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MODERATOR: Welcome back, everyone. Next, we have Aethlon Medical incorporated. It trades on the NASDAQ under the symbol AEMD and is a medical therapeutic company focused on developing the Hemopurifier, a clinical stage immunotherapy therapeutic device which is designed to combat cancer and life threatening viral infections and for use in organ transplants.

Today, we'll be speaking with CEO and CFO, Jim Frakes, but we're going to first start with a video introduction. Roll it.

JIM FRAKES: Thank you, Anna, and thanks to the audience for taking time out of their busy days to listen to our presentation and to learn a little bit about our company, Aethlon Medical. My is Jim Frakes. I'm the chief executive officer and chief financial officer of Aethlon Medical. And I'm joined by Dr. Stephen LaRosa our chief medical officer. We'll go through our presentation now.

Here is our forward looking statement. You can read this at your convenience. Investment highlights. We're developing a novel patented device called the Aethlon Hemopurifier. It's a blood purification device. Early clinical trials have demonstrated viral and extracellular vesicle clearance, both in vitro and in patients. Steve will talk more about extracellular vesicles during his portion of this presentation.

We have two FDA breakthrough device designations for the treatment of individuals with advanced or metastatic cancer and for the treatment of life threatening viruses that are not addressed with approved therapies.

We're focused on multiple therapeutic targets in cancer and viral disease. We have a clinical trial going on in Australia and being initiated in India, that Steve will talk about shortly. We have a broad patent portfolio and an experienced management team.

So I slide difficulty, sir. Here's a picture of the Aethlon Hemopurifier, again, designated-- FDA designated breakthrough device and viral and oncology indications. It's been safely administered in 165 sessions in 39 patients. Its proprietary patented technology.

We've demonstrated clearance of life threatening viruses and is designed to clear tumor derived EVs or extracellular vesicles and their associated cargo, which is applicable, especially in oncology. And now, I'll turn the presentation over to Dr. LaRosa if I can deal with the slides here. Go ahead, Steve.

STEVEN LAROSA: So I'd like to go over just briefly how the device works. The Hemopurifier. It's a combination of plasma separation, size exclusion, and affinity binding of viruses and extracellular vesicles. The patient has a double lumen vascular catheter that's typically used to in dialysis, inserted into a large vein.

Blood is pumped via dialysis machine to the device. It enters the lumen of the device, which is a series of hollow fibers where all the cellular elements remain, but the plasma is pumped through the pores in the fibers, which have a 200 to 500 nanometer diameter.

So plasma with molecules smaller than that traverse into the space outside the fibers where our proprietary affinity resin resides. This resin is composed of a plant lectin called GNA with diatomaceous Earth and GNA binds mannose substances. So a type of sugar that's found in the outer coating of viruses and extracellular vesicles produced by cells.

These viruses and with mannose on their surface envelope and extracellular vesicles bind to the resin and are removed from the plasma. The plasma traverses the cartridge, goes back into the lumen to rejoin the cellular elements, and the blood is returned to the patient. Next slide.

This slide is our clinical pipeline. The company has its roots in virology and our early studies before the advent of effective drugs were done in HIV and hepatitis C. We've also done emergency use and had a clinical trial in COVID and have performed emergency use in Ebola virus as well.

Our current efforts focus on oncology, specifically a solid tumors that are failing anti-PD-1 therapies such as Keytruda and Opdivo. As Jim mentioned, we have a trial that is recruiting in Australia and a clinical trial that's going to be initiated in India. We've also done some preclinical work in kidney transplantation and we're currently doing some preclinical work in long COVID, which I'll talk about later.

So let's start first with oncology. So we mentioned tumor derived extracellular vesicles and extracellular vesicles have been implicated in the spread of cancers and also resistance to immunotherapy drugs.

So we actually did in vitro studies. And we have some in vivo experience that shows that we can remove cancer derived drives with our Hemopurifier technology. So just briefly to go over in vitro studies.

Our first study, we actually got plasma samples from a number of tumor types, a number of different patients. The extracellular vesicles were isolated and put in a buffer and run over a miniature version of our device. And regardless of the tumor type, we removed 92% to 99% of buffer suspended tumor derived extracellular vesicles.

We then thought it was important to demonstrate direct removal of EVs from plasma. So not in buffer by our device. And so we received a patient sample from a patient with non-small cell lung cancer and ran the plasma directly over a miniature version of the device and showed that we effectively removed extracellular vesicles.

We also have some single patient experience in both severe COVID and in head and neck cancer in a patient who was treated under emergency use with severe COVID. They had eight different chemo treatments over the course of 10 days and we were able to demonstrate decreases in total exosome concentrations over the course of those treatments. And that data was published in Frontiers in medicine.

Additionally, from our US head and neck cancer study, we had a single patient who got two Hemopurifier treatments approximately 21 days apart and we were able to show decreases in total lead concentrations following each of those treatments. So that was the basis behind going into the clinical trial, which I'll now talk about.

So we have an ongoing trial that's enrolling recruiting in Australia. It's a safety, feasibility, and dose finding clinical trial in patients with stable or progressive malignancies, solid tumors following a two month run in period of either pembrolizumab or nivolumab.

We have III clinical sites open as of tomorrow. III clinical sites that will be recruiting. Two patients, of those three that were enrolled were withdrawn prior to the purifier treatment phase because one patient had a response to the anti-PD-1 therapy. Another patient had immune related adverse event due to the anti-PD-1 therapy, so those people do not progress to the Hemopurifier phase of the study.

A third patient who did not respond to their anti-PD-1 therapy, was treated with the Hemopurifier. So our first patient treated in this trial on January 29, 2025. This patient received the full four hour Hemopurifier treatment without any device deficiencies and no immediate complications. They were brought back at their pre-specified seven day safety follow up period and at that time did not have any clinically significant changes in lab data or adverse events, noted.

Our next steps in this trial is to enroll all three patients in this first treatment cohort. That data will then be sent to an independent data safety monitoring board, who will rule on advancing to the second cohort, where patients will receive two treatments during a given week.

Additionally, once we have all three patients in this cohort completed, our central our central laboratory will provide data on the removal of extracellular vesicles following the Hemopurifier treatment. As well as changes in anti-tumor CD8 T cell numbers following treatment. So that would be the next-- those would be the next bits of news that you'd expect from this trial. Next slide.

Additionally, following the initiation of the trial, our investigators made some suggestions that they believe could possibly increase patient enrollment shorten the time to patients receiving Hemopurifier for treatment and shorten the time to read out of EV and T cell data.

The changes they recommended included enrolling patients with a demonstrated lack of improvement of anti-PD-1 therapy from the beginning. So there would be no need to identify patients who are just starting anti-PD-1 therapy as is current-- as is in the initial protocol. And no need to wait for the two month run in period with its associated dropouts that I mentioned.

They also recommended removal of some prohibited concomitant meds that would not have no effect on the patient safety of the patients participating in the trial. And the allowance for all possible dosing strategies of pembrolizumab and nivolumab.

All these changes were incorporated into a protocol Amendment and this protocol Amendment has now been approved by all the ethics committees and research governance offices at all III clinical sites. And all three sites will recruit-- will be recruiting under this protocol Amendment as of the 14 of February.

Switching gears now to virology, which is, as I mentioned, it was really the roots, the beginnings of this company. I'll mention some important topics. So envelope love viruses contain the sugar mannose that I mentioned earlier. That is the target for our proprietary GNA affinity resin and our Hemopurifier.

And Aethlon to date has amassed a catalog of in vitro binding data for envelope viruses, including three that have had a lot of recent interest. You're probably well aware of the news regarding H5N1, known as the bird flu. There are 68 confirmed cases and one death in the US per the CDC.

Marburg virus, which is a hemorrhagic fever virus, has been an outbreak with nine cases and eight deaths in Tanzania. And finally, there's been a recent Ebola outbreak in Kampala, Uganda, with seven cases confirmed by the WHO.

And here's just some in vitro data on those topics, so on the left hand side of the slide is in vitro binding data where H5N1 bird flu was put in cell culture fluid and run over the a miniature version of the Hemopurifier. And this was done by Battelle Memorial labs and within six hours of running over the Hemopurifier, 99% of the virus was removed.

On the right side of the slide is some data that was performed by Koch and colleagues at Goethe University in Frankfurt, where they took Marburg virus again in cell culture media, ran it over our miniature version of our Hemopurifier and had a 50% to 70% reduction in Marburg virus in three hours.

We also had in vitro data in Ebola and have previously published a case where a 38-year-old physician who developed severe disease from Ebola, including multi-organ failure, was treated under emergency use with a single Hemopurifier treatment.

And on the left hand side of the slide, you can see where the patient's Ebola viral load in their blood started and how quickly it dropped even within 30 minutes. And it stayed persistently down following the Hemopurifier treatment. And this patient, despite having multi-organ system failure, went on to have clinical improvement and discharge. this was published in 2014.

Additionally, we're doing some work right now in long COVID in the preclinical area. Long COVID, just from a definition perspective, is people who have persistence of symptoms at least three months following their acute infection with the SARS-CoV-2 virus.

A CDC estimates that between 6% to 7% of the general population suffers from long COVID. And the global incidence is estimated to be approximately 400 million, with an economic burden of about $1 trillion per year.

There have been publications that demonstrate extracellular vesicles, including those containing the COVID spike protein, have been implicated in the pathogenesis of the long COVID symptoms.

With that in mind, Aethlon applied for and received patient samples from the long COVID cohort known as Linc at the University of California, San Francisco. And the lab is currently determining if our proprietary gene affinity resin that's in our Hemopurifier removes extracellular vesicles from these patient samples. I'll turn it over to Jim to discuss the patent portfolio.

JIM FRAKES: Thank you, Steve. We have a broad patent portfolio, both in the United States and internationally. And we continue to apply for additional patents as we make further discoveries.

We believe we have an experienced management team. You're seeing two of the members. Also, John Nguyen, our vice president of manufacturing has 25 years of biotech manufacturing experience.

Some key financial highlights. As of December 31, we had approximately $4.8 million of cash. We have no debt of any sort on our balance sheet. As of February 10, we had approximately $14.5 million shares outstanding and our market cap also as of February 10, was approximately $9.4 million, and we trade on the NASDAQ under the ticker AEMD. That concludes our presentation and I'm happy to take questions with you, Anna. Thank you.

MODERATOR: For that, let's jump in with a few questions. Talk a little bit about how the treatment went for the first oncology patient in Australia. Break that down for us.

JIM FRAKES: Yeah. I'm pleased to disclose that it went quite well. We actually watched the four hour treatment, adding on time before and after. We were probably on a long distance Zoom call in a room in a hospital in Australia for six plus hours.

Because of their version of HIPAA, we could not see the patient, but we watched the pumping equipment, the dialysis equipment, and our cartridge and noted all the readings of the various meters on the machines and there were no issues.

The patient seemed as content as you can be after sitting in a chair, hooked up to a dialysis machine for 4 plus hours. And then as we noted in the presentation, we had the standard seven day safety checkup, the follow up and everything was good, no issues.

And we're anxiously awaiting to treatments of two more patients. So we will have finished. Then the first cohort of three that will have had one treatment each. And then we'll process all the plasma from those patients and get some readouts on reductions in extracellular vesicles. We used to call them exosomes and also on changes in their T cells, which was particularly interesting to me.

So that was a great start to the trial. It can only help the enthusiasm of the other PIS. We completed our site investigation meeting training at our third hospital, which is in Sydney, a large city, of course, in Australia, large population to-- I mean, regrettably, people get cancer.

And there should be a large pool of potential patients there in Sydney. That hospital is affiliated with the University of Sydney, by the way which is where we're doing our lab work on these patients as well.

MODERATOR: And talk a little bit about the change in the Australian protocol for enrolling patients. Explain that, if you will.

JIM FRAKES: Thank you for that question. The original protocol, which was developed with the help of some oncologists here in the US and in Australia was to measure those various markers. I just described EVs, extracellular vesicles, and T cells for two months.

Before they started there, the patients started their Opdivo or Keytruda treatments and see how they progress for two months. And if they did not improve, if they either stayed, that the tumor stayed the same or got worse, then they were eligible to go on to the treatment phase with our Hemopurifier.

The PIS in Australia, during the training that we conducted a few months ago, they said they had thought about it and really it would be better just to get rid of that two month run in period, we call it. And just when the patients have failed through Opdivo slash Keytruda treatments, then there they can go on to the treatment.

So personally, I like it's the run in periods confusing and patients fall out like we had two fall out of three patients we had signed up. One improved, good for that patient, certainly. The other one had a bad reaction to the his or her Keytruda slash Opdivo treatment.

So the one out of three is very statistically valid. That's about how many the percentage that actually improve with those very important drugs. So the two month period is gone. All the concomitant Med issues are gone. So it just will make recruitment hopefully much easier and faster and a little less expensive because of the various tests over that two month period, are not necessary anymore.

MODERATOR: And so-- yeah, thank you. Yeah. Well, what has happened since then? And how have your efforts gone in the reductions in your expenses and December quarter if you can talk some financials?

JIM FRAKES: Sure, sure. Well, we ended December with $4.8 million of cash. Again, no debt on our balance sheet of any sort. We actually reduced our expenses by 50% on that. It went down from $3.6 million to $1.8. That's a bit misleading. The 3.6 in the December 2023 quater included a severance charge for the prior CEO. Much of that was non-cash acceleration of stock options.

But nonetheless, there were real significant large expense reductions. And as you may recall, when I became CEO, I told the board and the public I was going to focus the company on oncology and try to reduce expenses in order to lengthen our runway to achieve something on the oncology front.

So I'm very pleased. We know expenses will rise as the trial continues. In fact, our 300,000-- there was a $300,000 increase related to the clinical trial expenses in the G&A, general and administrative expense line.

So that 50% reduction even included that 300,000. So it was actually more than 50% if you look at it that way. So all the slashing and burning I've been doing for the last year really showed. And I think we've set the stage for some good things going forward.

MODERATOR: Well, with that said, our viewer Marshall says it doesn't seem like you're getting a realistic value in the market based on the technology you have. So how are you keeping up with the burn and this economic environment? And what are your thoughts on that?

JIM FRAKES: Well, I guess I'm not supposed to comment on my personal opinion of her market cap, but I just think the company's been around a long time. It's tried various things over the years.

I like to use this analogy and I might have used it on you before, and if so, I apologize. But I described us as being like firemen. We're sitting in a fire station waiting for a viral outbreak and our product has great relevance to the viral issues. But it's not a vaccine. It's like a first line of response until vaccines are developed.

So we burned a lot of cash and a lot of time elapsed waiting to help with viruses. So that's why I focus so much on oncology because it's real. Viruses are real too, but they come and go. And cancer is just there. It's a massive problem. It's a dire situation for the poor patients.

So we can-- it's a real market we can plunge into. So I just think we need to rack up some more patients and most importantly, show some data. I think that data readouts, which hopefully will be in the June quarter, will be key. That's a key milestone for us.

Like all small cap companies, they don't have approved products. We have no revenues. Therefore, we'll have to raise money sooner or later. We've been fortunate. We have some cash, we have a clean balance sheet. And I think part of our market cap is people know we will need to keep raising money. But that's why all these investment banks focus on the micro cap life science market, because they're continually raising money. It's a great market for them.

So Yes, it's public information, we will need to raise more money. So that the fact we need to raise money could be a positive or a negative. It could be a positive when we raise it or better capitalized. But people can say, oh, dilution is coming. So that argument works both directions.

MODERATOR: Well, Frank asks, is there anything like your Hemopurifier in the market currently? What's the closest competitive solution?

JIM FRAKES: There are several extracorporeal devices. Cytosorbents, public company in New Jersey removes inflammatory markers. Different technology, different mechanism of action. Probably the closest one is Xterra's product, which is a privately held company.

They've done some good work in COVID and they're working on cancer. But again, different product, different mechanism of action. So that's probably the closest is a privately held company we're friendly with them. So other than those two, nothing else is even close.

MODERATOR: And Sabrina asks what type of approvals are required for such devices?

JIM FRAKES: Well, it's a medical device. So in most countries, including the US, it's a 2-step process. You do a safety trial like the ones we're doing in Australia and India and then you have a somewhat larger efficacy trial to show that it actually can be helpful.

So they're much smaller in size than in drug trials. For instance, 10 to 12 patients in a safety trial is typical. The efficacy trial will be larger, but I don't-- It's not going to be thousands like a drug trial. So shorter, less expensive. That's one thing that's always attracted me to the medical device end of the market.

MODERATOR: Absolutely. And so Carli asks, with regard to your COVID studies in India, are you moving to treat all similar viruses with this technology?

JIM FRAKES: We actually concluded that we should stop doing that trial. We were burning-- there were some expenses associated with it and there were just no patients in the ICUs in India, just like there haven't been any in the US.

So we actually stopped that. Our main focus in India, like in the US, is in oncology. And we have a very similar trial ready to launch. We're just working on some import export stuff with the bureaucracy in India right now.

We are working on long COVID. We've had some samples from the University of California, San Francisco, as Steve mentioned just a few minutes ago. And our lab is measuring our device and the levels of EVs in those long COVID samples and how our device can play.

So there's no therapeutic solution for long COVID. It's troubling for many, many people. So it's out there. We're-- I've pushed the work on those samples aside while we focused on oncology.

But now that everything's teed up for oncology, the lab is all set in Australia to test this oncology plasma samples. I've turned the lab back on to the long COVID samples, which are very precious to us.

MODERATOR: Yeah. Jim, last question from Brendan. What's the next big trial and results that the viewers should expect?

JIM FRAKES: I would say the next set of results will be for this first cohort of three patients that have been treated once, like the patient that was just treated at the end of January. We need two more. We'll amass that data and make it public. So our hope is that will happen during the June quarter. But sometimes things slide. But we're one third of the way there.

MODERATOR: Wonderful. Well, thank you so much for this update. We really appreciate it. And we look forward to seeing you again real soon.

JIM FRAKES: Great. Thank you, Anna, and thanks, everybody, for taking time out of your busy days to follow our company.

MODERATOR: Wonderful. Thank you, Jim. Thank you, everyone. We'll be right back.