Trickle Research

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Initiating Research Coverage

Aethlon Medical

(NASDAQ: AEMD)

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Disclosure: Portions of this report are excerpted from Aethlon Medical's filings, website(s), presentations or other public collateral. We have attempted to identify those excerpts by *italicizing* them in the text.

Company Overview

Aethlon Medical, Inc. ("AEMD" or "Aethlon or the "Company") is a medical technology/device company *focused on developing products to diagnose and treat life and organ threatening diseases. The Aethlon Hemopurifier® is a clinical-stage immunotherapeutic device designed to combat cancer and life-threatening viral infections. In cancer, the Hemopurifier is designed to deplete the presence of circulating tumor-derived exosomes that promote immune suppression, seed the spread of metastasis and inhibit the benefit of leading cancer therapies. The U.S. Food and Drug Administration, or FDA, has designated the Hemopurifier as a "Breakthrough Device" for two independent indications:*

- *The 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*.
- *The treatment of life-threatening viruses that are not addressed with approved therapies.*

The Hemopurifier is a blood filter *designed to remove exosomes and life-threatening viruses from the human circulatory system. In the United States, the Hemopurifier is classified as a combination product whose regulatory jurisdiction is The Center for Devices and Radiological Health, or CDRH, the branch of FDA responsible for the premarket approval of all medical devices. In application, the Hemopurifier can be used on the established infrastructure of continuous renal replacement therapy, or CRRT, and dialysis machines located in hospitals and clinics worldwide. It could also potentially be developed as part of a proprietary closed system with its own pump and tubing set, negating the requirement for dialysis infrastructure. Incorporated within the Hemopurifier is a protein called a lectin that binds to a glycosylated, or sugar substituted, membrane, which exosomes and most infectious viruses share*.

Historically, the Company has largely focused its efforts on the Hemopurifier's application in fighting viruses. In that regard, the Company has demonstrated in-vitro success in capturing some of the world's most deadly and/or most recognized viruses including: *Zika virus, Lassa virus, MERS-CoV, cytomegalovirus, Epstein-Barr virus, Herpes simplex virus, Chikungunya virus, Dengue virus, West Nile virus, smallpox-related viruses, H1N1 swine flu virus, H5N1 bird flu virus, and the reconstructed Spanish flu virus of 1918. In several cases, these validations were conducted in collaboration with leading government or non-government research institutes*. Additionally, the Company has demonstrated a highly positive safety profile when treating humans, and it has also demonstrated at least anecdotal efficacy treating a small number of patients who were substantially compromised by life-threatening viruses and they have also demonstrated the efficacy of the product in terms of the verification of viral capture contained within the Hemopurifier post-treatment. We will address that further in this report.

While again, the Company's past efforts were largely focused on addressing viral pathogens and they believed then and believe today that the Hemopurifier will be an effective therapy in that regard. However, that endeavor has proven difficult from a regulatory perspective because of a number of challenges involved in conducting clinical trials around viral outbreaks for instance attracting a sufficient a pool of patient enrollees into a trial as well as others. Here again, we will address some of those challenges further in this report.

Because of some of the challenges inhibiting their progress on the viral front, in late 2018, the Company brought in new management to pivot the Company's focused towards developing their Hemopurifier technology to capture and clear exosomes as a potential treatment for cancer. Since that time, the Company has made marked progress towards that end. However, the recent Covid19 pandemic has created an opening for the Company to *clinically* demonstrate the efficacy of the Hemopurifier. As a result, of these developments, the Company is currently in the process of enrolling patients in both studies to determine Hemopurifier's safety and efficacy in both cancer as well as Covid. Consequently, we believe the next 12 months *could* provide milestone events and data points that could markedly impact the value of the Company. The Company has been granted "Breakthrough Status" for its Hemopurifier for the treatment of both viral pathogens and exosomes/cancer.

Industry and Regulatory Overview

Obviously, the cancer "market" is large and unfortunately growing. For instance, the world's leading immunotherapy (Merck's Keytruda) marked $11 billion in 2019 sales and is slated to become the world's number one drug over the next few years. Certainly, one of the reasons for Keytruda's marked success is that it has, over time, been approved (and continues to be approved) for a growing number of indications. Clearly, therapies with mechanisms of action that can mitigate multiple types of cancer are particularly valuable. We will revisit that notion with respect to Aethlon and the Hemopurifier further in this report because we think it also has the potential to address multiple types of cancer.

While the cancer market is relatively well defined in terms of size and potential growth, the virus "market" is perhaps more elusive. Part of the problem defining the virus market stems from the nature of the pathogens. That is, they are by design not predictable in either their form or their occurrence. Unfortunately, the world is becoming more familiar with those ominous characteristics. As a result, the quest to recognize, treat and ultimately eradicate viral pathogens is typically a moving and evolving target. Consequently, much like cancer, the "Holy Grail" in addressing viral threats, is to identify markers or other shared characteristics that can allow for mitigations that can impact multiple forms of the disease(s). Here again, we believe the mechanism of action of the Hemopurifier has been demonstrated to address a variety of viruses. As we will illustrate, the device has clearly demonstrated the capability to reduce viral load in treated patients across multiple viral indications. The greater question, and one we think the Company is perhaps finally in a position to address is, "does reducing viral load in infected patients lead to measurably better outcomes"?

As we addressed, the Hemopurifier is a medical device. That alone makes it generally atypical amongst both cancer and virus therapies. As a result, it has a different pathway to FDA approval than more typical pharmaceutical approaches. In that regard, there are generally three potential pathways to FDA approval available to medical device companies. The simplest and quickest of these is referred to as a "self-registration, the second is a 510k filing while the third is called a pre-market approval ("PMA"), which requires considerably more rigor to achieve. Further, the FDA divides medical devices into classes ("Class I", "Class II" and "Class III") and the classes are delineated by the potential risks associated with each. For instance, an invasive medical device would on the face be more likely to be designated a Class III device than a non-invasive device. Recognize, Aethlon has not yet determined the best or most applicable pathway to approvals (although we believe that will be Class III/PMA) so we think this particular narrative is germane to this coverage. Below is a brief overview of the FDA medical device classifications:

Class	Risk	Examples	Safety/Controls	Regulatory Filing/Pathway	Prevalence
I	Low	Examples include enema kits and elastic bandages.	General Controls These devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices.	Self-Registration or 510(k) filing	47% of medical devices fall under this category and 95% of these are exempt from the regulatory process.
II	Medium	Examples of Class II devices include powered wheelchairs and some pregnancy test kits.	General Controls and Special Controls Most medical devices are considered Class II devices	Typically 510(k) Some require PMA 10%-15% require clinical trials	43% of medical devices fall under this category.
III	High	Examples of Class III devices include implantable pacemakers, breast implants and stints.	General Controls and Special Controls Pre-Market Approval (PMA). These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.	Generally all require PMA Most require clinical trials	10% of medical devices fall under this category.

Data From: www.fda.gov

To clarify some of the labels noted above, the FDA provides a list of "General Controls" that are applicable to ALL medical devices. The FDA provides the following guidance with respect to General Controls:

> *General Controls apply to all three classes of medical devices; however, they are the only level of controls that apply to Class I devices.*
>
> *Class I devices are not intended to be:*
> - *For use in supporting or sustaining life;*
> - *Of importance in preventing impairment to human life; and may not*
> - *Present a potential unreasonable risk of illness or injury*
>
> *General Controls include the provisions of the Act pertaining to:*
> - *Adulteration;*
> - *Misbranding;*
> - *Device registration and listing;*
> - *Premarket notification;*
> - *Banned devices;*
> - *Notification and repair, replacement, and refund;*
> - *Records and reports;*
> - *Restricted devices; and*
> - *Good Manufacturing Practices.*

Some of these requirements under General Controls, are likely familiar to many who follow the medical device space, for instance the "misbranding" requirements cover packaging or other claims that are false or misleading or even difficult for the "ordinary person" to read and understand. Good manufacturing practices are also often cited by device manufactures with respect to "approved" third party manufacturers and facilities that are inspected and approved by the FDA. The fact that the Company's goal is to demonstrate that the device can be used to "*sustain* the *lives*" of cancer and/or virus infected patients, likely prohibits designation of the Hemopurifier as a "Class I" device. As a result, the device will require not only General Controls, but also "Special Controls".

> *Devices classified into class II are devices for which special controls, combined with general controls, are necessary to provide reasonable assurance of safety and effectiveness. The FDA sets forth the special controls for the applicable Class II devices. Thus, a manufacturer who intends to market a device within a generic type of device covered by these documents must:*
>
> - *conform to the general controls in Section 513(a)(1)(A) of the Federal Food Drug & Cosmetic Act (the Act);*
> - *address the specific risks (Section 513(a)(1)(B) of the FD&C Act) to health identified, either by meeting the recommendations in the guidance/guidelines or by some other means that provides equivalent assurances of safety and effectiveness; and*
> - *for devices not exempt from premarket notification, obtain a substantial equivalence determination (Sections 510(k) and 513(i) of the FD&C Act, and 21 CFR 807.100) from FDA prior to marketing the device.*

To expand these bullet points, Special Controls include some rigors beyond General Controls that are aimed at scientific determinations of the safety and efficacy of the device(s), as well as some nuances ("*substantial equivalents*" for instance) that help determine the required approval pathway. Further, the importance of determining the class of a medical device is relevant because it impacts the type of filing which must be submitted to the FDA for ultimate approval. Again, once a device is determined to be a Class II device it by extension likely requires either a 510(k) filing or in some cases a more extensive PMA, while Class III devices will generally require a PMA.

- **510(k) Filings**

Per the FDA:

> *"A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent ("SE"), to a legally marketed device (section 513(i)(1)(A) FD&C Act). A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is as safe and effective as the predicate. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalence claims. A legally marketed device is a device that was legally marketed prior to May 28, 1976 (reamendments device), or a device which has been reclassified from Class III to Class II or I, a device which has been found SE through the 510(k) process, or a device that was granted marketing authorization via the De Novo classification process under section 513(f)(2) of the FD&C Act that is not exempt from premarket notification requirements. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate. Legally marketed also means that the predicate cannot be one that is in violation of the FD&C Act.*
>
> *Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device. Once the device is determined to be SE, it can then be marketed in the U.S. The SE determination is usually made within 90 days and is made based on the information submitted by the submitter".*

- Premarket Approval Application (PMA)

> To reiterate, Class III devices are the most regulated devices in the U.S. *As the FDA notes, "a Class III device is one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury . Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices".*
>
> *"A PMA application is a scientific, regulatory documentation to FDA to demonstrate the safety and effectiveness of the Class III device. There are administrative elements of a PMA application, but good science and scientific writing is a key to the approval of PMA application. If a PMA application lacks valid clinical information and scientific analysis on sound scientific reasoning, it could impact FDA's review and approval".*
>
> *Although the manufacturer may submit any form of evidence to the FDA in an attempt to substantiate the safety and effectiveness of a device, the FDA relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in §860.7, FDA will determine whether the evidence submitted or otherwise available to the FDA is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.*

In case the above PMA narrative from the FDA is not clear, PMAs essentially require clinical trials much like pharmaceuticals. The FDA's guidelines therein address appropriate approaches to generating "valid scientific evidence" that most familiar with clinical trial vernacular will recognize. That being said, here is our point to this

discussion regarding the classification and approval of medical devices by the FDA, and more specifically Aethlon's Hemopurifier.

As we recall, we have followed Aethlon for much of the past decade. Our motivation to continue keeping track of the story for all those years was simple. We believed then and still believe today, their device will filter viral pathogens from the blood of infected patients, and in turn measurably reduce those patients' viral loads. We also believe, that reducing patients' viral loads will lead to better outcomes. The addition of the exosome/cancer potential further bolsters our enthusiasm. On the other hand, we submit, the unique attributes of the Hemopurifier in the context of the above FDA narrative regarding the pathways to approval for medical devices, as well as the unique attributes of treating viral pathogens have collectively inhibited their progress.

First, it is important to recognize the difficulty involved in treating viral pathogens that are ever evolving. As we have learned over the past few months, it is difficult to prepare for a virus we know little about until it finally manifests itself. Moreover, fortunately, the world has managed to avoid pandemic type infections from some of the more lethal viruses that have appeared over the past several years. For instance, the World Health Organization notes that Ebola "*has a high risk of death, killing 25% to 90% of those infected, with an average of about 50%".* Granted, Ebola is generally spread through bodily fluids which makes it much less contagious than the current Covid19 virus, however, the fact remains, there will likely be more viruses on the horizon and they will likely have varying characteristics in terms of contagion and mortalities.

Again, as the public has learned there are a number of challenges involved in recognizing and then combating new viral strains. Ironically, the rigors of developing scientific data around potential therapies for "new" viruses, is one of the greater challenges. For example, again consider Ebola. The virus was first identified in 1976 in two areas of the world; Sudan and Democratic Republic of the Congo and there have been various outbreaks of the disease throughout sub-Saharan Africa since, with the most recent being July 2019 (Congo) during which the World Health Organization declared the outbreak a world health emergency. Generally, the time from contacting the disease to symptoms is between 2 and 21 days, while the time from onset of symptoms to death is typically around 1 to 2 weeks. In terms of the challenges, the relatively short period of time between the onset of symptoms and death make it difficult to develop scientific studies around potential therapies for Ebola. From even a practical standpoint, it is difficult to "enroll" patients in a study when the time from disease determination and death are measured in days. Further, deploying personnel and required equipment into new outbreaks in order to conduct scientific trials, especially in lesser developed parts of the world is also problematic.

To that notion, we know that Aethlon has treated an Ebola patient (a comatose physician with multiple organ failure) and we know that patient recovered. However, the patient was actually treated in Frankfurt, Germany after being infected in Sierra Leone. To our point regarding challenges, they were not able to treat him at the location of the outbreak. What we also know is that success with one patient does not constitute the scientific rigor required for FDA approval. Further, because of that lack of rigor we do not know with any certainty that the Hemopurifier was responsible for his recovery. That example/instance underscores the challenges Aethlon has had. That brings us back to the FDA.

Clearly, the Company's intent is to treat patients with life threatening illnesses, and that falls into the category of "life sustaining" treatments. That would certainly suggest a Class III device and a requirement for clinical trials. As we have suggested here, the viral space in general is not always conducive to robust clinical trials. On the other hand, the device has demonstrated a considerable safety profile, and it can be administered via standard dialysis machines, and there are other approved blood filter devices that have been approved by the FDA. In short, we believe there is at least reason to believe that it may fit the definition of a substantially equivalent "predicate" device. Again, we think a handful of variables have led to challenges that have prohibited the Company's goal of an FDA approval. However, two things have happened over the course of the past 18 months that we believe have provided potential openings for an approval, specifically, their new efforts in cancer, and, Covid19.

Since the onslaught of the pandemic, the street has seen an abundance of public companies, large and small, entering the Covid19 fray. The entries have included companies working on tests, therapies, vaccines and other associated offerings. In addition, given the negative global impact of the pandemic, world health authorities, including the FDA have attempted to accommodate potential new discoveries by expediting their own processes to foster new discoveries. Moreover, as we noted, whereas being able to effectively enroll enough applicable patients has often impeded the scientific study of some prior viruses, Covid19 has unfortunately provided a large population of patients in parts of the world that are well equipped to administer and conduct trials around new drugs/therapies.

While certainly not something to celebrate, the current environment has nonetheless created the "perfect storm" in terms of some of the challenges Aethlon has faced in its efforts to gain approval for the treatment of viral pathogens. In our view, the Company's June 18, 2020 announcement that the FDA had granted them an Investigational Device Exemption ("IDE") to treat laboratory diagnosed Covid19 patients is a watershed event for Aethlon, especially considering their past challenges to essentially get to this clinical point. We believe the trial, which will include "*up to 40 patients in up to 20 centers",* will provide some of the answers many of us have speculated about over the years with respect to the efficacy of the Hemopurifier as a therapy for viral infection.

To reiterate, we are confident that these trials will demonstrate the device's safety. We note that because the Company's release about the trials suggests that it is "equivalent to a Phase I trial". With all due respect, and while we can appreciate the Company's efforts to avoid hyping the trial, we do not think the goal here is to demonstrate the safety of the device. We believe they have already covered that ground. We submit, the size of the study may look like a Phase I trial, but we think it has additional endpoints in mind. In short, we think they are enrolling the trial as we write this, and as such the results therein will be gathered relatively quickly. We do not know how much time they will take to interpret that information and the Company has offered no guidance therein. However, as we noted, the FDA is doing all they can to provide support to approaches that might help stem the Covid19 tide. In our view, if the Hemopurifier proves effective in treating Covid19, we should know it in short order. Obviously, positive results would likely create a marked valuation catalyst.

Lastly, while all eyes appear to be on the Covid19 piece of the Aethlon equation, keep in mind that the Company recently announced the filing of a clinical trial to measure the efficacy of the Hemopurifier in combination with Merck's Keytruda. The trial specifics are available here:

https://clinicaltrials.gov/ct2/show/NCT04453046?term=04453046&draw=2&rank=1

While the Company has not provided specific information regarding enrollment, we believe that process is in play. Again, favorable results from this study would in our view provide an additional valuation catalyst.

Technology/Product Overview

The Hemopurifier is an affinity hemofiltration device designed for the single-use removal of exosomes and life-threatening viruses from the human circulatory system. In the United States, the Hemopurifier is classified as a combination product whose regulatory jurisdiction is The Center for Devices and Radiological Health, or CDRH, the branch of FDA responsible for the premarket approval of all medical devices.

In application, the Hemopurifier can be used on the established infrastructure of continuous renal replacement therapy, or CRRT, and dialysis instruments located in hospitals and clinics worldwide. It could also potentially be developed as part of a proprietary closed system with its own pump and tubing set, negating the requirement for dialysis infrastructure.

Incorporated within the Hemopurifier is a protein called a lectin that binds to a glycosylated, or sugar substituted, membrane, which exosomes and most infectious viruses share.

The following description of the Hemopurifier is excerpted from the Case Report published by physicians and others who treated the Ebola patient we referenced above. The description is a bit technical, but it certainly describes the mechanisms better than we can. That Case Report can be found at the following location:

https://www.karger.com/Article/PDF/375229

Case Report

Lectin affinity plasmapheresis therapy is based on the concept of affinity chromatography developed in the 1970s. It combines plasma separation using a hollow fiber plasmafilter with virus capture via immobilized affinity agents residing in the extracapillary spaces of the plasma filter. Research has shown that a unique lectin protein (Galanthus nivalis agglutinin, GNA) from Galanthus nivalis (the common snowdrop) has a high affinity to the mannose-rich glycoproteins ("GP") that are universal constituents on the surface of enveloped viruses to inter alia mediate entry into host cells. GP are also shed directly from infected cells. As blood enters the plasmafilter, a portion of the plasma is forced through the pores of the membrane (≈ 200 nm) due to the blood side pressure. Because the hollow fiber bundle creates a resistance to the flow of blood, a pressure drop is created along the length of the device such that the blood-side pressure is higher at the blood inlet and lower at the blood outlet. This causes plasma to flow away from the blood and into the extracapillary space (where the affinity resin resides) along the proximal third of the fiber bundle. In the distal third of the fiber bundle, the pressure gradient is reversed; this causes the plasma to flow backward through the membrane recombining with the blood but without the viruses and GPs that have been bound by the GNA. This technique does not result in the loss of any plasma since the plasma never leaves the device (the plasma ports are left capped). Also, in the submissions of summary human clinical data provided by the manufacturer of this device to the US and German medical device regulatory agencies, there has been no indication that any beneficial biomolecules are being adsorbed to any clinically significant level.

Specifically, as a point of reference, the Ebola subject was treated with the Hemopruifer for a period of 6.5 hours.

In addition the description above, the conclusion of this Case Report provide some additional points that we think are highly relevant to some of the points we have noted above regarding both our views of the value of reducing viral load but also the ongoing challenges associated with eventual paths to approval for Aethlon. As a precursor, the conclusion below references regarding "all approaches" are centered on a variety of therapies that were being used to treat infected patients, and they include passive and active immunotherapy, convalescent plasma treatments and various vaccines.

> **(1)** ***All approaches share one proposition: they benefit from a reduction in viral load. Rapidly lowering the number of circulating viruses, and GP frees up the available components (e.g., neutralizing antibodies) of the host immune response to attack the remaining viruses and eventually eradicate them wherever they reside. Also, every virus that is extracted from the circulation is no longer available to infect other cells.*** *This is of great importance, since higher levels of viremia are associated with higher mortality. Filtration and capture of circulating EBOV and GP represents an emerging device strategy for*

extracorporeal virus elimination. Furthermore, affinity binding to lectins provides a mechanism to address all strains of Ebola. The data contained in this case study represents a 'proof of concept' for extracorporeal virus removal in EVD. Furthermore, since the attachment epitope is the same, it is highly likely that GP are also extracted by this process.

*We consider that LAP is a new option to expand best supportive care toward a virus-targeted therapy for EVD. One advantage this new concept might bring is the fact that only the virus is removed while other plasma components like antibodies remain in the patient. Thus, this treatment option will not interfere with an evolving immune response. Another advantage is, if a net viral clearance can be achieved by filtering, this would be without adding further drug toxicity or introducing new drug interaction risks. Also, it appears that, from the limited time we used LAP, no additional risk or harm was incurred during concurrent hemodialysis therapy. One factor that must be considered with the provision of this LAP technique is that, as time passes, more and more of the binding sites on the affinity resin will be occupied with virus or shed GP and the efficiency of extraction will decline (*the patient might need multiple Hemopurifiers*)* . **(2)** ***At the moment there is insufficient experience to be able to determine the best time for treatment initiation or the optimal time to change out the cartridge for a new one. Further investigations are needed to address the best timing of initiation, the best treatment duration, and the possibility to enhance viral clearance with more devices used in series or in parallel.***

The use of lectin affinity plasmapheresis is reported for the first time in the treatment of a critically ill patient with the severe Ebola virus disease. **(3)** ***Although the impressive number of 253 million captured genomic copies of EBOV provides definitive evidence of the ability of this device to extract virus, the favorable outcome of the patient described in this case study cannot be attributed to the LAP treatment alone. It should be noted that, besides intensive supportive care for treatment of multi-organ failure and other experimental interventions, the device was used late in the course of the illness, and viral load was already declining before the start of the treatment****. As described by Chertow et al, the critical phase seems to be between days 7 and 12 with most deaths occurring in this time frame. Also, nearly all patients who survived to day 13 ultimately lived. For that reason, the real contribution of LAP is not clearly known.*

However, this limited experience provides optimism that lectin affinity plasmapheresis is a promising new tool for the treatment of severe Ebola virus infection and warrants further evaluation as well as technical development. **(4)** ***The possibility to capture viruses efficiently out of an infected individual may also provide an interesting strategy for treating other viral diseases caused by enveloped viruses including (therapy resistant) HIV, hepatitis B or C (induced liver failure), and even influenza****.*

We have highlighted and numbered certain excerpts from this narrative that we think require some color.

Item (1). This is the cornerstone of our thesis regarding Aethlon. To reiterate, we are confident that the Company's Covid19 studies will indicate that the Hemopurifier will clear considerable numbers of the virus in treated patients, thus markedly reducing their viral loads. (Incidentally, we think the device will prove effective in clearing exosomes in their cancer studies as well).

Item (3). Item (3) underscore some of the challenges we covered in terms of being able to even enroll potential clinical studies. First, as item (3) opines, the Hemopurifier reduced the patient's viral load. However, while it seems reasonable to assume that reducing viral load will improve outcomes, scientific rigor does not allow much room for assumption. The Company needs to demonstrate that their device and/or reducing viral load directly leads to better outcomes. For instance, as the excerpt notes, in this particular instance the patient was being treated with a number of therapies since his condition was dire and they were trying to save his life through whatever means possible. As a result, his viral loads were decreasing prior to the Hemopurifier treatment, which obviously raises issues about which treatment contributed to the viral load reduction and to what degree. While we submit, this particular outcome has some loose ends in terms of identifying the source of all the viral load reductions, and

again, even whether or not viral load reduction was the basis of the patient's recovery at all. In fact, we would suggest that over the time since this treatment, this element of the Company's Ebola "experience" has been a point of contention among some of the Company's detractors in the investment community. That is, some have suggested that since the patient's viral load was decreasing prior to the treatment with the Hemopurifier, then the Hemopurifier was not responsible for the viral load reductions *at all*.

With all due respect to that view, investors should keep in mind that this patient's viral load prior to the Hemopurifier treatment was 400,000 virus copies per milliliter of blood (copies/ml), while the post-treatment viral load measurement had dropped to 1,000 copies/ml. **We know the Hemopurifier contributed to the viral load reduction because they were able to measure the virus counts captured by the device.** Clearly, we can argue about what contributed to the patient's recovery, but we are not sure that people can effectively argue that the Hemopurifier did not contribute to viral load reduction. In a separate study the Company conducted *"a single proof-of-principle treatment study at the Sigma New Life Hospital (India) in an AIDS patient* ***who was not being administered HIV antiviral drugs****. In the study, viral load was reduced by 93% as the result of 12 Hemopurifier treatments (each four hours in duration) that were administered over the course of one month"*. We will stand by our assertion that the device can substantially reduce viral load in patients infected with any of a number of viruses.

Item (2). Like Item (3), Item (2) speaks to the need of clinical trials in determining not only the efficacy of the Hemopurifier, but also the proper protocols that might lead to the optimization of treatments. In effect, this item is not significantly different from determining dosing regimens for a drug. Even with definitive determinations that the Hemopurifier reduces viral load and reducing viral load leads to better patient outcomes, it would still be necessary to frame the treatment. That is, they would still need to determine things like when in the course of disease is the Hemopurifier most effective, how long should the optimal treatment last, how many treatments are necessary and a host of others. Simply put, using the Hemopurifier to treat viral infection is going to require clinical trials.

Item (4). Item (4), might be the most promising possibility regarding the device's potential with respect to treating viruses. We think ubiquitous therapies that can reduce viral loads across a variety of viral pathogens, might be the best front line solution to tempering the spread of new viral iterations. As Covid19 has demonstrated, treating each new viral outbreak will require an initial understanding of the new form and/or strain. As a result, scientists need time to understand, develop and test vaccines or other specific therapies. However, in the meantime, the disease(s) spread and people die. In our view, a therapy like the Hemopurifier, that could be affective against a broad spectrum of viruses could be an integral part of that battle. Item (4) addresses this notion.

To expand on the prior paragraph, Company collateral notes the following, which we view as topical:

> *Based on our studies to date, the Hemopurifier can potentially clear many viruses that are pathogenic in humans, including HCV, HIV and Ebola. We do have data suggesting that it could clear a closely related coronavirus (MERS).*
>
> *To date, Hemopurifier therapy has been administered to individuals infected with Ebola virus, Hepatitis C virus (HCV) and the Human Immunodeficiency virus (HIV). However, beyond human treatment experiences, pre-clinical Hemopurifier studies have validated the broad-spectrum capture of numerous viral threats. These include: Chikungunya, Dengue and West Nile virus, as well as Vaccinia and Monkey pox, which serve as models for human Smallpox infection. Specific to pandemic influenza threats, Aethlon has validated the capture of H5N1 avian flu, H1N1 swine flu, and the reconstructed 1918 influenza virus, which represents a model for the strain of influenza that killed an estimated 50 million victims in 1918 and 1919. In vitro studies of other viral threats are ongoing.*

One last point of note on the virus side of the equation. As we suggested, there are many companies chasing the Covid19 virus and those include companies developing tests, therapies and/or vaccines. Frankly, when we look at

the valuations that some of these companies have garnered around the Covid19 rush, we feel that Aethlon, given some of its proven history in reducing viral loads, represents a compelling relative value. Specifically, we have seen some of these small companies trading at valuations several times that of the current valuation of Aethlon. Granted, that may just mean that many of the others are overvalued, but in general, we think Aethlon represents compelling potential in addressing a portion of the Covid19 problem as well as perhaps viral threats in general. Interestingly enough, we have seen some of these companies pursuing Covid19 therapies from platforms that were once addressing other viruses. Hepatitis C is a good example of that. As cures for Hepatitis C emerged many of these programs were shuttered as the commercial promise of those particular approaches were diminished by those who got there first. Aethlon has some history in that regard in terms of its own work with Hepatitis. However, some of that research has been resurrected around Coivd19 with the belief that these therapies may have some therapeutic value in addressing other viruses as well. In short, much like in cancer, which we will address next, the viral arsenal going forward is likely to contain a number of therapies that may be used in varying combinations to address infected populations. We believe a big part of that therapy will need to include treatments with broad viral application that can mitigate multiple viral types that still share some common characteristics (glycoproteins for instance). We think Hemopurifier and/or perhaps other filter devices could be part of that arsenal.

- **Hemopurifier Potential to Mitigate Exosome Loads to Address Multiple Cancer**.

To reiterate, pre-Covid19 the Company's pivoted its focus to address other potential applications for the device, notably the reduction of exosomes that are implicated in the metastasis of certain cancers. Here again, we will provide some of the Company's narrative to address the point. To be clear, that "pivot" was driven by the addition of management with deep experience in cancer therapies. We will address that further as well in the Management Overview.

> *Recently, our primary focus has been on the evaluation of the Hemopurifier in cancer, where we have shown in non-clinical studies that it is capable of clearing exosomes, which are subcellular particles that are secreted by both normal and malignant cells. Tumor derived exosomes, have been shown in multiple laboratories to be critical components in the progression of cancers. They can mediate resistance to chemotherapy, resistance to targeted agents such as trastuzumab (Herceptin), metastasis and resistance to the newer immuno-oncology agents, such as pembrolizumab (Keytruda). Based on these observations and data, in November 2019 the FDA granted us a second Breakthrough Designation "…for the 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."*
>
> *In June 2019, we met with the FDA in Bethesda, Maryland to discuss the development program for the Hemopurifier in cancer. Following this meeting, in September 2019, we filed an IDE to support initiating an Early Feasibility Study, or EFS, to investigate the Hemopurifier in patients with advanced and/or metastatic squamous cell carcinoma of the head and neck in combination with pembrolizumab (Keytruda) which was recently approved in the front line setting. The IDE was approved on October 4, 2019. We are now preparing to initiate the trial, which will enroll 10 to 12 subjects at the UPMC Hillman Cancer Center in Pittsburgh. The trial has received IRB approval and we expect it to open for enrollment in the September quarter. Endpoints for the trial will include safety, clearance and characterization of cleared exosomes and clinical tumor response and survival.*
>
> *We are the majority owner of Exosome Sciences, Inc., or ESI, a company focused on the discovery of exosomal biomarkers to diagnose and monitor life-threatening disease conditions that may be current or future therapeutic targets for Aethlon Medical. At present, the priority of ESI is directed toward exosomal biomarkers to diagnose and monitor cancer and neurological disorders.*

Since it began operations in 2013, ESI researchers disclosed the discovery of an exosomal biomarker that may be associated with neurodegenerative diseases that involve the abnormal accumulation of tau protein in the brain. These diseases, known as tauopathies, are a family of 21 different neurological disorders that include Alzheimer's disease and Chronic Traumatic Encephalopathy, or CTE. Related to CTE, the ESI team was invited to participate in an NIH-funded research study with The Boston University CTE Center. In the study, ESI researchers investigated an exosomal tau biomarker, or TauSome, as a candidate to diagnose and monitor CTE in living individuals. At the present time, CTE can only be diagnosed through post-mortem brain autopsy.

The results of the study indicated that TauSome levels in the blood of former professional American football players, a high CTE risk group, were significantly higher as compared to same-age group control subjects who did not participate in activities that involved repetitive head trauma. Additionally, high TauSome levels also correlated with poor performance in cognitive decline testing. These results were published in an article entitled "Preliminary Study of Plasma Exosomal Tau as a Potential Biomarker for Chronic Traumatic Encephalopathy" in the Journal of Alzheimer's Disease on April 12, 2016. That study is available here:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4833534/

To further validate these observations, ESI has initiated a follow-on study to evaluate TauSome levels in up to 200 former professional football players and control subjects. If fully enrolled, the study would be the largest study to date related to the advancement of a candidate biomarker to diagnose and monitor CTE in the living. Enrollment of study participants began in March 2018 at the Translational Genomics Research Institute, or TGEN, in Phoenix, AZ. Kendall Van Keuren-Jensen, Ph.D., Co-Director of TGEN's Center for Noninvasive Diagnostics is the principal investigator at this site location. Dr. Van Keuren-Jensen is neurodegenerative disease thought leader whose research includes discovery and detection of biomarkers for central nervous system disorders. Additional site locations are anticipated.

In September 2019, we announced that ESI had entered into a collaboration with the Hoag Hospital Presbyterian in Newport Beach, California to identify and characterize potential early disease markers for cancer diagnostics, cancer progression and treatment resistance. The Principal Investigator on this study is Michael Demeure, M.D., program director of Precision Medicine at Hoag. Samples from patients at Hoag will be analyzed by ESI scientists to identify and characterize exosomal "liquid biopsy" markers of cancer incidence and progression. We believe that our recently announced NCI-SBIR Phase II contract to develop a benchtop instrument to isolate and characterize exosomes could substantially expand the capabilities of the ESI programs.

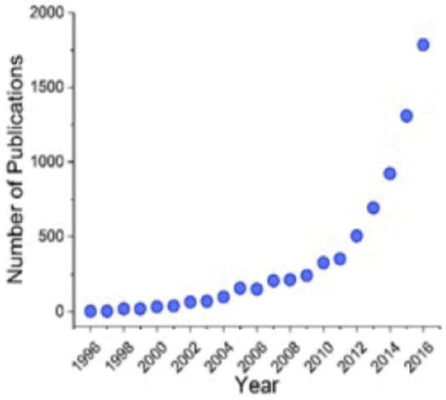
On June 22, 2020, the Company announced the presentation of an e-poster at the American Association for Cancer Research (AACR) Virtual Annual Meeting II. The conclusion of that presentation is as follows:

The results demonstrate that the GNA affinity capture mechanism of the Hemopurifier is effective for clearing 92-99% of exosomes from input concentrations of 109-1010 exosomes per mL of plasma. The device captures exosomes from diverse tumor types including head and neck cancer, melanoma, ovarian cancer, esophageal cancer and breast cancer. Analysis of plasma samples from Stages III and IV triple negative and human epidermal growth factor receptor 2 overexpressing breast cancer showed that Hemopurifier-bound material comprised the appropriately-sized vesicles expressing tumor susceptibility gene 101 and tetraspanins. In comparison to mini-SEC-isolated exosomes, tumor-specific epitopes and immunosuppressive proteins exhibited equivalent expression among Hemopurifier-isolated exosomes. The immunosuppressive functions of Hemopurifier- and mini-SEC-isolated exosomes were also equivalent. The Hemopurifier effectively clears exosomes present in plasma that originate from diverse types of cancer. The Hemopurifier-captured exosomes exhibit signatures of malignancy and immunosuppression and are therefore relevant therapeutic targets.

This research was supported by the National Cancer Institute of the National Institutes of Health under award number 1R43CA232977-01.
The poster is available at:

https://vcusa.sparx-ip.net/aacr2020ep/?c=a&searchfor=hemofiltration&view=2&item=2020AB_4509

Much like the reduction of viral loads, it has not been determined that the reduction of exosomes will necessarily lead to better outcomes for cancer patients. In fact, as we understand it, the entire study/understanding of the role of exosomes in cancer metastasis has only recently begun the gather momentum. To that end, the Company notes that *in 2006 there were fewer than 100 peer reviewed papers focused on the role of exosomes. On the other hand, today there are more than 5,000 and 25% of those were published in the past two years*. They provide the following graphic to illustrate that momentum :



J Cancer Immunol Ther. 2018; 1(1): 9-16

If one spends some time reviewing some of these publications, we think they will discover narrative much like that of these presentations that we have come across:

Exosomes and Their Role in Cancer Progression
Yonago Acta Med. 2019 Jun; 62(2): 182–190. Published online 2019 Jun 20. doi: 10.33160/yam.2019.06.002
PMCID: PMC6584259 PMID: 31320822

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6584259/#:~:text=Exosomes%20are%20actively%20involved%20in,distant%20organ%20through%20the%20blood.

...Recently it has been reported that exosomes modulate cell-cell communication contributing to the maintenance of tissue homeostasis by molecules including exosomes. Moreover, exosomes released from cancer cells are involved in cancer progression. Thus, data regarding the role of the exosomes in malignant cancer will lead to development of novel diagnostic and therapeutic methods...

Exosomes play roles in sequential processes of tumor metastasis
2019 Apr 1;144(7):1486-1495. doi: 10.1002/ijc.31774. Epub 2018 Nov 4.

https://pubmed.ncbi.nlm.nih.gov/30155891/

Overwhelming evidence demonstrates that exosomes, a series of biologically functional small vesicles of endocytic origin carrying a variety of active constituents, especially tumor-derived exosomes, contribute to tumor progression and metastasis…Further studies have shown that exosomes play a vital role in cancer metastasis, namely, contributing in forming the premetastatic niche, infuencing tumor cells and microenvironment, and determining specifc organotropic metastasis…

As we said, these are just a few examples, but the point is, the study of exosomes in cancer is burgeoning and we think Aethlon is in the middle of that dynamic. Further, they will be enrolling their first clinical trial in the space shortly, so we suspect that could provide some additional insight into their potential to provide a viable and perhaps approvable therapy. In addition, for the sake of brevity we will not expand on it here because it is a bit further behind the other indications in terms of clinical trials, but as we touched on above, the Company is also studying the influence that exosomes may have on other disease such as Alzheimer's and Chronic Traumatic Encephalopathy ("CTE").

Operating and Clinical Overview

As we noted, Aethlon is essentially a pre-revenue company, and it is not likely to generate measurable revenues in the foreseeable future. For fiscal 2020 (ended March 31, 2020) the Company reported operating expenses of $6.6 million or approximately $1.65 million per quarter. Like most companies in "pandemic mode" we think the Company has attempted to tighten its belt, but we also believe they had some extraordinary expenses in fiscal 2020 that are not likely to reoccur in fiscal 2021. As a result, we are reflecting a quarterly burn rate in the $1.3 to $1.5 million. We do not expect the current clinical endeavors to impact that significantly due to their limited scale, but we did add some expenses beyond the current fiscal 2021 to account for some additional clinical activity. However, we may need to reassess that in the event of added clinical trials beyond those we know about today.

The Company ended fiscal 2020 (March 31, 2020) with a cash balance of $9.6 million and 9.4 million shares outstanding. Subsequently in late June 2020, they raised an additional $7.3 million in cash via the sale of 2.7 million common shares at $2.70 per share. As a result of that transaction, current outstanding shares are approximately 12.1 million. At 03/31/20, the Company had approximately 2 million warrants outstanding of which 1.7 million are exercisable at $4.80 per share. The remainders are exercisable at considerably higher prices. We believe the Company should have sufficient cash to carry them through fiscal 2021, although again, new clinical developments could impact cash requirements. Given the recent raise, the Company's current cash position represents roughly ½ of its total market capitalization.

The Company's currently owns 80% of the Exosome Science, Inc., which we believe is responsible for the development of all exosome related endeavors.

There is one other operating item worth noting because it is a question the Company gets asked quite often (we have asked it a number of times over the years), which is, what are the estimated costs of goods sold for the production of a Hemopurifier at scale. They are still not answering that question, however, we do not believe the cost to be particularly prohibitive. For reference, we have always believed the cost to be in the $100 per unit range, but again, that is the result of much speculation amongst some of us who have followed it, so that is conjecture at this point. To that point, we do not believe their ultimate pricing would be based on unit costs, which is perhaps another way of saying we would expect margins on the device to be quite robust. As a point of reference, Gilead Sciences, Inc. (Nasdaq: GILD) recently announced pricing for their Covid19 therapy Remdesivir

at roughly $3,000. We could certainly envision a price tag for Hemopurifier treatments in that range if it proves clinically effective. Incidentally, Gilead has added approximately $16 *billion* in market capitalization since the first of the year. We suspect much of that is related to Remdesivir. The market capitalization of Aethlon Medical is currently under $30 *million*.

Obviously, we will adjust our model as more financial metrics become available.

On the clinical side, the Company has achieved a number of milestones that we think are worth noting. These are excerpted from company collateral, but we have included some additional color to some of these as well :

- *On June 17, 2020, the FDA approved a supplement to the Company's open IDE for the Company's Hemopurifier in viral disease to allow for the testing of the Hemopurifier in patients with SARS-CoV-2/COVID-19 in a New Feasibility Study. That study's plan is to enroll up to 40 subjects at up to 20 centers in the U.S. Subjects will have established laboratory diagnosis of COVID-19, be admitted to an intensive care unit, orICU, and will have acute lung injury and/or severe or life threatening disease among other criteria. Endpoints for this study, in addition to safety, will include reduction in circulating virus as well as clinical outcomes.*

To edify, an "IDE" is an investigational device exemption, which allows the device to be used in a clinical trial so the developer can gather safety and efficacy data. We think this is an important milestone for the Company and represents its most comprehensive viral study to date. We have provided a bit of a precursor to this, which involved a smaller study in HCV (Hepatitis C) patients in 2017. The results of that study demonstrated the safety profile of the device as there were no adverse events associated with those who were treated despite all being markedly compromised by HCV.

- *On October 4, 2019, the FDA approved our Investigational Device Exemption, or IDE, application to initiate an Early Feasibility Study, or EFS, of the Hemopurifier in patients with head and neck cancer in combination with standard of care pembrolizumab (Keytruda). The primary endpoint for the EFS, which will enroll 10 to 12 subjects at a single center, will be safety, with secondary endpoints including measures of exosome clearance and characterization, as well as response and survival rates. This study, which will be conducted at the UPMC Hillman Cancer Center in Pittsburgh, PA, has been approved by the Institutional Review Board, or IRB and is in the process of starting up*.

This marks the Company's first human study aimed at exosome clearing. As with the recent viral IDE, we think this also represents a considerable step forward for Aethlon. The combination study with Keytruda is interesting. Keep in mind, Keytruda, while currently at the forefront of immunotherapies, is typically successful about 20% to 30% of the time depending on the specific cancer/indication. To edify, for a variety of reasons, there are a number of ongoing clinical trials in combination with Keytruda, so this trial is not unique in that sense. Further, patients (up to 12) will receive only 2 Hemopurifier treatments, so we do not necessarily expect any results that the street will see as definitive. Keep in mind, the study endpoint is to measure the capture of exosomes as opposed to really trying to determine the device's impact on patient outcomes. Moreover, this is a "first line" trial, which means that these patients will be receiving Keytruda for the first time. That will make it more difficult to ascertain what impact the Hemopurifier had on patients versus the Keytruda (as opposed to a third or fourth line trial where Keytruda may have already failed initially). On the other hand, we do think positive results could impact FDA support of more as well as more definitive trials. This is a milestone development in our view.

- *On September 12, 2019, the NCI awarded to us a Small Business Innovation Research, or SBIR, Phase II Award Contract, for NIH/NCI Topic 359, entitled "A Device Prototype for Isolation of Melanoma Exosomes for Diagnostics and Treatment Monitoring", referred to as the Award Contract. The Award Contract amount is $1,860,561 and runs for the period from September 16, 2019 through September 15, 2021.*

The work to be performed pursuant to this Award Contract will focus on melanoma exosomes. This work follows from our completion of a Phase I contract for the Topic 359 solicitation that ran from September 2017 through June 2018 (see Phase 1 Melanoma Cancer Contract below). Following on the Phase I work, the deliverables in the Phase II program involve the design and testing of a pre-commercial prototype of a more advanced version of the exosome isolation platform.

We think this grants/awards of this nature provide some validation for and recognition of the Hemopurifier's potential to treat cancer patients. Also, we noted above that Aethlon is a "pre-revenue" company. This is not completely true as we think this grant will generate about $800,000 worth of "revenue" in the current fiscal year. This announcement also dovetails into the following collaboration.

- *In September 2019, we announced that ESI had entered into a collaboration with the Hoag Hospital Presbyterian in Newport Beach, California to identify and characterize potential early disease markers for cancer diagnostics, cancer progression and treatment resistance. The Principal Investigator on this study is Michael Demeure, M.D., program director of Precision Medicine at Hoag. Samples from patients at Hoag will be analyzed by ESI scientists to identify and characterize exosomal "liquid biopsy" markers of cancer incidence and progression. We believe that our recently announced NCI-SBIR Phase II contract to develop a benchtop instrument to isolate and characterize exosomes could substantially expand the capabilities of the ESI programs.*

This provides a potential diagnostic element to Hemopurifier and perhaps an additional oar in the water for the technology. Cancer diagnostics is another growing field of endeavor.

- *On March 13, 2017, we concluded an FDA-approved early feasibility study under an IDE in end stage renal disease patients on dialysis who were infected with HCV. The study was conducted at DaVita MedCenter Dialysis in Houston, Texas. We reported that there were no device-related adverse events in enrolled subjects who met the study inclusion-exclusion criteria. We also reported that an average capture of 154 million copies of HCV (in International Units, I.U.) within the Hemopurifier during four-hour treatments. Prior to this approval, we collected supporting Hemopurifier data through investigational human studies conducted overseas.*

This is the study we referenced above as a precursor of sorts to the current Covid19 trial. The results of this trial were telling in that they demonstrated a clear safety profile (which probably helped with the Covid IDE). However, it also provided positive data in terms of the device's efficacy. Unfortunately, as we noted, curative HCV treatments from other companies were not far behind these results, which negated any reasons for the Company to pursue additional HCV trials.

Management Overview

- ***Timothy C. Rodell, M.D., FCCP - Chief Executive Officer and Director***

Timothy C. Rodell, M.D., FCCP, joined Aethlon in December 2018 as Interim Chief Executive Officer and was appointed Chief Executive Officer in February 2020. Previously Dr. Rodell was President, Chief Executive Officer and a member of the board of directors of GlobeImmune, Inc. from 2002 until 2016 prior to a majority acquisition of the company. He remains a member of the GlobeImmune board of directors.

During his over 30 year career in the biopharma industry, Dr. Rodell has built a wealth of experience in global product development, operations and financing including raising over $300 million in domestic and foreign private and public financings. At GlobeImmune, Dr. Rodell led the company through the advancement of five products from the bench into human clinical trials and closed multiple financings, including an IPO and the

establishment of two major corporate alliances. Prior to GlobeImmune, Dr. Rodell was President and Chief Executive Officer at RxKinetix, Inc. and has held senior management positions at OXIS International, Inc. and Cortech, Inc.

Before moving to industry Dr. Rodell practiced and taught as a faculty member at the University Of Colorado School Of Medicine. Dr. Rodell holds an M.D. from the University of North Carolina at Chapel Hill, is board certified in Internal Medicine and Pulmonary Medicine and is a Fellow of the American College of Chest Physicians.

- ***Charles J. Fisher, Jr., M.D. - Chairman of the Board***

Dr. Fisher, founder & CEO of Margaux Biologics, Inc., is a physician scientist with a distinguished career in both academia and industry spanning over 30 years. Prior to joining industry, Dr. Fisher served as Professor and Head of Critical Care Medicine at The Cleveland Clinic Foundation, and has held professor, division chief and director positions at the University of California at Davis Medical Center, Case Western Reserve University and The Cleveland Clinic Foundation. His research in sepsis, host defense and endothelial dysfunction led to his assisting in the founding of Incyte, and his later recruitment to Eli Lilly & Co, where he led the Xigris (activated Protein C) Global Product Team and successfully registered the first drug approved for the treatment of sepsis. He was recruited to Abbott Laboratories as Vice President for Global Pharmaceutical Development and, among other accomplishments, led the registration of Humira (first fully humanized anti-TNF mab). Other medical firsts include his contributions to the development of, and later approval of, sTNF:fc (Enbrel, 1st soluble anti-TNF tx) and IL-1ra (Kinneret, 1st anti-IL-1 tx). Dr. Fisher has numerous patents and publications to his credit. Prior to founding Margaux Biologics, he was Chief Medical Officer and Executive Vice President of Cardiome Pharma Corp. where he led the team that invented, developed, registered and sold to Merck ($800M) vernakalant, a novel, first in class, multi-ion channel drug for atrial fibrillation (Brinavess).

Additionally, Dr. Fisher is a decorated, multi tour combat veteran, with extensive military experience in special operations. He is a Life Member of the Special Operations Medical Association (SOMA), has served as a member of the Defense Science Research Council and on DARPA panels, including one focused on universal host defense. His unique background of direct patient care, basic and clinical research, on the ground combat experience, and leadership at all levels, has led to an exemplary track record of building teams, delivering results, medical firsts and saving lives.

- ***James B. Frakes - Chief Financial Officer and Senior Vice President – Finance***

Mr. Frakes joined Aethlon Medical in January 2008. He has 27 years of CFO level financial responsibility for publicly traded companies, as well as, specific knowledge and experience in equity (IPO, follow-on public offerings and private placements) and debt transactions, acquisitions, public reporting and Sarbanes-Oxley section 404 internal control requirements.

Mr. Frakes received an MBA from the University of Southern California, and completed his BA with Honors at Stanford University.

- ***Thomas L. Taccini - Vice President, Manufacturing and Product Development***

Mr. Taccini joined Aethlon Medical in May 2020. For the past 35 years he has built and led teams in engineering, project management, manufacturing, quality systems and regulatory affairs for several classes of medical devices. Mr. Taccini has developed medical products for organ preservation, transplantation, diagnostics, IVDs, anesthesia, respiratory and asthma treatment. His expertise incorporates product design in the medical, industrial, military, and commercial arenas.

Mr. Taccini holds a B.S. in Electrical Engineering with honors from Northeastern University.

- ***Annette Marleau, PhD - Senior Director of Research***

An expert in immunology, virology, and cell biology who formerly held academic research positions at the The Scripps Research Institute (La Jolla, CA) and the University of Nebraska Medical Center (Omaha, NE). Dr. Marleau holds a Bachelor's degree in Biomedical Sciences from the University of Waterloo, a Master's degree in Reproductive Immunology from the Ontario Veterinary College at the University of Guelph, and a PhD in Immunology from the University of Western Ontario in Canada.

- ***Lisa M. Boswell - Director, Quality Systems and Regulatory Affairs***

Ms. Boswell has over 15 years of experience in Quality Control, Quality Assurance and Regulatory Affairs in both the biopharmaceutical and medical device industries, most recently as Director, Quality Assurance and Regulatory Affairs at ZOLL Data Systems, Inc. Prior to ZOLL, Ms. Boswell spent 10 years in positions of increasing responsibility in Quality Control at GlobeImmune, Inc. Ms. Boswell holds undergraduate degrees in Chemistry and Biology from St. Andrews Presbyterian College and an M.S. in Engineering Management from Tufts University.

- ***Michael Jacobs - Senior Scientist***

Michael has an extensive and diverse background in medical device product development and process improvement. His previous research has led to multiple publications in various peer-reviewed journals from Elsevier and the Royal Society of Chemistry. Michael holds a Bachelor's degree in Biology and a Master's degree in Biomedical Engineering from the University of Texas at Dallas.

Risks and Caveats

Aethlon Medical is a small undercapitalized Company competing in a healthcare space that is dominated by large well capitalized competitors. Further, given the uniqueness of the product, they also effectively compete with large pharmaceutical manufacturers as well. That is an ominous posture for any small company. Moreover, as we suggested, Covid19 has flooded the virus mitigation industry with companies chasing answers, which has by extension created more competition at least from a research perspective. Actually, we would make the same argument about the cancer space, which is also full of companies researching potential therapies. We know of other companies, private and public that have or are working on blood filters as well although generally for other indications. Similar competitive offerings could also diminish Aethlon's prospects.

We have spent a good portion of this report noting that Aethlon has faced a number of challenges trying to determine and pursue a path towards an FDA approval. In addition, we also covered the FDA approval process above and while we think there are some reasons to believe that the Hemopurifier looks more like a Class II device than a Class III device, we believe it will require the clinical trial path it has started down. That process will almost certainly require more trials beyond those currently on the calendar. Clinical trials are expensive and time consuming, neither of which is typically good for the stock price of small healthcare companies.

As an extension of the FDA approval process, while we have made some assumptions about the Hemopurifier's ability to reduce viral loads as well as exosome counts in compromised patients, we have also noted that neither of those two benefits will necessarily improve outcomes for those same patients. The Company may or may not be able to demonstrate efficacy sufficient to obtain an FDA approval.

The Company has no measurable revenues and is likely to be without any for the foreseeable future. As a result, they will likely be required to raise more capital which they may or may not be able to do. In the best case (they *are* able to continue raising money), the results will likely be more dilution. In that regard, the Company has executed two stock splits over the past five years, a 1:50 reverse in 2015 and a 1:15 reverse in 2019, and each has been markedly negative for the stock price and legacy shareholders. We would add, the expansion of companies searching for answers to Covid19 could dilute the capital available to the space as well.

Ironically, while Covid19 has in our view created an opening for Aethlon in terms of its efforts to develop a clinical trial protocol around their virus technology, the pandemic has created a number of macro risks for many companies that were not on the radar prior to the pandemic. We think certainly some of those apply to Aethlon as well.

The Company relies on a small group of individuals in terms of the management and direction of the Company. The loss of key people in that regard could prove considerably negative.

Aethlon's stock is sometimes thinly traded and often quite volatile. Investors should consider those characteristics in terms of their own risk tolerance, liquidity needs and investment time horizons.

We believe the Company has been diligent about attempting to protect its intellectual property with patents and other related processes. Currently, the Company holds *a portfolio of over 50 issued patents and pending applications worldwide*. Those attempts may or may not protect their intellectual property nor do the ensure that the Company is not infringing on those of others.

These are just some of the risks we have identified with respect to Aethlon Medical. There are likely others we have missed or are not apparent at this time.

Valuation, Summary and Conclusion

To recap some of the above, we have followed Aethlon for a number of years now, and to be honest, over much of that time frame we have generally been frustrated and perplexed by its lack of progress in terms of establishing a commercial avenue around the Hemopurifier. The Company has had a number of successes over the years treating small numbers of patients with some of the worst viruses known to man. Granted, those successes represent small numbers and anecdotal conclusions about the actual impact their treatments had on those patients' outcomes. As we noted with the Ebola patient they treated, there were certainly cogent reasons to believe that treatment with the Hemopurifier helped the patient survive, however, there were also reasons to believe that it may not have. That is why the FDA requires rigorous and broad clinical trials before it allows devices and drugs to be used on the public. As an aside to that notion, the stock had many instances over the years where it traded significantly higher around the prospects presented by some of these results, so it was not like the investment community ignored the information or did not believe it. In our view, the problem has been that the Company has never been able to rationalize, articulate and consummate a clear path to commercialization.

To be fair, the environment has not been particularly conducive to the Company's efforts in that regard. As we noted, given the nature of most of the viral outbreaks the world has endured over the relevant years, the ability to design and conduct bona fide clinical trials has not been practical. We believe the current pandemic, however terrible it may be, has provided an environment where appropriate clinical trials can be conducted around the Company's device as well as other potential treatments from other enterprises that might be able to address this pandemic. In our view, the current pandemic represents a macro level catalyst for Aethlon.

The above said, the difficulty of conducting clinical trials have not been the only roadblock the Company has faced in the past. The current pandemic has exposed the world's lack of preparedness in terms of dealing with

pandemic capable viral pathogens. For instance, we can recall times in the past that we believed the Hemopurifier might find a market among government agencies attempting to stockpile potential therapies *in anticipation* of an event like Covid19. In retrospect, perhaps the lack of clinical data contributed to that reluctance, but given the current circumstances, it seems reasonable to assume that preparing for a *potential* pandemic may not have been as high on the list of priorities as we thought (and others suggested) at the time. Clearly, it is now.

The Company has clinically demonstrated the safety of the Hemopurifier. Further, we believe they have also demonstrated its ability to reduce viral load in infected patients. There have been instances where some have challenged that notion at least in part, because the Hemopurifier has in some cases been used in conjunction with other lifesaving treatments as doctors were trying to save sick people. We accept that it may be difficult to draw conclusions about the sources of reductions in a patients' viral load before and after treatments, but it seems to us that the Company has clearly demonstrated the ability to capture and measure the amount of viruses it collects.

The above said, while it seems reasonable to us to assume that reducing viral loads in sick infected patients should improve their outcomes, we also submit proving *that* requires scientific scrutiny and rigor. However, we would also reiterate something we touched on above in that regard. Much like treating cancer, we believe treating current and future viral outbreaks will likely require multiple therapies and approaches especially on the front end of new outbreaks where the mechanisms and nature of the pathogen are not understood. While vaccines may be the endgame in ultimately eradicating a virus, we know that developing vaccines are time and resource intensives, so other front line answers will be required to keep outbreaks from turning into pandemics and/or killing many citizens before those can be developed. Moreover, we also know (influenza for instance) that vaccines require redevelopment around even known but evolving viruses. In short, a broad and robust viral arsenal will require effective ways to treat people infected prior to the development of vaccines, which by the way, may or may not ever be developed at all. Keep in mind, the first known Ebola outbreak occurred in 1976 however, as the National Institute of Allergy and Infectious Diseases notes, *"**currently there are no licensed vaccines to prevent Ebola virus disease.** However, multiple investigational Ebola vaccines have been tested in numerous clinical trials around the world"*.

We believe the Hemopurifier has demonstrated clinically supported potential to be part of a "broad and robust viral arsenal", and we think the Company's current, albeit relatively small, Covid19 trial they are preparing to conduct will support that view. Obviously, the degree to which that proves accurate or otherwise will likely impact the shares of Aethlon Medical. However, the Company is also in the midst of initiating their clinical trial to assess the Hemopurifier 's ability to reduce exosome levels and perhaps improve outcomes for cancer patients. Further, the Company's majority owned subsidiary Exosome Sciences, Inc. is also studying the influence that exosomes may have on other disease such as Alzheimer's and Chronic Traumatic Encephalopathy, which we believe represents another line in the water for Aethlon's prospects. Succinctly, with multiple indications in the que, we think it is reasonable to argue that Aethlon may represent a value relative to some others in the Covid19 space carrying market capitalizations several times higher than that of Aethlon.

We would add one additional point that we alluded to but did not expand on above, yet we think is highly topical to the current pandemic situation. While the Company could ultimately develop its own delivery system, the Hemopurifier can be/is used with a typical dialysis machine. To put that into perspective, according to their 2019 report, Fresenius Medical Care is *"the world's leading provider of products and services for people with chronic kidney disease"*. That report notes that they *"performed approximately **52 million dialysis treatments in 2019".*** Further, a 2019 Reuters article addressing the growth of home dialysis noted that industry leaders DaVita Inc and Fresenius Medical Care AG, *"operate more than 5,000 U.S. dialysis clinics and control around 70 percent of the market"*.

https://www.reuters.com/article/us-usa-healthcare-dialysis/us-seeks-to-cut-dialysis-costs-with-more-home-care-versus-clinics-idUSKCN1QL0G6#:~:text=The%20changes%20pose%20a%20particular,70%20percent%20of%20the%20market.

Our point here is that there are thousands of dialysis clinics (and associated machines) performing millions of dialysis treatments each year. In the past, some have questioned the scalability of using a medical device solution

to address a pandemic like Covid19. We have actually seen some of that notion play out as potential ventilator shortages loomed over initial Covid19 outbreaks in New York. Given the fact that the Hemopurifier could conceivably be deployed into the existing infrastructure of the dialysis industry, we would argue that it could in fact scale to help address a pandemic.

To be clear, we are microcap generalists so healthcare and/or medical device valuation is not our sole focus. That said, we do not think there is any magic approach to evaluating outcomes with limited visibility and the biopharma/ medical device industry(s) certainly fit in that bucket. However, our approach to the space is not different from our typical approach, which is to assume things like (in this case) future FDA approvals and associated revenues in line with industry metrics (market pricing, patient census etc.) and then discount that with steep rates to address the risks associated with the assumptions. Obviously that approach is burdened by the notion that there are multiple variables that can upend those assumptions, including poor clinical results and/or delays in approvals, changing market opportunities due to competitors getting there first, changing regulatory environments and many others. To translate, valuations and associated targets rely on an array of unknowns so they are not particularly definitive.

In that context our approach to Aethlon's valuation is to assume success in the Covid19 trials(s) that leads to an FDA approval and Hemopurifier sales starting in calendar 2022. In the context of the number of Covd19 infections and hospitalizations, we think we have made modest assumptions about unit sales in that scenario. That approach centers on our notion that treatments will likely involve combinations of therapies and we are assuming that Hemopurifier will simply be one cog in that wheel. We submit, Covid19 may or may not be topical by then, however, even in that case, we would reiterate, we think the device could prove applicable to a broad spectrum of potential viral pathogens, which could provide additional markets especially with a PMA in hand. For instance, while over the years we have received varying opinions from medical professionals regarding the notion, we think the device could prove beneficial to some influenza patients. Moreover, in our view, that broad spectrum status could make it an attractive part of future stockpiling and preparedness protocols that we think are likely to evolve out of the experiences of Covid19.

We have assumed unit pricing in line with the recently published treatment cost of Remdesivir.

Our current valuation is largely based on the viral assumptions we noted here and therefore are not driven by assumed success in exosome studies. Obviously, clinical success in cancer would provide an additional valuation pillar, which we think leaves the story quite open-ended. As we suggested, the Company has multiple potential shots on goal, which may mitigate certain risks. We will monitor future clinical and other data points and adjust our targets and associated valuation metrics accordingly.

We are initiating coverage of Aethlon Medical with an allocation of 4 and a 12-24 month price target of $9.00 per share.

Projected Operating Model

Aethlon Medical Inc.						
Projected Statement of Operations						
Prepared By: Trickle Research LLC						
	(Estimate)	(Estimate)	(Estimate)	(Estimate)	(Estimate)	(Estimate)
	6/30/2020	**9/30/2020**	**12/31/2020**	**3/31/2021**	**Fiscal 2021**	**Fiscal 2022**
REVENUES:						
Grant Revenue	$ 206,636	$ 206,636	$ 206,636	$ 206,636	$ 826,542	$ 413,271
Product Sales	$ -	$ -	$ -	$ -	$ -	$ -
Cost of Sales	$ -	$ -	$ -	$ -	$ -	$ -
Gross Margin	**$ 206,636**	**$ 206,636**	**$ 206,636**	**$ 206,636**	**$ 826,542**	**$ 413,271**
OPERATING COSTS AND EXPENSES						
Professional fees	$ 575,000	$ 581,900	$ 588,883	$ 825,000	$ 2,570,783	$ 3,050,000
Payroll and related expenses	$ 525,000	$ 531,300	$ 537,676	$ 544,128	$ 2,138,103	$ 2,242,594
General and administrative	$ 290,000	$ 293,480	$ 319,000	$ 319,000	$ 1,221,480	$ 1,276,000
Other Operating Expenses	$ -	$ -	$ -	$ -	$ -	$ -
Total operating expenses	$ 1,390,000	$ 1,406,680	$ 1,445,558	$ 1,688,128	**$ 5,930,366**	**$ 6,568,594**
OPERATING LOSS	**$ (1,183,365)**	**$ (1,200,045)**	**$ (1,238,923)**	**$ (1,481,492)**	**$(5,103,824)**	**$ (6,155,323)**
OTHER EXPENSE						
Loss on debt extinguishment	$ -	$ -	$ -	$ -	$ -	$ -
(Gain) on share for warrant exchanges	$ -	$ -	$ -	$ -	$ -	$ -
Interest and other expenses	$ -	$ -	$ -	$ -	$ -	$ -
Other Non-Operating Expenses	$ -	$ -	$ -	$ -	$ -	$ -
Total other expense	$ -	$ -	$ -	$ -	$ -	$ -
NET LOSS BEFORE NONCONTROLLING INTERESTS	**$ (1,183,365)**	**$ (1,200,045)**	**$ (1,238,923)**	**$ (1,481,492)**	**$(5,103,824)**	**$ (6,155,323)**
LOSS ATTRIBUTABLE TO NONCONTROLLING INTERESTS	**$ -**	**$ -**	**$ -**	**$ -**	$ -	$ -
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	**$ (1,183,365)**	**$ (1,200,045)**	**$ (1,238,923)**	**$ (1,481,492)**	$ (5,103,824)	$ (6,155,323)
Basic net loss per share attributable to common stockholders	**$ (0.10)**	**$ (0.10)**	**$ (0.10)**	**$ (0.12)**	**$ (0.42)**	**$ (0.51)**
Basic and diluted net loss per share attributable to common stockholders	**$ (0.10)**	**$ (0.10)**	**$ (0.10)**	**$ (0.12)**	**$ (0.42)**	**$ (0.51)**
Weighted average number of common shares outstanding - basic	**12,067,171**	**12,079,238**	**12,091,317**	**12,103,409**	**12,091,321**	**12,139,759**
Weighted average number of common shares outstanding - basic and diluted	**12,067,171**	**12,079,238**	**12,091,317**	**12,103,409**	**12,091,321**	**12,139,759**

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Portions of this publication excerpted from company filings or other sources are noted in *italics* and referenced throughout the report.

Rating System Overview:

There are no letters in the rating system (Buy, Sell Hold), only numbers. The numbers range from 1 to 10, with 1 representing 1 "investment unit" (for my performance purposes, 1 "investment unit" equals $250) and 10 representing 10 investment units or $2,500. Obviously, a rating of 10 would suggest that I favor the stock (at respective/current levels) more than a stock with a rating of 1. As a guideline, here is a suggestion on how to use the allocation system.

Our belief at Trickle is that the best way to participate in the micro-cap/small cap space is by employing a diversified strategy. In simple terms, that means you are generally best off owning a number of issues rather than just two or three. To that point, our goal is to have at least 20 companies under coverage at any point in time, so let's use that as a guideline. Hypothetically, if you think you would like to commit $25,000 to buying micro-cap stocks, that would assume an investment of $1000 per stock (using the diversification approach we just mentioned, and the 20-stock coverage list we suggested and leaving some room to add to positions around allocation upgrades. We generally start initial coverage stocks with an allocation of 4. Thus, at $1000 invested per stock and a typical starting allocation of 4, your "investment unit" would be the same $250 we used in the example above. Thus, if we initiate a stock at a 4, you might consider putting $1000 into the position ($250 * 4). If we later raise the allocation to 6, you might consider adding two additional units or $500 to the position. If we then reduce the allocation from 6 to 4 you might consider selling whatever number of shares you purchased with 2 of the original 4 investment units. Again, this is just a suggestion as to how you might be able to use the allocation system to manage your portfolio.

For those attached to more traditional rating systems (Buy, Sell, Hold) we would submit the following guidelines.

A Trickle rating of 1 thru 3 would best correspond to a "Speculative Buy" although we would caution that a rating in that range should not assume that the stock is necessarily riskier than a stock with a higher rating. It may carry a lower rating because the stock is trading closer to a price target we are unwilling to raise at that point. This by the way applies to all of our ratings.

A Trickle rating of 4 thru 6 might best (although not perfectly) correspond to a standard "Buy" rating.

A Trickle rating of 7 thru 10 would best correspond to a "Strong Buy" however, ratings at the higher end of that range would indicate something that we deem as quite extraordinary..... an "Extreme Buy" if you will. You will not see a lot of these.