Aethlon Medical, Inc (AEMD)

Company Profile

Description: Aethlon Medical, Inc. (Nasdaq: AEMD-$4.75) Perfect Study Case for the 21st Century "Cures" Act

Late News Notes:

- AEMD just announced that it had successfully completed its FDA-sanctioned, human "safety" trial. Through the Houston, Texas DaVita dialysis center, the Company showed on eight End Stage Renal Disease patients that their Hemopurifier showed no detrimental or harmful effects on these very ill patients as they had their blood "purified" of viral elements.
- AEMD announced on March 14th that their device was able to extract "Tausomes" from patient's bloods indicating the test was able to "point" to these patients—as a potential diagnostic-- as suffering from Alzheimer's. The company's Hemopurifier was used by a study performed by Boston University medical scientists to extract and "test" for Tausomes as a potential indicator of CTE found amongst professional NFL football athletes. The Company extended the trial protocol to include those observed as suffering from Alzheimer's and from these results discovered abnormally high Tausome levels.

Aethlon Medical produces a blood filter that subtracts particles on "biological character" and not size. Imagine a plastic, 2x10-inch canister filled with microscopic straws running the length of the canister and where the straws are coated with a secret "filtration sauce". The patients' blood courses through the device, propelled by an auxiliary pump, and back into the body. The filter is able to separate out certain bad characters from the blood stream and return purified and treated blood back to the patient, reducing the overall load of disease the patient's own body has to defend against. This is accomplished--an interesting discovery of Aethlon itself and also the bane of the its existence because the company as to prove this miracle to the scientific world—because the bad characters coat themselves with a certain telltale glycol-protein that the secret sauce expresses a very strong affinity to. So, the canister pulls out the bad characters like a magnet--subtracting out iron filings from a mixture of floor scraps and shavings—if you will…leaving other good things still in the blood.

One primary target for the filter is viruses (we believe all of the 300+ viruses that can be found in nature and many of which being passed on to humans which typically have a deleterious effect on our health). As such, the device behaves similarly to the patient's own liver, seeking out and ridding the body of these viruses, and does so without adding any chemical toxicity or having any deleterious side effect upon the patient's wellbeing. It has been demonstrated to have significant effectiveness in vitro, subtracting HIV; Dengue fever; Marburg fever; bird, swine, and Spanish flus; monkey pox (the analogue disease to small pox) and other virus from blood. In humans, there have been successful demonstrations of filtering-out HIV, Hepatitis C, Dengue fever and Zaire Ebola.

This wonder device is just now beginning to be discovered since the Hemopurifier was one of Time Magazine's, top-25 scientific advances of 2014, as well as one of the same magazine's top-11 medical advances for that same year.

Just this last year (and announced its completion on March 12, 2017), the company initiated its first USA-based, FDA-approved, human trial to demonstrate safety in use of the device when treating patients for any or all of the above viral diseases. The trial specifically is demonstrating its safety when treating end-stage renal disease, Hepatitis C patients.

Now, the company's management and FDA face a particularly critical and complex decision tree as to which pathway to market should be followed. There exist three routes the company/FDA could pursue regarding a path to commercialization: 1) The 21st Century "Cures" Act passed by Congress last December 'allows for the commercialization of a device if it is shown to be not a risk to a patient and has demonstrated to be beneficial in treating a patient expressing a certain disease using alternative study research and where there is no alternative drug or device therapy that is available.' Given the number of treated patients (20 with HepC, 1 with HIV and 1 with Ebola) showing significant benefit, the Hemopurifier would appear to be a perfect model to test the new Act with the Agency.

Separately, since the device has been publicized as a viable therapy against Class A pandemic diseases, this essentially provides a road-block to further human testing. To pass as an 'approved' device, the proponent company has to demonstrate safety (which Aethlon has just done to the FDAs satisfaction) and now must show "trial efficacy". But, that is practically and humanely impossible. To do so, the company would have to infect subjects with a deadly disease where there is no known cure and then go ahead and prove that the device would be effective in combating said virus. How acceptable do you think it would be for the Agency to allow the infection of 100 to 300 patients with Ebola just to let AEMD test the Hemopurifier on them. That is an end-point before it gets started. But as we disclosed above, outside, US Governmental and independent contractors have already tested the device *in vitro* on an array of Class A viral diseased blood. The company has shown human efficacy on three diseases (two Class A threats) with considerable success. Safety. Since the device works outside the body—the appropriate term here is "extracorporeal", there should be no fear of toxicity, drug-drug interactions, or other "drug-like" negative effects.

This is where it gets really interesting. If the Hemopurifier was a drug candidate, it would be "passed" for use against Class A pathogens. (Drugs for such diseases and/or radiation sickness only need to pass a two "animal rule" and a safety study. With AEMD's Hemopurifier, they have had two animals—mice and "ah," Humans. They have also proven it to be "safe."

There is another little opportunity that could raise it head. The US Government is basically10 years and $50 billion behind in what the "BioShield" legislation created and projected in 2006/2007. There are really only a couple of vaccines that have been approved and stockpiled since its formation and launch. The Hemopurifier should be the perfect contender since it acts as a "broad-spectrum, single-use removal device for viral pathogens." Incidentally, it has a longer shelf-life than vaccines and can work on mutates viral pathogens as well as "new" zoonotic pathogens that have been transferred from the animal kingdom to man. This means HHS, in its effort to catch up BioShield via PHEMCE (Public Health Emergency Medical Countermeasures Enterprise) mandate of 2016 could procure 50,000, 500,0000, maybe 5 million Hemopurifiers to supply emergency countermeasure and pandemic emergency treatment facilities around the country just to fulfill requirements.

Management owns 10%

Institutions own 26%

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