming more apparent; even as the reliability of other forms of evidence is increasing as the methodologies for evaluating different forms of data continue to improve. That includes RWE."

- "FDA needs to think of itself as a curator of information. Not just an arbiter, where a single truth standard is secured to a fixed orthodoxy. The latter concept is increasingly at odds with the way decisions are being made by others who depend on reliable evidence to guide their paths, including doctors and health plans. FDA is often an important, independent evaluator of information."
- "The fact is there's often no single truth standard when it comes to the evidence used to support medical decisions. Clinical choices are made all the time, based on a mosaic of information of various precision and certainty. That continuum includes real world evidence, as well as the facts gleaned from rigorous and carefully fashioned trials...and a lot of evidence constructs in between."
- "…there's nothing in our statute or regulations that prevent FDA from using a broad range of informative sources of evidence. On the contrary, many of our statutory responsibilities boil down to one principal calculus: What do we know, and how do we balance benefits and risk based on the fullest possible information."
- "For those who'd challenge the suitability of our effort to incorporate real world evidence into our regulatory model, I'd challenge you with the opposite intention: Should a product be marketed based on a data set that speaks to a limited and rigidly constructed circumstance, when the clinical use, and in turn the evidence we might have to evaluate the product, could have been far richer, far more diverse, and more informative?"
- "That means embracing the full continuum of evidence that informs their [i.e. novel medical devices] clinical use. We see this approach gaining more rapid and widespread acceptance when it comes to some medical products. But we need to continue to more widely advance this life cycle concept of regulation."

We do not know if the use of Real World Data is potentially on the table in designing a U.S. regulatory program for Hemopurifier or even if it is, if it can be of any benefit. But given the (effective) impossibility of conducting, for example, an RCT in Ebola, yet the lack of any serious treatment-related adverse events in any human application of Hemopurifier, coupled with the complete dearth of any drug or device that can effectively treat many of these glycosylated viruses and evidence that Hemopurifier can capture these substances, it makes sense to us that RWD will be (at least) under consideration. And if that is the case, it could help to define a feasible U.S. approval pathway. We should know a lot more after AEMD's meeting with FDA.

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

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 expects to initiate the largest study to-date 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 management had hoped to have the study well underway by now, the timeline has slipped as they locked down institutional review board approval at the primary site in Arizona. But with IRB approval now secured at the Translational Genomics Research Institute, study progress should now begin to accelerate.

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), this new study is expected to enroll up to 200 former NFL players at several U.S. sites – at full enrollment it would 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.

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 (including IRB approval at the primary study site).

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.

We also look forward to hearing results of the anticipated upcoming sit-down meeting with FDA given that it is expected to produce substantive guidance on next steps in the U.S. regulatory validation process. 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. Given the potential significance of this meeting and depending on the specific guidance/feedback that FDA provides, outcomes from this sit-down could represent a value-inflection point for AEMD shares.

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. While we do not expect much in the way of near-term performance-related updates, with IRB approval now secured, we do look forward to hearing updates on progression of enrollment over the coming months.

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. As such, we value AEMD at approximately $120M or ~$8.00/share

PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

	2015 A	2016 A	Q1 A	Q2 A	Q3 A	Q4 A	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E
Revenue	$762.4	$886.6	$4.6	$387.4	$0.0	$0.0	$392.1	$0.0	$0.0	$75.0	$89.0	$164.0	$135.0
YOY Growth	*-53.0%*	*16.3%*	*-97.6%*	*105.7%*	*-100.0%*	*-100.0%*	*-55.8%*	*-100.0%*	*-100.0%*	-	-	*3438.5%*	*-65.2%*
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	$762.4	$886.6	$4.6	$387.4	$0.0	$0.0	$392.1	$0.0	$0.0	$75.0	$89.0	$164.0	$135.0
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	-	-	*100.0%*	-	-	-	-	-	-
SG&A	$3,727.7	$4,489.4	$1,018.3	$2,333.3	$1,057.1	$1,408.8	$5,817.4	$1,002.8	$1,067.6	$1,201.0	$1,309.0	$4,580.4	$6,812.0
% SG&A	*488.9%*	*506.4%*	*21969.5%*	*602.2%*	-	-	*1483.6%*	-	-	-	-	-	-
R&D	$1,027.6	$782.0	$118.0	$280.9	$178.4	$95.7	$673.0	$157.5	$168.6	$241.0	$355.0	$922.0	$2,160.0
% R&D	*134.8%*	*88.2%*	*2545.6%*	*72.5%*	-	-	*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	($3,992.8)	($4,384.8)	($1,131.7)	($2,226.7)	($1,235.5)	($1,504.5)	($6,098.4)	($1,160.2)	($1,236.2)	($1,367.0)	($1,575.0)	($5,338.4)	($8,837.0)
Operating Margin	-	*-494.6%*	-	-	-	-	*-1555.4%*	-	-	-	-	-	-
Loss on extinguishment of debt	$2,754.0	$0.0	$616.9	$0.0	($58.7)	$0.0	$558.2	$376.9	$0.0	$0.0	$0.0	$376.9	$0.0
(Gain)/loss on derivative liability	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$119.8	$10.4	$0.0	$0.0	$130.2	$0.0
Interest (income), net	$452.3	$573.8	$42.2	$36.6	$36.6	$189.0	$304.3	$188.6	$62.0	$101.0	$99.0	$450.6	$375.0
Other expense	($219.6)	$0.0	$345.8	$0.0	$0.0	$0.0	$345.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($6,979.5)	($4,958.6)	($2,136.5)	($2,263.3)	($1,213.4)	($1,693.5)	($7,306.7)	($1,845.6)	($1,308.6)	($1,468.0)	($1,674.0)	($6,296.1)	($9,212.0)
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	($6,797.2)	($4,872.4)	($2,128.8)	($2,255.6)	($1,205.7)	($1,686.0)	($7,276.1)	($1,841.8)	($1,303.9)	($1,468.0)	($1,674.0)	($6,287.7)	($9,212.0)
Net Margin	*-891.5%*	*-549.6%*	-	-	-	-	*-1855.6%*	-	-	-	-	*-3834.0%*	*-6823.7%*
EPS	($1.22)	($0.66)	($0.28)	($0.29)	($0.15)	($0.22)	($0.94)	($0.21)	($0.14)	($0.12)	($0.11)	($0.56)	($0.52)
YOY Growth	*-64.7%*	*-45.8%*	-	-	-	-	*42.2%*	-	-	-	-	*-39.5%*	*-7.4%*
Diluted Shares O/S	5,594	7,394	7,622	7,757	7,927	7,751	7,764	8,806	9,032	12,232	15,080	11,287	17,855

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
* 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…

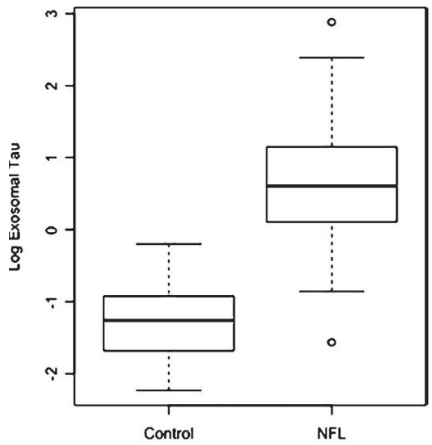
As a reminder, Aethlon's majority-owned subsidiary Exosome Sciences (ESI) has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. ESI has used what they learned in how to isolate certain brain-specific 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[1]);

- 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

[1] 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

HISTORICAL STOCK PRICE



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