[MUSIC PLAYING]

ANTHONY VENDETTI: OK, good afternoon, everyone. For those of you that are just joining us, today is day one of our three-day Virtual Health Conference. I'm Anthony Vendetti, the Director of Research at Maxim Group.

Like I said, today is day one of the conference. We're hosting over 85 public companies. And with the vast majority of these 25, 30-minute webinars hosted by the CEOs of the companies, and we also have three panel discussions over the three days, which conclude this Thursday, October 17. So with that, I'm going to turn it over to Jim Frakes, who's the CEO and CFO of Aethlon Medical. Symbol is AEMD. And Jim will give us about a five or six-minute update on the company, and we'll turn it over to 20 minutes of questions from you, the audience, as well as questions that I have prepared.

So with that, Jim, take it away.

JIM FRAKES: Thank you, Anthony, and thanks for inviting us to participate in your conference. I like your format quite a bit. So my name is Jim Frakes. I'm the longtime CFO and now CEO of Aethlon Medical.

We're a small medical device company based in San Diego, California. Our product is the Aethlon Hemopurifier, which is a-- it fits on blood pumping equipment such as dialysis machines or Continuous Renal Replacement Therapy machines, CRRT, which are in hospitals and clinics worldwide and is designed to remove viral particles and cancerous particles called extracellular vesicles or exosomes from the bloodstream.

So an ill patient is hooked up to a pumping machine, and their blood runs through this device over, say, a four to six hour period, and every pass of the blood through the device removes viral particles and/or exosomes from their plasma. So it's a single use device. We have about 150 treatments with humans and about 36 patients.

Our main focus since I became CEO is on our oncology program. It's designed to treat patients with solid tumors that are failing anti-PD-1 therapy, such as Keytruda or Opdivo. We've signed up with three hospitals in Australia and one hospital in India. We've received ethics board approval for those hospitals. Our clinical ops team is actually in Australia right now training the hospitals.

Steve LoRosa, our Chief Medical Officer, has been posting on the company's LinkedIn page and his LinkedIn page some pictures and commentary. So it seems to be going quite well and they're beginning to recruit the patient recruitment process. So this is very exciting for our little company. So potentially quite a large market.

Right now, 30% to 40% of all cancer patients that are on Keytruda or Opdivo do not-- they're basically failed the program. I mean, it's great for the 30% to 40% that where it works. So almost a miracle. But regrettably, the majority do not receive a benefit from those treatments. So our hypothesis is by using this device for the patients that want to sign up for the clinical trial, by removing exosomes extracellular vesicles, as they're more commonly known now, we remove the EVs that block that are deploying the Keytruda or Opdivo away, and our hope is for those patients that are participating, they have a chance of responding to the immune checkpoint therapy.

It's potentially quite a large market. Keytruda has 40 approved US cancer indications their own literature says they could reach 2 million patients worldwide by the end of this year. And assuming 60% to 70% do not respond, that's a potential market not promising anything, but it's the potential market of 1.2 to 1.4 million patients that if this works, we could help a lot of people and hopefully our shareholders along the way.

And right now, 43% of cancer patients are eligible for immune checkpoint inhibitor therapy. So there is a payment stream for those excellent drugs that work for, unfortunately, a minority of people. So that's our primary focus since I became CEO last November, I've also reduced the burn rate from about, 3 million a quarter to 2 million a quarter, to give us a longer runway to execute on this.

So it's an exciting time for our little company. You can see, again, some of these, the commentary and some pictures on our LinkedIn page, or Steve LoRosa, our Chief Medical Officer's LinkedIn page with some real time commentary and pictures of the hospitals and the staff that will employ this device. That's a very high-level view, Anthony. Probably went too fast.

ANTHONY VENDETTI: No, no. That's good. That's actually just the right amount of time and a good time for me jump in here. So as you were mentioning, Jim, the checkpoint inhibitor market, just Keytruda alone public information Merck has out there, it's over $23 billion in annual sales. So it's a very large market.

And if cleaning the blood or removing exosomes, if that helps the 60% or 70% of patients that are not responding to these checkpoint inhibitors, then that would be a very large market and very, very compelling. The focus, obviously, is on oncology and cancer patients. I do remember during COVID, and you did mention at the beginning of your presentation, that the Hemopurifier cleans the blood of not just exosomes but of viral particles as well.

Is there an opportunity maybe, and I know you're focused on keeping the burn down, but is there an opportunity to find partners to work with you, maybe fund other development categories such as viral particles? Maybe touch upon that. And then give us a little more detail on exactly how you're pursuing the oncology space in Australia because from what I understand, it's easier to get that process underway. The timeline is shorter or faster, more efficient, and maybe just go into the details around your oncology program.

JIM FRAKES: Sure. Let me touch on the virus side of your question first. That is the origin of Aethlon Medical. We have quite a database of both human treatments. People with viruses such as Ebola, HIV, primarily hepatitis C, and then in vitro with probably 20 different grade A of viruses that all seem to be glycosylated as the sugary surface that's on top of viruses that coat virions of viral particles or exosomes. And that is what binds to the matrix inside of this cartridge, that sugary surface.

That had been the focus. We were somewhat active during COVID. It took a while to get our clinical trial approved and up and running, and eventually only treated one patient before the vaccines worked. And there were very few patients in the intensive care units. We also have a clinical trial in India in COVID, but only one patient has been treated there.

Very much the same as in the US. No patients are being admitted to the ICUs there. That could change or another pandemic could rear its ugly head. With our small company and limited resources, we couldn't just focus on pandemics, vaccine, responses before the vaccines are developed. There is a market, it'd be a great market and help to people.

But we couldn't base our company around it. Oncology is real. We all know people that have died from cancer and my sister included. And it's just a recurring big market that's it's just easier to construct the company around that.

But we are like firemen. If there's a fire, we could help participate as a first response before vaccines are developed for future pandemics, or if COVID mutates and becomes quite dangerous again. And we'd love to partner up with a larger life science company in that. And we've had no serious conversations, but we're quite open to that. That is the normal ultimate outcome for all small biotech companies is to partner up with somebody. And that's hopefully our outcome as well down the road.

Moving on to the international oncology part of the question. I'm not sure if I mentioned our oncology trial in India. The same hospital, Medanta Medicity, which is a world-class hospital in Delhi. They've approved our similar oncology trial. The only reason it's not the same trial is they have a slightly different treatment protocol for Keytruda and Opdivo than they do in Australia, different number of months between doses. So we can't technically be the same trial, but it's virtually the same trial.

The physicians that are going to administer the Hemopurifier treatments there have done many clinical trials for us in the past, mostly in hepatitis C. They are the world's experts really in using this device. So we're excited to work with them again. They supporters of our company. But why Australia? I think that was your third aspect of your question.

First of all, great medicine. World class. Many drugs and medical devices have had clinical trials there that the FDA or the FDA has accepted the data. They have a great-- they call it a tax credit of 43%. So for every dollar we spend in Australia on our clinical trial, theoretically we get $0.43 back in cash. They call it a tax credit, but it's actually a cash rebate, not a tax rebate.

So that helps materially to defray the costs of the clinical trial there. And some of our colleagues have had good success in Australia, and we speak the same language. Some of the PIs in our hospitals there have done many medical device, extracorporeal device clinical trials. So they're a pioneer. So we're excited to work with them, too.

ANTHONY VENDETTI: Is the timeline faster in terms of the trial of potentially getting approval in Australia?

JIM FRAKES: Yeah, sorry I missed-- you did ask that as well. So the process is a bit different in Australia and India than in the US. In Australia, the key is to get the ethics board approval similar to the Institutional Review Board here in the United States. Then you notify-- notify, not seek approval from the national regulators versus here in the US where the FDA has to approve it first then you go to the IRBs.

So it's a much quicker process. It's merely a notification. In India, we had already gotten approval before the fact, before the Ethics Committee approved it at Medanta Medicity. So their process it's a bit closer to the US, but we'd already taken care of that a while back. So every country's a little different. But it's a faster process to get going in Australia.

I think it's still a two-step process. Safety trial first, then efficacy trial like in the US. But my understanding is things do move more quickly, even than in Australia than here.

ANTHONY VENDETTI: Good, good. So the set up a or construction of the trial in Australia, how many patients ideally would you enroll? What would that look like? And then when do you hope to have some data to move forward?

JIM FRAKES: So both countries, because again technically they're different trials, are 9 to 18 patients. We'll have a co-- the first cohort of three patients will be one time a week, treatment once a week. Then we'll take that data or the blood samples pre and post-treatment. We're using a central lab in Sydney actually for both trials. We're going to ship the blood samples from India to Sydney.

We're working with a lab there at the University of Sydney that's excellent. And we've learned a lot about tracking exosome reductions. They're well known for that, too. So between our efforts, we have the protocols set up for the labs to measure exosome or EV reductions. We finally learned to say exosomes. And now the industry has changed it to EVs or extracellular vesicles. So I kind of drift between the two.

ANTHONY VENDETTI: That's fine.

JIM FRAKES: I apologize, but we're looking at T cell reduction or T cell marker improvements EV or exosome reductions. So looking at a variety of factors that could be important. But the main thing is safety. So first cohort samples collected sent to the lab. They analyze it. They'll give us the data.

Of course, we'll know if the treatments, if they were administered safely as a treatment. But so once that's analyzed, we'll probably make that information public. So there will be again three cohorts. First one is just once a week. Second one is twice a week. Third one is three times a week to see-- Steve LoRosa would call it a dose finding study. So we'll see how much of a difference there is between once a week, twice a week or three times.

ANTHONY VENDETTI: In terms of the reduction in extracellular vesicles.

JIM FRAKES: Right.

ANTHONY VENDETTI: And when you say once a week to up to three times a week, that's hooked up to the purifier and filtering the blood for four to six hours each time, correct?

JIM FRAKES: That's right.

ANTHONY VENDETTI: And is that done post a checkpoint inhibitor treatment or pre?

JIM FRAKES: Yes, correct. So patients sign up for the Study and begin their therapy, Keytruda or Opdivo. So day one effectively. And I believe it's day 60 in Australia. And it's a different day in India. Then their physician their oncologist realizes that they're not improving. That's when the ones that have signed up as potentially being interested could go on to our therapy.

They go through our therapy and then go back to their oncologist and keep going with Keytruda or Opdivo and see if the hypothesis is working.

ANTHONY VENDETTI: Know if it starts working.

JIM FRAKES: I'm sorry.

ANTHONY VENDETTI: Go ahead.

JIM FRAKES: I think it's important, Anthony. Oncology trials can last many years and they have endpoints way down the road. We're only looking at safety and these changes in EVs, exosomes, and T cell markers. That's what we're looking at. So we don't have this enormously long process here.

ANTHONY VENDETTI: You're not looking for the endpoints of efficacy at this point. You're trying to get safety and reduction in EVs.

JIM FRAKES: Yes.

ANTHONY VENDETTI: And so where we stand today, what's the timeline, do you think, for enrolling 9 to 8 patients in both India and Australia, and then hitting safety and reduction in EVs. Is that something you hope to have by the end of '25 or?

JIM FRAKES: Well, I'd be disappointed if we don't have patients enrolled this quarter. I mean, they've all just all three hospitals in Australia and India, there's still some import export things we need to go through. So they can't start recruiting yet, but we're just starting. But hopefully we'll have some patients treated this quarter. That's the goal.

Could slip to early next quarter. And again it's only three patients for the first cohort. So hopefully, we'll start getting some data to let's say a quarter after that. I mean, we're so excited that we're finally going and moving. It's a little frustrating that we want to know how this works. But it's not that far off.

ANTHONY VENDETTI: And then once, assuming you get the safety data, I mean, anything can happen, but filtering blood and taking out things that could potentially be dangerous seems pretty safe. But let's assume you get to that point and it's safe. Then the next step would be to conduct a larger pilot or pivotal trial that would try to get to an endpoint of efficacy.

JIM FRAKES: Absolutely

ANTHONY VENDETTI: And so what would that potentially look like in terms of number of patients and timeline in terms of how long that would take to have an initial readout?

JIM FRAKES: Well, the crystal ball gets a little fuzzier that far out. But unlike drugs where there are thousands of patients in the later stage trials, with medical devices, they're much smaller. It would depend on our dialogue with the regulators. But if we start with 9 to 18 in the first phase, which we're starting, and there are only two phases, as you said, safety and then the pivotal trial, it's unlikely to be 100. It's more likely to be sub 100. But I can only speculate on that.

And I don't know. It depends on recruitment. I would think if you have cancer and you're not responding, I don't know why most people wouldn't want to give this a try. It's a lot less harsh than going through chemotherapy or having parts of your body carved out. So only time will tell.

But there's a big market. If we can help a little bit, I think this is-- there's a lot of risk in our little company, but the reward could be good, too.

ANTHONY VENDETTI: Do you have-- do you have KOLs identified or are you identifying KOLs here in the US, or are you anticipating the pivotal trial to also be conducted in Australia and India?

JIM FRAKES: That's a good question. The PI at both-- and I should mention the cites. Royal Adelaide and Adelaide, Australia, Pandora and Gold Coast and then in Sydney, they're the three areas where we have the trial. I know the PIs at Gold Coast and Adelaide are quite well known. They are knowledge leaders. I would like to think they'd want to handle the next phase.

And we are talking to people here in the US, too. We just have to focus on one indication. And Australia just makes so much sense from dollar and cents perspective that that's our primary. And then the Indian doctors are expert with our device. So those two just made the most sense to me.

ANTHONY VENDETTI: OK, we have about a minute left. So if there's anything else, Jim, that you would like to share with investors that we haven't yet covered, please do so.

JIM FRAKES: I think you've covered it well. We're a small team. We're focused. And I feel like we have the company moving.

ANTHONY VENDETTI: That's great. Thank you so much. I think this was very informative, so thanks for attending our conference. For those that are signing off at after this event tonight, we'll be back tomorrow for a full slate of one-on-ones and panels. And we look forward to further updates from Aethlon, Jim, and look forward to speaking with you soon.

Thanks so much for joining, everyone.

JIM FRAKES: Thank you, Anthony. Thank you, everybody, for listening in.