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Zacks Small-Cap Research

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Aethlon Medical (AEMD-NASDAQ)

AEMD: Breakthrough Device Designation Granted for Cancer Therapy. Could Be Game-Changer for AEMD

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 (11/27/18)	$1.36
Valuation	**$6.75**

OUTLOOK

Today's news of FDA granting the Breakthrough Designation comes earlier than we would have anticipated but, more importantly opens up new lanes of dialogue and presumed direct assistance with FDA towards advancing Hemopurifier towards a formal cancer-therapy focused development program. This could be somewhat of a game-changer, in our opinion as while the highly glycosylated virus program had substantial potential, there remains an overarching question of just exactly what a viable regulatory program would encompass (we have covered this topic in detail in prior reports).

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

SUMMARY DATA

52-Week High	**$2.04**
52-Week Low	**$0.82**
One-Year Return (%)	**10.38**
Beta	**2.11**
Average Daily Volume (sh)	**47,412**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$21**
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	0.1 E	0.3 E	0.6 E
2020					1.1 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	-$0.08 A	-$0.07 E	-$0.07 E	-$0.29 E
2020					-$0.29 E

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

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Breakthrough Device Designation Granted for Cancer Therapy

This morning Aethlon announced that they received Breakthrough Device designation from FDA for their Hemopurifier in the treatment of cancer. This is now the second such designation for their flagship device, As a reminder, 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." As we noted following granting of EAP designation, 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.

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

AEMD's shift towards cancer…

Management outlined somewhat of a shift in their overall development gameplan for Hemopurifier on the fiscal Q2'19 call (Nov 6th 2018). As we initially noted in our Q2 update (Nov 9th: *Pivot Towards Cancer Makes Sense. FDA Filing For Breakthrough Device in Cancer*), it appears the decision was based on the seemingly ever-growing opportunities to evaluate their flagship device in cancer applications and the apparent difficulties in moving their life-threatening highly glycosylated viruses program along. As a reminder, management indicated on the Q1 call in August that while they continued to have regular dialogue with FDA related to a virus program under the Breakthrough Device designation, that until their 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.

We gathered that the message on the Q2'19 call was clearly focused on pursuing a formal cancer clinical regulatory program. Management outlined several cancer-related milestones on the Q2 call and noted that in late-September they filed a follow-on submission to FDA for Breakthrough Device designation for use of Hemopurifier 'for exosome depletion as an adjunct therapy diagnosed with metastatic cancer".

Today's news of FDA granting the Breakthrough Designation comes earlier than we would have anticipated but, more importantly opens up new lanes of dialogue and presumed direct assistance with FDA towards advancing Hemopurifier towards a formal cancer-therapy focused development program. This could be somewhat of a game-changer, in our opinion as while the highly glycosylated virus program had substantial potential, there remains an overarching question of just exactly what a viable regulatory program would encompass (we have covered this topic in detail in prior reports).

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

Hemopurifier Cancer programs (a refresher)…

Cancer as a target of Hemopurifier has gained a lot of traction as of late. Part of the reason relates to recent NCI grants – but also relates to the growing body of evidence surrounding exosomes' role in cancer progression. As it relates to the NCI grants, AEMD recently successfully completed a phase I contract evaluating Hemopurifier in the removal of melanoma-derived exosomes and will submit for a subsequent phase II contract. They were also just awarded an NCI grant for the removal of breast cancer derived exosomes from the blood. Continued successful completion should significantly bolster the already compelling evidence demonstrating the potential of Hemopurifier to reduce circulating exosomes from the blood and cancer metastasis.

In fiscal Q1 '19 AEMD received final payment from the phase I grant funded by the National Cancer Institute. The contract, dubbed "Device Strategy for Selective Isolation of Oncosomes and Non-Malignant Exosomes", paid $299k over nine months. The University of Pittsburgh and Massachusetts General Hospital worked under AEMD to complete the contract. Deliverables included demonstrating the ability of Hemopurifier to capture melanoma

exosomes from plasma and to isolate tumor-derived exosomes from non-malignant exosomes. A follow-on phase II contract, worth approximately $2M over two years, could follow. AEMD is now preparing the submission and expects to make the filing later this month.

And, in September 2018 AEMD was awarded another NCI contract. Titled, “The Hemopurifier device for targeted removal of breast cancer exosomes from the blood circulation”, the award will pay $298k over 12 months. The work is also being done in conjunction with the University of Pittsburgh and Massachusetts General Hospital. Then, in late-October 2019 AEMD received notification of a U.S. DoD Army Breakthrough Award. Titled “Isolation of triple negative breast cancer exosomes using the Hemopurifier”, AEMD noted that they are now in the contracting process.

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

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’ Opdivo (nivolumab), a checkpoint inhibitor which currently generates $6B in annualized revenue. While funding was not approved following the initial submission, AEMD indicated on the Q2 ’19 call that an amended filing could be in the works. If eventually funded, the company believes that this human study could form the basis of a clinical study protocol for an eventual IDE submission to FDA. Eventual approval of an IDE for such a study protocol could represent the first significant step towards a possible regulatory program positioning Hemopurifier as an adjunct to already established cancer therapies. That could open up new opportunities for AEMD in relation to development of Hemopurifier, potentially including collaborations with the likes of Bristol-Myers. While too early to speculate on chances of such an opportunity materializing, given the potential upside to AEMD, it is something that we will be closely watching.

PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

	2016 A	2017 A	Q1 A	Q2 A	Q3 A	Q4 A	2018 A	Q1 A	Q2 A	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	$74.6	$324.6	$548.8	$1,149.2
YOY Growth	*16.3%*	*-55.8%*	*-100.0%*	*-100.0%*	-	-	*3128.2%*	-	-	-	-	*417%*	*#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	$74.6	$324.6	$548.8	$1,149.2
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	$1,139.2	$1,118.0	$1,266.0	$4,575.3	$5,977.2
%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	$207.8	$212.2	$311.0	$925.8	$1,954.8
%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)	($1,347.0)	($1,255.6)	($1,252.4)	($4,952.2)	($6,782.8)
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)	($1,402.1)	($1,310.7)	($1,307.5)	($5,172.6)	($7,027.8)
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	$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)	($1,396.4)	($1,305.4)	($1,302.3)	($5,150.4)	($6,999.7)
Net Margin	*-549.6%*	*-1855.8%*	-	-	-	-	*-3795.9%*	-	-	-	-	*0.0%*	*-609.1%*
EPS	($0.66)	($0.94)	($0.21)	($0.14)	($0.08)	($0.08)	($0.46)	($0.06)	($0.08)	($0.07)	($0.07)	($0.29)	($0.29)
YOY Growth	*-45.8%*	*42.2%*	-	-	-	-	*65.1%*	-	-	-	-	*0.0%*	*91.7%*
Diluted Shares O/S	7,394	7,764	8,806	9,032	14,951	16,480	12,317	17,755	17,789	17,860	18,854	18,064	24,000

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