Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

AEMD: 2017 Off To Busy Start Including New CTE Study

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 $15/share

Current Price (01/27/17)	$3.86
Valuation	**$15.00**

OUTLOOK

Aethlon is off to a busy start in 2017 with several irons in the fire and making progress on many fronts. While the U.S. feasibility study has dragged on much longer than hoped, with it now 90% enrolled it is nearing the finish line. And as results of this study are a gating factor towards moving forward on other fronts – including larger human studies, we continue to eagerly await completion and read-out (while safety-oriented, also expect some efficacy-related data points). This could be the year that Hemopurifier moves into a in a larger, efficacy-powered U.S. clinical study which could serve as the next major step towards bringing the device to the U.S. market. And the TauSome biomarker could similarly make another significant step towards proving its clinical utility. Success in DETECT was a major milestone, in our opinion, but this larger, follow-on study should provide more definitive information relative to its place in the detection of CTE – 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 treatment and monitoring of the disease. As such, we look forward to updates on the progress of both the Hemopurifier and ESI related programs throughout 2017.

SUMMARY DATA

52-Week High	**$9.09**
52-Week Low	**$3.55**
One-Year Return (%)	**-40.06**
Beta	**2.69**
Average Daily Volume (sh)	**20,792**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$30**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**10**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-17.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**N/A**
Industry	**Med-Hmo**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2015	0.1 A	0.5 A	0.0 A	0.2 A	0.8 A
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 E	0.0 E	0.4 E
2018					0.0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2015	-$0.80 A	-$0.16 A	-$0.26 A	-$0.13 A	-$1.22 A
2016	-$0.18 A	-$0.16 A	-$0.16 A	-$0.16 A	-$0.66 A
2017	-$0.28 A	-$0.29 A	-$0.16 E	-$0.17 E	-$0.90 E
2018					-$0.81 E

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

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Operational Update: ***New CTE TauSome Study, Feasibility Study 90% Enrolled, PHEMCE Program Progress…***
Following conclusion of the DARPA DLT sepsis-related program, AEMD wasted little time in allocating its focus on other high-priority programs, including further validation of Hemopurifier in the capture of certain viruses and pathogens - progress which could lead towards eventually utility of the device in a variety applications including as a broad spectrum countermeasure against viral pathogens – an objective which also aligned with the Public Health Emergency Medical Countermeasures Enterprise's (PHEMCE) goal of developing broad-spectrum medical countermeasures (MCM). The company also continues to move forward on other applications of Hemopurifier, including potentially in sepsis.

And in concert with recently announced plans to begin additional Hemopurifier studies, AEMD's Exosome Sciences (ESI) subsidiary expects to initiate a new clinical study aimed at further assessing the company's TauSome biomarker as a potential blood test for the diagnosis of CTE.

Relative to the Hemopurifier, as a reminder on their Q3 call in November AEMD noted that one of their main goals is to be able to fulfill the PHEMCE goal of developing broad-spectrum MCMs. They have recently made additional progress on this front and noted in January that they have identified the 9th (of a total of 10) patient for enrollment into their U.S. feasibility clinical study. This study, assuming positive, is expected to set the stage for an FDA IDE submission seeking approval to conduct a larger, controlled clinical study with individuals infected with a chronic viral pathogen - as well as potentially open up initial use (potentially via Humanitarian Use Device) for latent pathogens and pandemic threats such as Zika, Ebola, MERS and others. As such, results of this study will be an important pathway towards further development and validation of Hemopurifier.

And on a parallel front, AEMD announced in December that they initiated a study to assess the ability of Hemopurifier in the in vitro capture of Epstein-Barr virus (EBV), Cytomegalovirus (CMV) and Herpes Simplix virus (HSV), all of which have been associated with higher mortality among sepsis patients. Subsequent testing will be done for simultaneous capture of the three viruses. This program focuses, at least in part, on the connection between immune suppression and the reactivation of latent viral pathogens (such as EBV, HSV and CMV) and the relation to compromised patient outcomes. While this program is still in the early stages, AEMD noted that in late 2016 they, along with the University of Pittsburgh, initiated a study to detect the presence of EBV, CMV and HSV in the blood of intensive care unit patients. The Hemopurifier will then be assessed in the capture of these viral targets. AEMD noted that 10 patients had been enrolled as of early January.

Relative to ESI, Aethlon will look to build on the success of their findings as part of the DETECT study 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. 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 earlier this week and which is expected to commence in Q2, is to further validate TauSome as an accurate, non-invasive, reliable biomarker for the diagnosis of CTE in living individuals. 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. Aethlon expects to conduct an awareness-building campaign leading up the Super Bowl (Feb 5th) aimed in part at recruiting ex-NFL players for the study.

Aethlon is off to a busy start in 2017 with several irons in the fire and making progress on many fronts. While the U.S. feasibility study has dragged on much longer than hoped, with it now 90% enrolled it is nearing the finish line. And as results of this study are a gating factor towards moving forward on other fronts – including larger human studies, we continue to eagerly await completion and read-out (while safety-oriented, also expect some efficacy-related data points). This could be the year that Hemopurifier moves into a in a larger, efficacy-powered U.S. clinical study which could serve as the next major step towards bringing the device to the U.S. market.

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CTE Study Refresher…

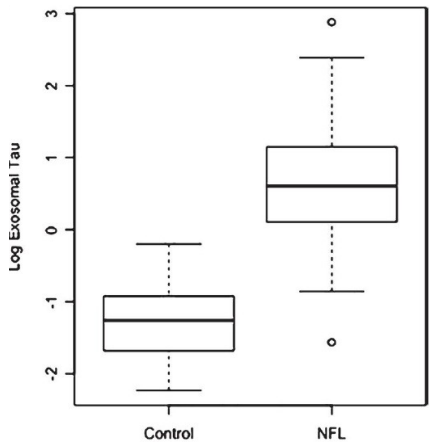
As a reminder, Aethlon's majority-owned subsidiary Exosome Sciences (ESI) has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. ESI has used what they learned in how to isolate certain brain-specific 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. Tau levels were also correlated to performance on cognition tests, with higher tau levels corresponding to poorer test performance.

Aethlon submitted a manuscript of the study in 2015, which was published in the online version of the Journal of Alzheimer's Disease in May. 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)



- 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 CTE diagnostic demonstrated
    - o exosome tau was significantly higher in NFL players 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

PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

	2014 A	2015 A	Q1 A	Q2 A	Q3 A	Q4 A	2016 A	Q1 A	Q2 A	Q3 E	Q4 E	2017 E
Revenue	$1,623.8	$762.4	$192.5	$188.4	$301.0	$204.6	$886.6	$4.6	$387.4	$8.0	$8.0	$408.1
YOY Growth	*32.0%*	*-53.0%*	*275.3%*	*-60.7%*	*800.4%*	*3.0%*	*16.3%*	*-97.6%*	*105.7%*	*-97.3%*	*-96.1%*	*-54.0%*
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
Gross Income	$1,623.8	$762.4	$192.5	$188.4	$301.0	$204.6	$886.6	$4.6	$387.4	$8.0	$8.0	$408.1
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$3,170.4	$3,727.7	$1,100.5	$1,105.1	$1,237.4	$1,046.5	$4,489.4	$1,018.3	$2,333.3	$1,131.0	$1,144.0	$5,626.5
%SG&A	*195.2%*	*488.9%*	*571.7%*	*586.7%*	*411.0%*	*511.4%*	*506.4%*	*21969.5%*	*602.2%*	*14137.5%*	*14300.0%*	*1378.8%*
R&D	$1,509.0	$1,027.6	$182.0	$207.7	$147.8	$244.5	$782.0	$118.0	$280.9	$120.0	$204.0	$722.9
%R&D	*92.9%*	*134.8%*	*94.5%*	*110.3%*	*49.1%*	*119.5%*	*88.2%*	*2545.8%*	*72.5%*	*1500.0%*	*2550.0%*	*177.1%*
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
Operating Income	($3,055.6)	($3,992.8)	($1,090.0)	($1,124.4)	($1,084.1)	($1,086.4)	($4,384.8)	($1,131.7)	($2,226.7)	($1,243.0)	($1,340.0)	($5,941.3)
Operating Margin	-	-	-	-	-	-	*-494.6%*	-	-	-	-	*-1455.9%*
Loss on extinguishment of debt	$40.3	$2,754.0	$0.0	$0.0	$0.0	$0.0	$0.0	$616.9	$0.0	$0.0	$0.0	$616.9
(Gain)/loss on derivative liability	$8,547.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest (income), net	$1,287.2	$452.3	$126.7	$127.2	$148.9	$171.0	$573.8	$42.2	$36.6	$37.0	$37.0	$152.7
Other expense	$508.6	($219.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$345.8	$0.0	$0.0	$0.0	$345.8
Pre-Tax Income	($13,438.6)	($6,979.5)	($1,216.7)	($1,251.6)	($1,233.0)	($1,257.3)	($4,958.6)	($2,136.5)	($2,263.3)	($1,280.0)	($1,377.0)	($7,056.8)
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
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%*
Net Income	($13,356.9)	($6,797.2)	($1,183.0)	($1,224.6)	($1,217.2)	($1,247.5)	($4,872.4)	($2,128.8)	($2,255.6)	($1,280.0)	($1,377.0)	($7,041.4)
Net Margin	-	*-891.5%*	-	-	-	-	*-549.6%*	-	-	-	-	*-1725.5%*
EPS	($3.44)	($1.22)	($0.18)	($0.16)	($0.16)	($0.16)	($0.66)	($0.28)	($0.29)	($0.16)	($0.17)	($0.90)
YOY Growth	*110.0%*	*-64.7%*	*-78.1%*				*-45.8%*					*37.1%*
Diluted Shares O/S	3,881	5,594	6,720	7,610	7,617	7,627	7,394	7,622	7,757	7,800	8,000	7,795

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