Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

AEMD: CTE Study Published in Journal of Alzheimer's Disease

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	11/11/2014
Current Price (02/26/16)	$4.81
Target Price	**$18.00**

OUTLOOK

AEMD's novel blood filtration device could have utility in the treatment of Hepatitis-C, HIV, sepsis, cancer, pandemic diseases and bioterror applications.
AEMD recently got FDA and IRB approvals to run a human study in HCV which is a major milestone. Enrollment commenced.
DARPA contracts have provided revenue/cash while also providing credibility of the technology and potentially facilitating the quest towards regulatory approval and commercialization.
Mgmt has been very resilient and successful in pursuing high potential opportunities in other areas including Ebola, cancer, Alzheimer's and CTE. Pandemic viruses such as Zika could offer attractive commercializable opportunities for Hemopurifier.
AEMD making more dedicated effort towards virus and Category A threat applications. New Aethlon ADAPT initiative could also help broaden scope of utility for their technology to other diseases.
Maintaining Buy recommendation.

SUMMARY DATA

52-Week High	**$14.00**
52-Week Low	**$4.34**
One-Year Return (%)	**-54.45**
Beta	**2.72**
Average Daily Volume (sh)	**28,473**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$36**
Short Interest Ratio (days)	**9.63**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-19.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Hmo**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2014	0.2 A	0.6 A	0.1 A	0.7 A	1.6 A
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	0.3 E	1.0 E
2017					0.4 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2014	-$0.09 A	-$0.89 A	-$0.56 A	-$1.74 A	-$3.44 A
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	-$0.20 E	-$0.69 E
2017					-$0.70 E

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

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CTE Study Published Online in Journal of Alzheimer's Disease

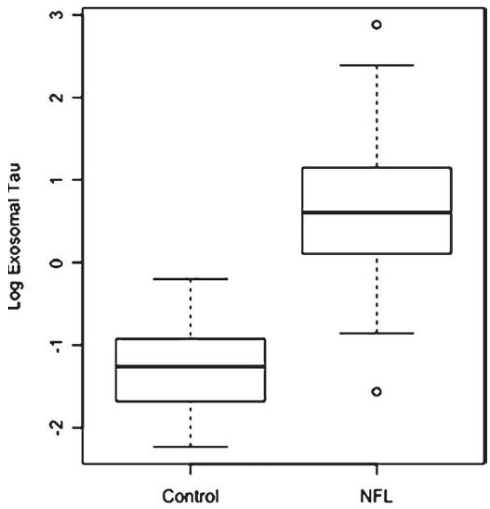
As a reminder, Aethlon's majority-owned subsidiary Exosome Sciences (ESI) has collaborated with Boston University's CTE Center for the development of a blood-based diagnostic that would be able to identify CTE in living individuals. ESI has used what they learned in how to isolate certain brain-specific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

Additional research is moving forward which includes a new $16M NIH funded study focused on detecting and diagnosing CTE in living individuals which ESI and their CTE diagnostic is part of. 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.

PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

	2013 A	2014 A	Q1 A	Q2 A	Q3 A	Q4 A	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E
Revenue	$1,230.0	$1,623.8	$51.3	$479.1	$33.4	$198.6	$762.4	$192.5	$188.4	$301.0	$273.0	$954.9	$433.0
YOY Growth	*-9.5%*	*32.0%*	*-73.8%*	*-25.7%*	*-56.2%*	*-71.9%*	*-53.0%*	*275.3%*	*-60.7%*	*800.4%*	*37.5%*	*25.2%*	*-54.7%*
Cost of Goods Sold	$0.0	$0.0					$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$1,230.0	$1,623.8	$51.3	$479.1	$33.4	$198.6	$762.4	$192.5	$188.4	$301.0	$273.0	$954.9	$433.0
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%*	*100.0%*
SG&A	$3,365.4	$3,170.4	$876.3	$829.9	$906.2	$1,115.3	$3,727.7	$1,100.5	$1,105.1	$1,237.4	$1,272.0	$4,714.9	$4,688.0
%SG&A	*273.6%*	*195.2%*	*1708.3%*	*173.2%*	*2710.6%*	*561.5%*	*488.9%*	*571.7%*	*586.7%*	*411.0%*	*465.9%*	*493.8%*	*1082.7%*
R&D	$1,440.0	$1,509.0	$347.0	$250.4	$214.2	$216.0	$1,027.6	$182.0	$207.7	$147.8	$351.0	$888.5	$1,512.0
%R&D	*117.1%*	*92.9%*	*676.5%*	*52.3%*	*640.6%*	*108.8%*	*134.8%*	*94.5%*	*110.3%*	*49.1%*	*128.6%*	*93.0%*	*349.2%*
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	($3,575.4)	($3,055.6)	($1,172.0)	($601.2)	($1,087.0)	($1,132.7)	($3,992.8)	($1,090.0)	($1,124.4)	($1,084.1)	($1,350.0)	($4,648.5)	($5,767.0)
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	*-486.8%*	*-1331.9%*
Loss on extinguishment of debt	$139.8	$40.3	$2,453.6	$208.9	$222.9	($131.4)	$2,754.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
(Gain)/loss on derivative liability	$44.7	$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	$1,107.1	$1,287.2	$78.7	$78.1	$148.7	$146.8	$452.3	$126.7	$127.2	$148.9	$149.0	$551.8	$252.0
Other expense	$25.0	$508.6	$0.0	($143.4)	$143.4	($219.6)	($219.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($4,892.0)	($13,438.6)	($3,704.3)	($744.8)	($1,602.0)	($928.4)	($6,979.5)	($1,216.7)	($1,251.6)	($1,233.0)	($1,499.0)	($5,200.3)	($6,019.0)
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	($4,892.0)	($13,356.9)	($3,655.9)	($704.0)	($1,550.5)	($886.8)	($6,797.2)	($1,183.0)	($1,224.6)	($1,217.2)	($1,499.0)	($5,123.8)	($6,019.0)
Net Margin	-	-	-	-	-	-	*-891.5%*	-	-	-	-	*-536.6%*	*-1390.1%*
EPS	($1.64)	($3.44)	($0.80)	($0.14)	($0.26)	($0.13)	($1.22)	($0.18)	($0.16)	($0.16)	($0.20)	($0.69)	($0.70)
YOY Growth	*1956.5%*	*110.0%*	*834.7%*	*-84.8%*	*-54.3%*	*-92.3%*	*-64.7%*	*-78.1%*				*-42.9%*	*0.3%*
Diluted Shares O/S	2,984	3,881	4,542	5,187	6,032	6,616	5,594	6,720	7,610	7,617	7,620	7,392	8,655

Brian Marckx, CFA

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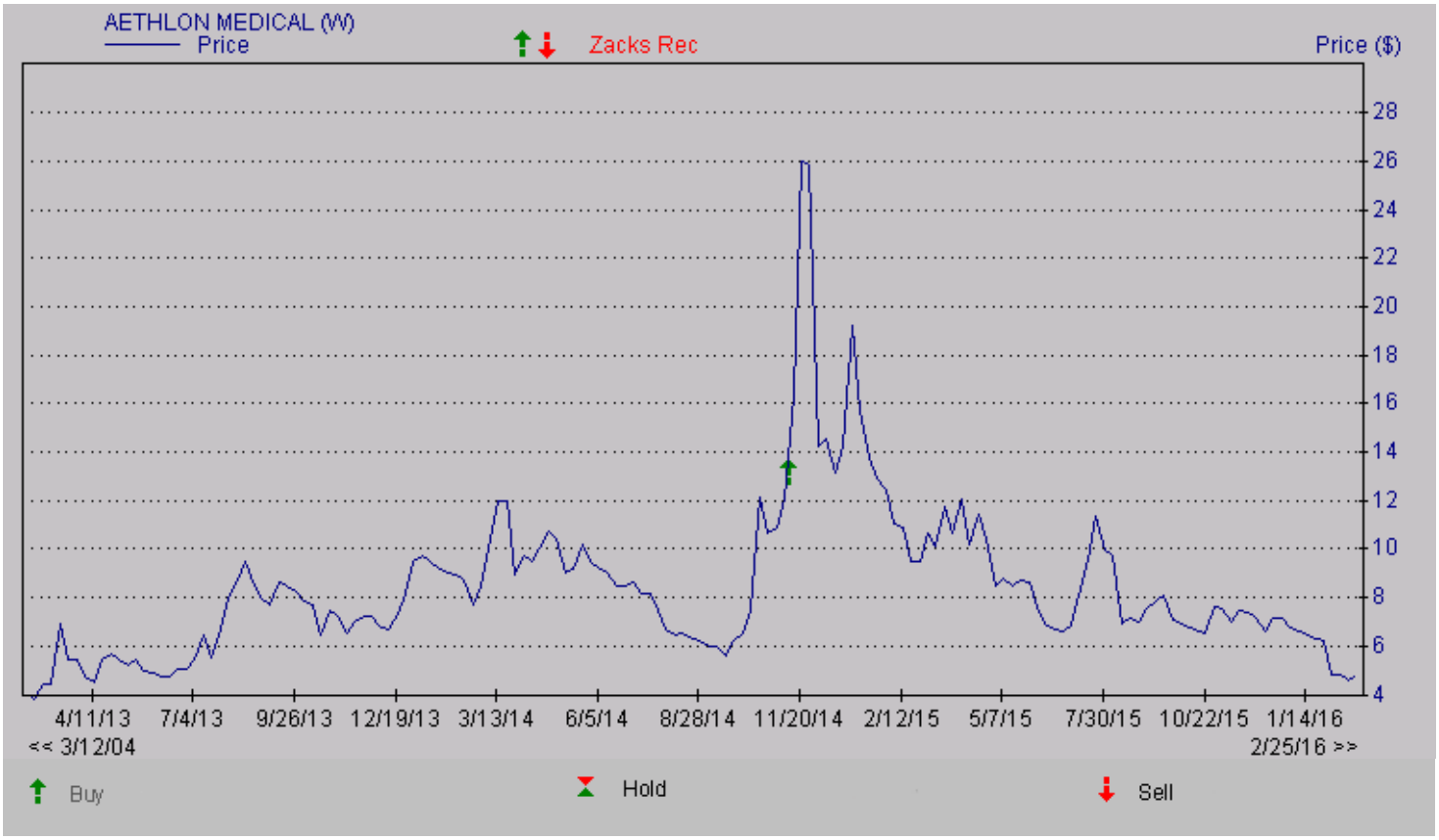

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