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Aethlon Medical (AEMD-NASDAQ)

Focus on Oncology Studies; In Vitro Binding Study Expected to Advance Clinical Trial Activities

Research Note

Moving forward towards oncology clinical studies in India & Australia

Aethlon Medical (NASDAQ: AEMD) reported 3Q F24 results yesterday and provided a business update, as the company continues to advance research and clinical development activities for medical device, the Hemopurifier®. Under interim CEO James Frakes, the company's long-standing CFO, AEMD has increased its focus on advancing the Hemopurifier as a potential treatment in oncology. We present key takeaways in this note.

Takeaways from Business Update

- Focus is on advancing Hemopurifier as a potential treatment in oncology area
- In advance of clinical trials, AEMD will pursue an in vitro binding study of relevant oncology targets
- AEMD optimistic - Hemopurifier has produced positive data in prior in vitro studies
- R&D spending expected to go further in Australia & India
- Existing COVID-19 trial in India remains open for enrollments, depending on severe COVID cases
- Pre-clinical proof of concept data of Hemopurifier in organ transplantation will lead to publication of article(s)
- Benefits of cost containment efforts obscured in 3Q F24 by non-recurring costs related to former CEO
- Cash ~$8.0m, no debt & ATM for enhanced financial flexibility

Immunotherapy helps many, but not most; AEMD hypothesis is that combined Hemopurifier / Immunotherapy treatment can improve outcomes for a higher percent of patients….

In October 2023, AEMD received clearance from the Drug Controller General of India (DCGI) to conduct a phase 1 safety, feasibility and dose-finding trial of the Hemopurifier in patients with solid tumors who have stable or progressive disease during anti-PD-1 monotherapy treatment such as Keytruda® or Opdivo®. PD-1 (Programmed cell death protein 1), is a protein found on the cell surface that plays a role in inhibiting immune responses. Treatment such as Keytruda®, a type of immunotherapy, helps to block the PD-1 pathway to prevent cancer cells from hiding and, in turn, help the immune system work. While Keytruda® and other anti-PD-1 monotherapy treatments represent a substantial advance in cancer treatment, with certain tumor types it does not work on the majority of cancer patients.

For example, according to NIH, "Pembrolizumab (Keytruda® is the brand name) has provided a new first-line option for patients with advanced NSCLC (Non-Small Cell Lung Cancer) and patients can achieve sustained remission once they respond to it, but less than 30% of patients will respond to pembrolizumab." That means that the majority of patients do not respond to checkpoint inhibitors. Aethlon's hypothesis is that using the Hemopurifier in conjunction with treatment of checkpoint inhibitors can increase the percent of patients who can benefit from combined treatment.

…An in vitro study first…

In advance of the trial, AEMD will pursue an *in vitro* binding study of relevant targets. Prior *in vitro* studies have documented that the Hemopurifier® captures exosomes underlying various types of cancer. This particular in vitro

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study will specifically evaluate the Hemopurifier against PD-1 proteins. The company expects the Hemopurifier, in conjunction with an inhibitor, can help improve overall patient outcomes and demonstrate proof of concept about the device's benefits in treating solid tumors.

AEMD's aim is to quantify the Hemopurifier's potential impact on plasma from cancer patients that have been treated with anti-PD-1 monotherapy treatment in order to provide pre-clinical evidence to support the design of the planned clinical trial. Data from the in vitro study will then be presented to the Ethics Boards of sites in India interested in participating in the clinical study. We would expect to see in vitro data by 2Q calendar 2024.

Hemopurifier has produced positive data in prior in vitro studies…

The Aethlon Hemopurifier® is a therapeutic blood filtration system that can bind and remove harmful exosomes and life-threatening viruses from blood. The device, which has received FDA *Breakthrough Device* designations, is a cylindrical cartridge encased with hollow fibers and affinity (i.e. - lectin protein that can bind any particle, virus or exosome, that has mannose sugars on its surface membrane) binding agents. The device is used on existing blood circulatory equipment such as dialysis and CRRT machines that are already installed in hospitals and clinics. This makes the Hemopurifier essentially a plug & play device that can be leveraged easily. The Hemopurifier is designed to aid the body's ability to fight disease by removing viruses and other injurious substances from the blood. After the blood is cleansed, it is then returned to the bloodstream.

The Hemopurifier has demonstrated effectiveness against multiple indications in previous in vitro studies and the company believes the Hemopurifier has potential applications in cancer, where cancer associated exosomes may promote immune suppression and metastasis, as well as in life-threatening infectious diseases, including removal of COVID-19 virus, associated variants, and related exosomes. Data from previous pre-clinical efforts, clinical trials, in vitro studies and single use emergency cases support multiple benefit of the Hemopurifier.



Source: Company presentation

If in vitro study demonstrates Hemopurifier benefits, AEMD will move forward with clinical efforts

If the in vitro study demonstrates that the Hemopurifier can remove harmful exosomes from a cancer patient's blood – and potentially improve patient outcomes – AEMD is optimistic that it will attain approval to move forward with clinical efforts. The in vitro binding study is complex and at this early stage, the company has relatively limited internal resources. AEMD therefore has engaged third-party laboratories to perform independent assays on the samples. Concurrently, AEMD's R&D group will continue to pursue and refine their analysis. Including independent laboratories likely shortens the time before clinical studies can begin, if the in vitro data warrants moving forward, and is likely to reinforce proof of concept.

The company has a strong clinical working relationship with Medanta Medicity Hospital in Delhi, India, which is currently participating in a study of the Hemopurifier in COVID patients (see below) and it would not surprise us if Medanta Medicity Hospital had interest in participating in the study. In addition to two venues in India, AEMD also has two interested sites in Australia that are waiting the data from the upcoming in vitro binding study.

R&D spending expected to go further in Australia & India

Moving ahead with clinical activities in Australia and India initially aligned with the company's cost containment goals, as clinical R&D expenses are substantially lower in these markets. AEMD expects to realize benefits from attractive economic incentives the Australian government provides for clinical development efforts. In India, R&D expenses are substantially lower than in the U.S., according to management. Australia offers an R&D tax incentives rebate program, which enables companies to receive a tax rebate of up to 43.5% on clinical trial related R&D costs and is expected to help it reduce costs, lower risk, and accelerate time to market.

… and maintaining COVID study in India…

While AEMD's primary focus is on studying the Hemopurifier as an oncology treatment, the company had established a COVID-19 trial in India. The COVID-19 trial in India remains open and intends to maintain the study depending on patient enrollments. The company has two sites participating in this trial -- the Medanta Medicity Hospital, as noted, and Maulana Azad Medical College, or MAMC. One patient has been treated thus far. A new COVID-19 subvariant has recently been detected in India. This might have an impact on patient enrollments, if there are COVID-19 admissions to the intensive care units at the two participating sites.

… with plans to publish an article about Hemopurifier for organ transplants …

Aethlon has generated data from preliminary efforts to investigate the Hemopurifier's ability to remove viruses and exosomes from harvested organs to increase the number of organs that can be transplanted successfully. In vitro studies using a scaled-down version of the Hemopurifier demonstrated the removal of multiple viruses and exosomes from buffer solutions. The company disclosed interesting pre-clinical proof of concept data of the Hemopurifier in organ transplantation over the past few months.

AEMD intends to submit one or more articles for publication on the pre-clinical data. We would not anticipate additional efforts at this point, as AEMD focuses on oncology, but down the road, if / when the oncology clinical efforts are further along, it would not surprise us if this become an area where AEMD allocates time and investment to position the Hemopurifier as an additive way to increase the supply of viable organs available to be transplanted. The company believes that if the Hemopurifier can remove these substances from the organs, the device could lower the risk of complications following transplantation, including potentially viral infection, delayed graft function and organ rejection.

Benefits of cost cutting efforts likely to be clearer in subsequent quarters…

AEMD has also increased its focus on containing costs. The benefits of these efforts were partially obscured in 3Q F24, reflecting non-recurring costs associated with the departure of the former CEO. Operating expenses in 3Q F24 of about $3.6 million were up compared to $2.8 million in the prior year comparable period, but much of this related to separation charges for the company's former CEO. Payroll and related expenses increased by roughly $871,000 primarily due to separation expenses for AEMD's former chief executive officer of $873,000, plus increased salary expense of $81,000 associated with an increase in average headcount. The expense related to severance for the former CEO was non-cash. It included $393,139 of stock based compensation for the acceleration of vesting of his options and accrual for upcoming monthly severance payments.

The above-noted increases were partially offset by lower G&A expense (~$92,000), professional fees (~$61,000) and stock-based compensation ($83,000). AEMD recorded a net loss of $3.6 million compared to a net loss of $2.8 million in 3Q F23.

Aethlon had a cash balance of approximately $8.0 million as of December 31, 2023 to further its clinical activities and no debt. AEMD has an ATM (At The Market offering) in place for enhanced financial flexibility. The company believes the cash balance is sufficient to support operations for about a year, including usings its ATM facility from time to time depending on market conditions.

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