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Zacks Small-Cap Research

Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

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scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Aethlon Medical (AEMD-NASDAQ)

Coronavirus 2019 (COVID-19) Could Represent New Opportunity

We are maintaining our sum-of-the-parts valuation methodology in which we place a 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 ~$13/share.

Current Price (03/05/20)	$2.25
Valuation	**$13.00**

OUTLOOK

The ongoing coronavirus outbreak could represent a new potential opportunity for AEMD. Given the demonstrated ability of the technology to bind and clear other coronavirus diseases, such as MERS and effectiveness against all highly glycosylated viruses, it is conceivable that the device could have utility against COVID-19 as well. As more is learned about the disease, answers to key questions should become more apparent.

So, while COVD-19 potentially represents a new opportunity to validate Hemopurifier against another deadly disease, we do not view it as a likely near-term revenue opportunity for the company. But, depending on the severity of the outbreak and progress and success of testing Hemopurifier against the virus, it is possible that it could eventually represent a meaningful growth opportunity for the company. This will be something we will be closely watching.

Meanwhile, progress continues to be made towards commencement of AEMD's first U.S. clinical cancer trial. As a reminder, in October 2019 AEMD announced that FDA approved their IDE seeking approval to initiate a small U.S.-based clinical trial in head and neck cancer. While initiation of the clinical program is contingent on standard trial-site sign-off, IDE approval means the most significant hurdle is cleared.

SUMMARY DATA

52-Week High	**$16.05**
52-Week Low	**$0.76**
One-Year Return (%)	**-74.43**
Beta	**-0.10**
Average Daily Volume (sh)	**20,314**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**12**
Insider Ownership (%)	**4**
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 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2019	0.2 A	0.0 A	0.0 A	0.1 A	0.2 A
2020	0.0 A	0.0 A	0.4 A	0.3 E	0.7 E
2021					1.1 E
2022					0.2 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2019	-$0.97 A	-$1.17 A	-$1.67 A	-$1.30 A	-$5.12 A
2020	-$1.63 A	-$1.29 A	-$0.28 A	-$0.16 E	-$3.37 E
2021					-$0.51 E
2022					-$0.39 E

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

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Fiscal Q3 2020 Financials, Operational Update:

Aethlon reported fiscal Q3 2020 financial results and provided an operational update. Relative to the latter, which we discuss in more detail below, highlights include the possibility that the Hemopurifier might be tested as a potential therapy against the ongoing coronavirus disease. While a number of important questions will need to be answered before AEMD would know whether there may even be an opportunity to evaluate their device against this disease, known as COVID-19, based on demonstrated ability of Hemopurifier to bind and clear other coronavirus diseases, there is reasonable reasons to believe that it might have utility against the virus.

As it relates to the financials, fiscal Q3 2020 (ending December 2019) revenue of $414k related solely to the initial two milestones of the recently awarded SBIR Phase II NIH melanoma contract. As a reminder, this (follow-on) grant, awarded in September 2019, relates to the isolation of melanoma exosomes (for diagnostic and treatment monitoring). As we opined at the time of the award, this grant, which will pay $1.86M over two years, lends further validation to the potential utility of Aethlon's technology in cancer treatment.

Cash used in operating activities was $1.3k and $3.6M ($741k and $3.3M, ex-changes in working capital) in the three and nine months ending December 31, 2019 compared to $1.1M and $2.9M ($1.7M and $3.6M, ex-changes in working capital) in the respective prior-year periods.

Cash balance was nearly $4.1M at December 31st and that was substantially beefed up even further subsequent to Q3 quarter-end when AEMD raised $7.7M (gross) via a combination of common stock sales ($3.8M gross) and warrant exercises ($3.9M gross). The proceeds will be used for ongoing development of Hemopurifier as well as other R&D programs and also for general corporate purposes.

Coronavirus 2019 (COVID-19) Could Represent Opportunity for Hemopurifier

The ongoing coronavirus outbreak could represent a new potential opportunity for AEMD and their Hemopurifier. And, possibly, under the current Breakthrough Device designation related to use of Hemopurifier for the treatment of life-threatening viruses that are not controlled by other therapies. Given the demonstrated ability of the technology to bind and clear other coronavirus diseases, such as the recent MERS strain, and shown effectiveness against all highly glycosylated viruses that it has been validated with, it is conceivable that the device could have utility against COVID-19 as well.

Management noted on the earnings call that while they are pursuing this as a potential opportunity, that certain questions need to be answered before that might happen. As more is learned about the disease, answers to these questions should become more apparent. Among these are whether clearing the virus from circulation is therapeutically effective – if the answer is yes, Hemopurifier may have utility, if it is no, it likely will not. And while the Hemopurifier technology has shown to effectively bind and clear similar viruses, until COVID-19 is available to validate with the device, that will remain an unanswered question. In addition, given that the vase majority of cases are in China, the feasibility of human testing may require approval of Chinese regulators (CFDA) – a process which may be less clear or straightforward than, for example, as compared to that of the U.S. FDA.

So, while COVD-19 potentially represents a new opportunity to validate Hemopurifier against another deadly disease, we do not view it as a likely near-term revenue opportunity for the company. But, depending on the severity of the outbreak and progress and success of testing Hemopurifier against the virus, it is possible that it could eventually represent a meaningful growth opportunity for the company. This will be something we will be closely watching.

Hemopurifier U.S. Clinical Cancer Program Awaits Requisite Approvals, Kick-Off …

Meanwhile, we are also encouraged to hear that progress continues to be made towards commencement of AEMD's first U.S. clinical cancer trial. As a reminder, in October 2019 AEMD announced that FDA approved their IDE seeking approval to initiate a small U.S.-based clinical trial in head and neck cancer. While initiation of the clinical program is contingent on standard trial-site sign-off, IDE approval means the most significant hurdle is cleared. Management indicated on the fiscal Q3 2020 call in February that, while they could not provide any specifics, that progress continues and that the hope is requisite approvals will be in-hand shortly and kick-off of the study will happen in the near-term.

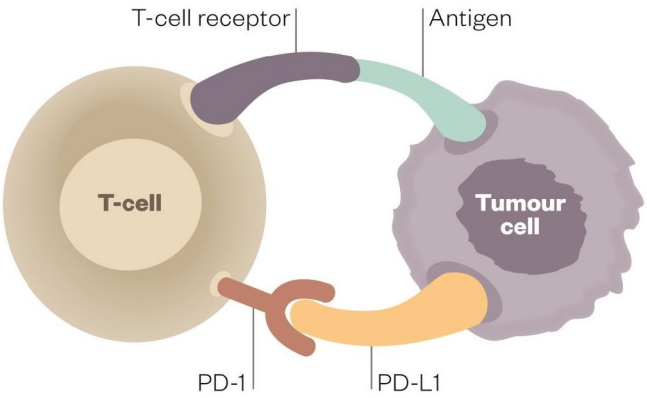
The Early Feasibility Study (EFS) – analogous to a Phase 1 safety-oriented study – will use Hemopurifier in conjunction with pembrolizumab in patients with advanced head and neck cancer. Pembrolizumab, marketed by

Merck (MRK) as Keytruda, is a next-gen cancer therapy used in immunotherapy against a variety of advanced cancers. A humanized antibody which was initially approved by FDA in 2014, pembrolizumab is one of a new class of drugs known as checkpoint inhibitors which work by manipulating immune system function. In June 2019 FDA approved Keytruda for first-line (i.e. standard of care) treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC).

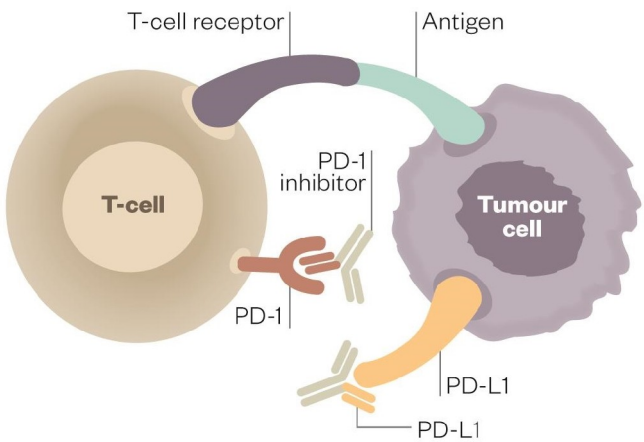
Pembrolizumab targets PD-1 ('programmed cell death protein 1'), a protein found on and responsible for turning on and off T cells' immunity response. When T cells encounter normal healthy cells, PD-1 attaches to PD-L1 ('programmed death-ligand 1'), a protein on the healthy cell which lets the immune cell know not to attack it. PD-L1 is also found on some cancer cells, however, which use it as a defense mechanism by tricking T cells into not destroying it.

In cancers that overexpress PD-L1, pembrolizumab inhibits tumor growth by targeting PD-1. More specifically, pembrolizumab attaches to the PD-1 receptor, thereby blocking PD-L1 (from turning the immune response off) and exposing PD-L1 overexpressed cancer cells to attack by the body's immune system.

Tumor Uses PD-L1 as Defense Mechanism



PD-1 Inhibitor Blocks Tumor's Defense Mechanism



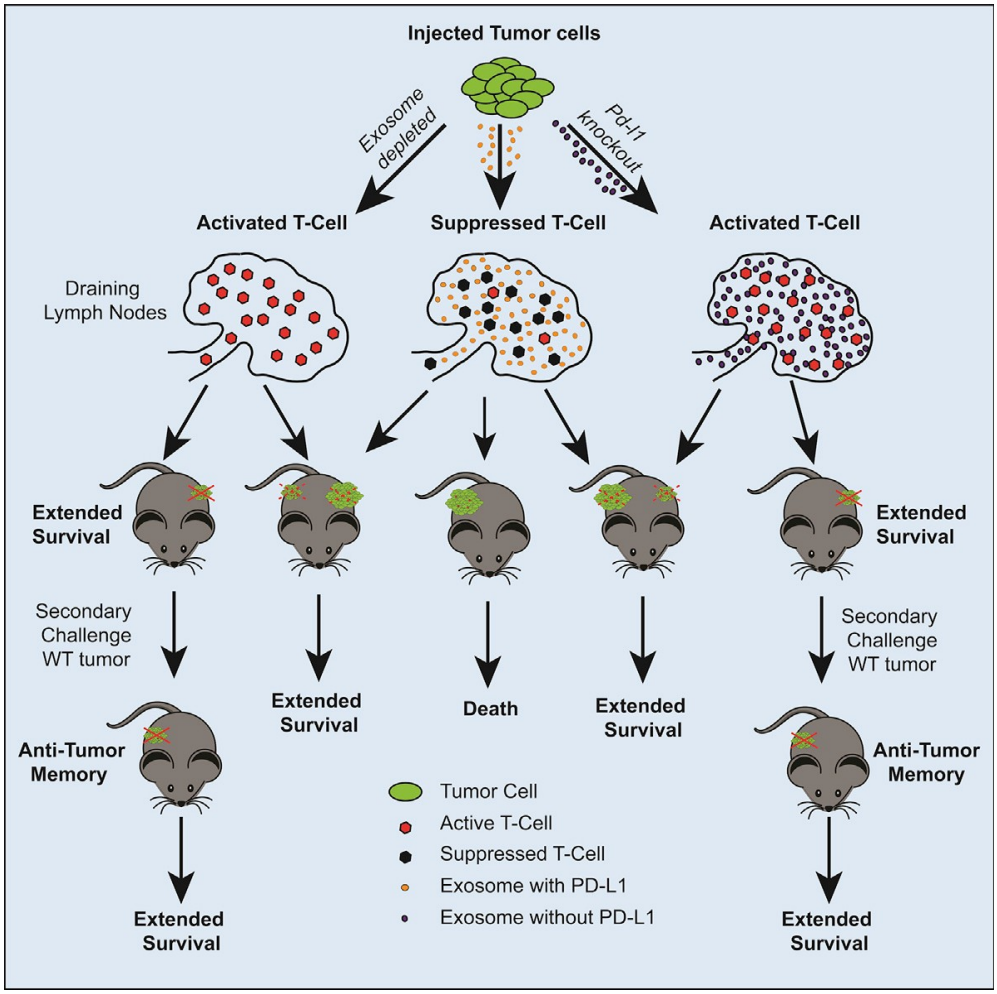
Source: The Pharmaceutical Journal, Nov 2014. Malini Guha

The hypothesis behind combining the inhibition of PD-1 (via pembrolizumab) and physical removal of tumor-derived exosomal PD-L1 (via Hemopurifier) from the body is to evaluate whether it is more effective than PD-1 inhibition alone in fighting these unresectable tumors. As it relates to the latter, more and more evidence continues to support therapeutic targeting of exosomes to fight certain solid cancers.

This includes compelling findings from a study (*Suppression of Exosomal PD-L1 Induces Systemic Anti-tumor Immunity and Memory*, April 2019) published earlier this year in the journal Cell which showed that not only do exosomes play a role in cancer, but also that removal of exosomal PD-L1 inhibits tumor growth (even with tumors resistant to anti-PD-L1 antibodies) and exposure to exosomal PD-L1-deficient tumor cells may result in anti-tumor memory and immunity. Moreover, exosomal PD-L1 of some solid cancers appears to be resistant to anti-PD-L1 therapy – suggesting that effective treatment may require the direct targeting of tumor derived exosomes. Perhaps the most compelling conclusion of the study is the finding that targeting exosomal PD-L1 provides incremental benefit (i.e. suppression of tumor growth) to that of checkpoint inhibitors. AEMD's EFS study, while small and not necessarily powered for conclusive efficacy, might still provide some insight into the potential utility of Hemopurifier in additive cancer therapy.

Removal of Exosomes Secreting PD-L1 Extends Cancer Survival[1]

[1] Poggio et al., *Suppression of Exosomal PD-L1 Induces Systemic Anti-tumor Immunity and Memory* 2019, Cell 177, 414–427



Potential Opportunity for Hemopurifier as Keytruda Adjunct…

Even if this EFS study is successful, there is no way for us to know what AEMD's next-steps will be for their cancer program (i.e. a formal U.S. regulatory program using Hemopurifier in combination with pembrolizumab would seem to be the most obvious, although other options could potentially be in play as well). So, while too early to even suggest that there is a reasonable chance that Hemopurifier could one day be used in combination with Keytruda in the treatment of certain cancers, we offer some background on the success of this cancer drug for some context of the significance of this market and the possible opportunity for AEMD.

Keytruda has shown to be a revolutionary drug in the treatment of cancer. Keytruda generated $7.2B in revenue in 2018, is expected to bring in approximately $10B in sales in 2019 and is Merck's most important product. Analysts are predicting that it could reach over $22B in revenue by 2025 and become the best-selling drug of all time. Keytruda has been successfully used to treat 25 different types of cancer, has regulatory approval in more than 22 oncological indications (including non-small cell lung cancer, head and neck cancer, melanoma, cervical cancer and many more) and has been used in over 1,000 clinical trials.[2]

Specific to head and neck cancer (i.e. subject of the EFS study), Keytruda is the only checkpoint inhibitor that has FDA approval as a first-line treatment for this indication (Bristol-Myers' Opdivio is FDA approved for patients that fail chemotherapy), which FDA granted in June of this year. An estimated 65k people in the U.S. are diagnosed each year with head and neck cancer. Which, given the approximate $12k per month cost of Keytruda treatment, means this indication alone (and just in the U.S.) represents an estimated annual market of more than $9B.

Early Feasibility Study

The design of the Early Feasibility Study is consistent with the indication granted to Hemopurifier under FDA's Breakthrough Device designation which, as a reminder was awarded in November 2018 and relates to "the

[2] BioSpace, Oct 4, 2019. Alex Keown

treatment of individuals with advanced or metastatic cancer who are either unresponsive to or intolerant of standard of care therapy, and with cancer types in which exosomes have been shown to participate in the development or severity of the disease. Therapy with the Hemopurifier device should be an adjunct to standard of care for cancer."

Per Aethlon's press release earlier this month, this initial human cancer study will enroll between 10 and 12 patients at a single trial site. Like all Phase 1 studies, the primary endpoint will be related to safety. The study will assess efficacy-related performance with secondary endpoints measuring exosome clearance and characterization as well as response and survival rates.

IDE approval is a major milestone in our opinion as while Hemopurifier has previously been tested in human subjects – with no instances of serious safety concerns – the totality of clinical experience to-date has been modest and in disease areas (hepatitis C virus) that would likely not have nearly the commercial opportunity as would oncological applications. To be clear, we are not trivializing the significance of the findings that have come from development to-date of Hemopurifier – including establishment of a safety profile sufficient to clear FDA's relatively stringent benefit-risk assessment and gain IDE approval. And much of that work likely has cross-over applicability to follow-on development in cancer applications – even more encouraging given that we have always believed (since we initiated coverage of AEMD in 2012; *March 13, 2012: Initiating With Neutral Rating*) that any commercial opportunity for Hemopurifier in HCV (AEMD's initial therapeutic target) would be limited and not particularly attractive from a development-spending or investment standpoint.

And while previous clinical testing has shown that Hemopurifier can successfully and safely remove viral toxins from the blood and preclinical testing has demonstrated its ability to remove tumor-derived exosomes, this Early Feasibility Study will be the first real world-type evaluation of whether it may have utility in the treatment of cancer. Unlike HCV, which new drugs have turned into a highly treatable and even curable disease, cancer cures (with some rare exceptions) remain elusive. Treatment of metastatic disease is largely related to one or more of a combination of investigational (drugs, immunotherapy, radiation) therapies and focused on marginal life extension (often with poor quality of life) and palliative care.

As such, cancer not only represents a potentially enormous commercial market but the (unfortunate) terminality and incidence of metastatic disease means that development-related opportunities (potentially including non-dilutive funding, partnerships, clinical trials, regulatory-related resources, etc) are likely much more abundant than what would be the case in most other diseases. In addition, the finality of terminal diseases means that demonstration of 'effectiveness' (as well as 'acceptable safety') may be comparably less onerous than in less serious conditions or those with currently available treatment options. Moreover, as side effects of some cancer drugs can be particularly challenging to manage and cope with, 'effectiveness' might also be defined (for example) as an improvement to quality of life.

These reasons underscore why we view FDA approval of the IDE as such a significant event. If all goes well it will also eventually prove to represent a development and commercial inflection in focus for AEMD. In the meantime, FDA's regulatory framework for clinical evaluation of novel therapeutics should provide ample opportunity over time to help judge the potential utility of the Hemopurifier in the treatment of cancer – and, by extension, regular and multiple opportunities for inflection in the market value of AEMD.

Outlook Valuation

Given the difficulty in designing clinical studies around highly virulent viruses, we think the BDD for cancer could be a game-changer for Aethlon. 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, coupled with existing human safety data, it is possible that a cancer pursuit could be relatively fast-moving.

We think that there is reason to believe that a cancer indication for the Hemopurifier is an eventual realistic outcome. Already-completed clinical studies should provide at least some support for the safety of the device, while preclinical studies support Hemopurifiers' ability to capture exosomes. Moreover, the fact that the BDD indication is for metastasized cancers and for which standard of care has failed (i.e. patients which are essentially out of options), implies a lower safety hurdle. Meanwhile, successful capture of exosomes in preclinical studies in a

variety of cancers including breast, ovarian and metastatic melanoma certainly lends credence to the effectiveness of the Hemopurifier in removing exosomes from the circulation of cancer patients. And, finally, receipt and successful competition of grants from the National Cancer Institute related to this topic – that is, removal of exosomes from circulation as a cancer therapy means that this is a pursuit that is not just of interest to Aethlon but to the U.S. government as well. Importantly, in September 2019 AEMD announced that NCI awarded them the Phase 2 (follow-on) grant related to isolation of melanoma exosomes (for diagnostic and treatment monitoring). The grant, which will pay $1.86M over two years, lends further validation to the potential utility of their technology in cancer treatment.

And, encouragingly, there is no shortage of new evidence supporting the role of exosomes in the progression of cancer and, similarly, that removing tumor-derived exosomes from circulation may inhibit tumor growth and/or potentially improve the effectiveness of immunotherapies. As this describes the basis for Aethlon's pursuit of the Hemopurifier in a potential cancer indication, a growing database of evidence can have important consequences including potentially influencing key opinion leaders and regulators alike.

And while highly virulent viruses likely represent a much more challenging target given the difficulty in designing appropriate clinical trials, the new COVID-19 outbreak may represent a new opportunity in this space for AEMD. As more is learned about the disease, answers to key questions related to the possibility of even testing the Hemopurifier against the virus should become more apparent. So, while COVD-19 potentially represents a new opportunity to validate Hemopurifier against another deadly disease, we do not view it as a likely near-term revenue opportunity for the company. But, depending on the severity of the outbreak and progress and success of testing Hemopurifier against the virus, it is possible that it could eventually represent a meaningful growth opportunity for the company – and possible upside to our current valuation.

Relative to ESI, in September 2019 AEMD announced a collaboration with Hoag Memorial Hospital Presbyterian (Newport Beach, CA) with a focus on learning more about exosomes in cancer including identifying unique exosome-based biomarkers with the intent of using these in the development of an early-stage cancer liquid biopsy. The idea is to develop a liquid biopsy which will be able to identify individuals at high risk of developing cancers that could benefit from Hemopurifier treatment.

ESI also continues to work on the ongoing CTE study which we continue to expect will 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 view IDE approval of the EFS study as a major milestone (for the reasons listed above) and one that could lead to meaningful inflection in the value of AEMD, we are currently maintaining our (sum-of-the-parts based) valuation. FDA approval of final site documentation is a near-term milestone we will be looking for and, given the its small size and single location, expect there may be opportunities for potential value-moving events on a regular basis shortly after the study begins.

We also note that while it is too early to gauge the potential value of the AEMD / SeaStar collaboration, that significant progress towards a joint product development program (or related synergies with AEMD's current individual pursuits) could offer value-creation and/or value-enhancement opportunity. Similarly, until more is known about the COVID-19 virus, we cannot reasonably gauge the potential opportunity that it may represent for AEMD and their Hemopurifier – but it is something we will be closely watching and update our outlook and models accordingly.

So, while our price target remains subject to change, we continue to see fair value of Hemopurifier in virus, pathogen, bioterror and cancer applications at ~$90M and value ESI at $30M. Sum-of-the-parts values AEMD at approximately $120M or ~$13/share. The shares currently trade at $2.25 each, representing total equity value of just $21M which we think grossly underrepresents the fundamental value of the common stock of the company.

PROJECTED INCOME STATMENT

Aethlon Medical, Inc.

	2018 A	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
Revenue	$149.6	$229.6	$30.0	$0.0	$413.5	$287.5	$731.0	$1,125.0	$150.0
YOY Growth	*3128.2%*	*53.5%*	*-79.9%*	-	-	*259.4%*	*218.3%*	*53.9%*	*-86.7%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$149.6	$229.6	$30.0	$0.0	$413.5	$287.5	$731.0	$1,125.0	$150.0
Gross Margin	-	-	-	-	-	-	-	-	-
SG&A	$4,402.1	$5,342.0	$1,347.3	$1,479.3	$1,071.3	$1,393.0	$5,291.0	$5,527.0	$3,953.0
% SG&A	-	-	-	-	-	-	-	-	-
R&D	$578.6	$886.6	$248.9	$222.9	$218.6	$278.0	$968.3	$1,147.0	$1,057.0
% R&D	-	-	-	-	-	-	-	-	-
Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($4,831.1)	($5,999.1)	($1,566.2)	($1,702.2)	($876.4)	($1,383.5)	($5,528.3)	($5,549.0)	($4,860.0)
Operating Margin	-	-	-	-	-	-	-	-	-
Other Expense, total	$868.7	$220.5	$501.1	$4.4	($55.5)	$8.7	$11.7	$3.5	$8.7
Pre-Tax Income	($5,699.8)	($6,219.5)	($2,067.3)	($1,706.6)	($820.9)	($1,392.2)	($5,540.0)	($5,552.5)	($4,868.7)
Taxes (benefit)	$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%*
Net Income	($5,679.6)	($6,194.8)	($2,066.4)	($1,705.0)	($819.6)	($1,386.6)	($5,977.7)	($5,530.3)	($4,849.2)
Net Margin	-	-	-	-	-	-	*-817.8%*	*-491.6%*	*-3232.8%*
EPS	($6.92)	($5.12)	($1.63)	($1.29)	($0.28)	($0.16)	($3.37)	($0.51)	($0.39)
YOY Growth	*65.1%*	-	-	-	-	-	-	-	-
Diluted Shares O/S	821	1,208	1,270	1,317	2,888	8,625	3,525	10,850	12,495

Brian Marckx, CFA

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