

Evaxion business update and fourth quarter 2023 financial results March 27, 2024

Corporate speakers:

- Christian Kanstrup; Evaxion Biotech; Chief Executive Officer
- Birgitte Rono; Evaxion Biotech; Chief Scientific Officer
- Jesper Nissen; Evaxion Biotech; Chief Operating Officer, Chief Financial Officer

Corporate participants:

- Ahu Demir; Ladenburg Thalmann; Analyst
- Swayampakula Ramakanth; HC Wainwright; Analyst
- Thomas Flaten; Lake Street Capital Markets; Analyst
- Richard Ramanius; Redeye; Analyst

Presentation
--

Operator^ Good day. And thank you for standing by. Welcome to the Evaxion Business Update Conference Call Full Year 2023. (Operator Instructions)

I'd now like to hand the conference over to your speaker today, Christian Kanstrup.

Please go ahead.

Christian Kanstrup^ Hello, everyone, and a very warm welcome to this Evaxion business update conference call on the back of our full year 2023 results.

I'm Christian Kanstrup. I'm the CEO of Evaxion.

With me today I have Birgitte Rono, our Chief Scientific Officer. I have Jesper Nyegaard Nissen, our Chief Operating Officer and Chief financial Officer.

What we will be covering today is I will be giving a brief welcome, also a brief corporate update. Then we will have Birgitte dive into the R&D and business update. And Jesper will be covering the 2023 financial results. After a few conclusive remarks by me, we will be heading into the Q&A session.

So looking forward to an interactive session.

Before getting started, I just want to direct your attention to the fact that we will be talking about the future today.

And of course when talking about the future, that entails uncertainty.

So I do direct your attention to the forward-looking statement slide, which is contained in the presentation deck for today.

With that, let me give you a brief summary of where we are today.

First of all, we have refined our strategy. We have launched it. And it's well anchored.

And just to remind you, this is about our 3-pronged business model, and I would touch upon it in a few seconds. Then we have also seen strong progress on our financing strategy.

We have now cash into Q1 2025 secured.

We have MSD GHI as our largest shareholder. Very pleased with that.

We have also seen solid progress on our R&D and business strategy.

We have reached a key milestone in the MSD vaccine collaboration.

We have our precision vaccine project on track. And yesterday, we also released exciting and strong EVX-B1 data. Across the business, we have been focusing on optimizing our cash burn, but important so without compromising our long-term growth opportunities.

That also entails that we have been optimizing the organization, and we are focusing on investing for maximum return on investment.

So all in all, I would say we are very pleased with where we are at this point in time in the Evaxion journey.

Let me just give you a brief corporate update.

I just wanted to recap a little bit on our strategy and our refined strategy.

We have a three-pronged business model, which is based upon our AI-Immunology platform.

Important here is also that we are having a multipartner approach to value realization.

So when you look at our strategy, the core of the strategy, that is the AI-Immunology platform.

Our leading and validated platform for fast and effective discovery, design and development of novel vaccines.

Based upon this platform, we have this 3-pronged business model to realize value, one is targets, one is pipeline and one is responders. The target piece, that's around a multipartner approach focusing around either single or multiple target discovery, design and development agreements. And here, the MSD vaccine collaboration we have is a good example of what we want to achieve within the target prong of our business model.

Then we have our pipeline. This is about our own development for select high-value programs, bringing these programs to a major value inflection point before we pursue partnering. And here, of course, we are excited about the upcoming 1-year Phase II data for EVX-B1, which we expect in the third quarter.

Finally, we have the responder prong, which is really about utilizing our core capabilities within data and predictive capabilities to develop responder models. And here, we had the proof of principle for our checkpoint inhibitor model in the fourth quarter last year and are looking to progress that in a partnership-based approach.

So our strategy, core AI-Immunology and then it's about targets, pipeline and responders in a multi-partner approach.

Then a brief update on our financing strategy, which has been a key element to progress that over the past months here. And I'm very pleased to see the strong progress we have seen here.

In December '23, we closed a \$5.3 million private placement. Here, we welcomed MSD Global Health Innovation Fund as a shareholder, very pleased to see MSD on the cap table.

In February, we closed a \$15 million gross public offering.

Also here, we had MSD GHI participating. And that now means that MSD GHI is the largest shareholder of Evaxion with just below 15% ownership.

In parallel with this, we have been intensifying our focus on value realization via partnering.

We have the ambition to fund our 2024 operational cash burn of \$14 million via business development income and to do so, it's critical that we have the right focus on advancing various partnership discussions.

So all in all, a significant progress on our financing strategy, and as I said, cash into Q1 2025.

So that was the brief corporate update I wanted to give before handing over to Birgitte -- to have Birgitte give us an update on all the exciting things that have happened within the R&D side of the business over the past months.

Birgitte, will you take it from here?

Birgitte Rono^ Yes. Thank you, Christian.

So today, I'm excited to give an update on the recent progress achieved in full specific R&D pipeline programs.

So let's turn to Slide 9.

We have communicated initial encouraging data from our EVX-01 personalized cancer vaccine Phase II trials.

We have increased our focus on developing a persistent cancer vaccine with broad applicability for our EVX-B1 staph aureus vaccine.

We have completed studies with an undisclosed partner, testing our AI-Immunology designed antigens in a large animal model of surgical site infection. Further, we've made significant progress in our EVX-B3 vaccine development program with MSD reaching the first milestones.

So if we turn to Slide 10, we see our pipeline, and we are advancing vaccine candidates for both cancer and infectious diseases, and all these vaccines are designed based on our AI immunology platform.

Our pipeline includes several vaccine candidates, candidates at various stages of development and that exemplifies our commitment to saving and improving lives with AI immunology.

If we look at our EVX-01 Phase II trial on Slide 11, this is our most advanced program in metastatic melanoma. And for each patient that is enrolled in the trial, we manufacture a tailored vaccine that is fitting the tumor profile and the immune system of the individual patients.

Once the patients are enrolled, they are administered with anti-PD-1 pembrolizumab, which is the standard of care for this indication, and then they are treated with our personalized EVX-01 vaccine at week 12.

If we move to Slide 12, we have monitored the ability of the EVX-01 vaccine to induce a specific T cell response in the first five patients. And on the graph to the right, you see the data from these initial analysis.

In all of the five patients we have assessed so far, we see a strong and specific response against the vaccine antigens. And further, we have confirmed the favorable safety profile of EVX-01, which we also observed in the Phase I study. And the next significant milestone is 1-year clinical readout in Q3 this year.

So on Slide 13, we have a little bit of information about one of our cancer vaccine innovation programs.

We have intensified our efforts significantly for this program. And based on the discovery of the highly conserved novel class of tumor antigens, so-called endogenous retroviruses, we have developed a precision-based cancer vaccine concept with potential to broaden the applicability and to treat more cancer patients with a vaccine. Upcoming milestone for this program is preclinical proof of concept in Q4 '24.

So if we turn to our infectious disease program on Slide 14, we have a little bit of highlights from our B1 project this morning as Christian mentioned, we announced that we have some very encouraging results from this program against *Staphylococcus aureus* infection.

So we and an undisclosed collaborator we tested our vaccine antigens against *Staphylococcus aureus* in a clinically relevant animal model of surgical site infections.

And we saw that our antigens, they protected the animals against surgical site infections indicating promising potential for our clinical efficacy. And currently, we are engaged in discussions with the collaborator regarding the path forward.

So for our EVX-B3 program, we have tested or we have designed a vaccine. And this program is conducted in collaboration with MSD.

We have used our proprietary platform, AI immunology and we have identified novel targets against a bacterial pathogen causing severe health issues.

So we have now concluded on the antigen discovery and design phases, and that marks a significant first milestone for the development of the vaccine candidate.

And next milestone is conclusion on target discovery and validation work in collaboration with MSD in the second half of 2024.

So in summary, we've made substantial progress across our pipeline candidates, and we are eagerly anticipating and inciting 2024, marked by some significant milestones ahead.

Christian Kanstrup^ Thank you so much for this update. Truly exciting events that has taken place here. And now I will hand over to COO and CFO, Jesper Nyegaard Nissen to take you through the 2023 financial results.

Jesper Nissen^ Thank you, Christian.

I will focus my comments on our financial results for the full year of 2023 compared to the full year of 2022. All the numbers that I review will be approximate for easy sharing during the call.

For additional information regarding our full year results and prior period comparisons, please refer to the business update and full year 2023 financial results press release and the Form 6-K as well as the Form 20-F that we both filed last week.

Starting with our cash burn. This we have in 2023, as Christian talked to had to focus on optimizing without compromising our long-term growth opportunities. The external spend as well as the organization has been slimmed to reflect our focused strategy and intensified focus on value-realizing via partnering.

We have reduced the organization in terms of FTEs to the tune of 30% during 2023 and more than half the cash burn when comparing to cash burn entailed in the approved budget for 2023 to the expected cash burn shared as part of the company milestones for 2024.

As of December 31, 2023, cash and cash equivalents were USD 5.6 million. Following the public offering in February 2024, resulting in net proceeds of \$12.7 million, we expect that our existing cash and cash equivalents will be sufficient to fund our operations and capital expenditure requirements into February 2025.

If all prefunded borrowings including the public offering are exercised, we expect necessary funding will be in place into April 2025.

If we look at our expenses, research and development expenses for 2023 amounted to \$11.9 million and general and administrative expenses to \$10.4 million for the period. R&D expenses decreased by \$5.1 million or about 30% compared to 2022. The decrease was primarily driven by a decrease in external development costs of \$3.2 million related to clinical trials.

Further, a decrease were seen in employee-related costs of \$1.8 million due to a reduced head count and a shift in our employee mix.

Looking at general and administrative expenses, they were at \$10.4 million, an increase of \$2.2 million or 27% compared to the period last year. The increase was primarily driven by an increase of \$1.3 million in external costs related to legal fees, professional fees and cost related to capital ratios and an increase in employee-related costs of \$1.9 million related to full-time effect of 2022 hires and changes in senior management.

These increases are due to the timing of funding of projects and business initiatives compared to 2022 and the expansions of the organization throughout 2022 to meet the requirements as a listed company.

Looking solely at Q4 2023 versus Q4 2022, the G&A costs were down [USD 0.53] million to USD 2.1 million or 13%. This is primarily driven by a reduction in our D&O insurance, but also following the reduction in other external spends. The net loss for 2023 amounted to a loss of \$22.1 million compared to a net loss of \$23.2 million last year.

And with that, I would like to turn back to you, Christian, for a few conclusive remarks before the Q&A.

Christian Kanstrup^ Thank you so much, Jesper. And to end up here with a few conclusive remarks.

I think if we look at the past six months in the Evaxion journey here, I think it's fair to say that the events we have seen unfolding confirms a strong strategy execution.

We launched our refined strategy.

We anchored that, and we are now executing upon it.

Importantly, of course, it also alluded to the progress with the MSD vaccine collaboration.

We had the encouraging initial Phase II data from EVX-01. And we are progressing our precision vaccine project, which I'm very excited about.

So strong progress on the strategy execution, and we are looking very much forward towards the upcoming milestones in 2024. The first milestone we had in our externally communicated milestones was of course EVX-B1, the conclusion of the final MTA started with a potential partner that we announced today with encouraging data.

Now we are in discussions with the collaborator on path forward.

It is throughout the remainder of the year, we would have several important milestones, both from a platform, from a compound and from a partnership point of view, and we are looking forward to keeping you all updated on the milestones as we progress them.

So with that, I would say thank you for listening to the presentation here. And now I'm looking forward to the Q&A session, and we will open the floor for questions.

Questions and answers

Operator^ (Operator Instructions) And the first question comes from the line of Ahu Demir from Ladenburg Thalmann.

Ahu Demir^ I have a couple. My first question is regarding the today's press release on EVX-B1. Curious if you could provide more color on the collaboration as well as data.

Is this the point, where there will be a go, no-go decision and if the collaborator is not willing to move forward, are you planning to move forward? Or is it something that you are not willing to do at this point?

Christian Kanstrup^ No. I mean I can say and then I'll have Birgitte add additional comments.

I mean we just got the data in and we're excited to see the data. And as you also see in the release this is, I would say, clinically relevant data here. And now we are in discussion of path forward. And of course, it's clear having a set of preclinical data in a large non-rodent model is important, especially considering you can say that staph aureus is an area where you have seen a number of clinical failure.

So having a model which hopefully, is more predictive for clinical outcome is important.

So right now we are in discussion with the collaborator and I would say the data is, of course, supportive of the compound. And Birgitte, I don't know if you have more comments to add to the question here?

Birgitte Rono^ I can add that we have conducted three separate studies in this animal model. And I think the data speaks for itself.

I mean it's very promising, and we believe that this model is I would say, a better indicator for clinical efficacy in the end.

I mean we've conducted mouse animal experiments in the past and with also a very promising outcome.

But I believe that this model in large non-rodent animals, it gives a better sign of what we will hope to see in the clinical slide.

And of course, we think this point is very important because it will be the conclusion on - or the dialogue with the collaborator is, of course, only relevant if the data was positive.

Christian Kanstrup^ So you can say, of course, it confirms our belief in a strong asset. And of course, it's important for our engaging in discussions around the way forward for this EVX-B1 in partnership-based model.

Ahu Demir^ And I have two other questions. The other question I have is on EVX-B3.

So since it's a major collaborator, MSD, curious, what are the next steps and when there would be a point to make decision?

Is it sometime in the near-term feature?

Christian Kanstrup^ Birgitte, do you want to take that one?

Birgitte Rono^ So what we have done so far is to use AI-Immunology to design the vaccine. And the next phase is to manufacture the vaccine and then tested in preclinical models. And we are aiming to reach that by the end of the year.

Ahu Demir^ And my last question is more general.

So the platform technology you have is versatile. You have PIONEER, EDEN, ObsERV, RAVEN.

So curious if you get any in-bounding interest or when you reach out, is there one particular vertical you have more special interest by the pharma or biotech firms.

So when you are establishing partnership, is there one that's more emphasized in your conversations?

Christian Kanstrup^ I would say, first of all, of course, we have been more focused in our external communication as a result of also refining strategy, focusing more on partnerships. And that has, of course, also resulted in more incoming request and I would say we are seeing interest in both the infectious disease side of the business and the oncology or on cancer side of business.

So I would not say that it's tilted more towards one or the other. Birgitte, of course, you are just in Washington now for the World Vaccine conference.

So I don't know if you have a little bit of flavor as well.

Birgitte Rono^ Yes.

But I think -- so our AI-Immunology platform, I think that the companies can see the benefit of us using all these different building blocks and make or create models that can solve complex immune-related health care issues.

We have interest in our infectious disease pipeline candidates, but we also see interest in our oncology assets.

So I think it will be difficult to answer more specifically than that.

Christian Kanstrup^ But of course, as you know then we had the R&D Day, what's it now a couple of weeks ago. And this was the first time we really talked about this I think, pretty unique modular architecture with the various building blocks, and that was also important for understanding what the platform can do and how flexible it is in tailoring it towards partner needs.

Operator^ And the next question comes from the line of Swayampakula Ramakanth from HC Wainwright.

Swayampakula Ramakanth^ So starting off with EVX-B3, so once MSD takes this into the clinic, do you have any additional obligations in terms of developing the molecule? And also as it enters the clinic, do you get another milestone? Or is it all dependent on how it progresses through the clinical phases that you get milestone payments.

Christian Kanstrup^ I would say, RK, first step is dependent upon the outcome of the current [using] discovery, design phase here which then, if successful, and of course, if aligned with what the MSD is seeing, then that would result in a traditional licensing agreement and the level of involvement from our end there is to be discussed and determined at that point in time.

Right now we have a work plan, which spans into the second half of this year. And then we will be discussing how do we best combine our capabilities of the two companies for the next phases of the vaccine development project.

I think it's fair to say, MSD is, of course, very capable in doing large-scale clinical trials, but we also have a lot to add in other phases and just the AI-Immunology platform -- so it's to be decided based upon the outcome, when we conclude the work here during the second half.

Swayampakula Ramakanth^ Fantastic. And then the EVX-B1, obviously it's very encouraging to see the way the data is progressing in large animals, also reiterating what you had seen in the mouse model.

So when do you think you would be able to publish some of this data for us to take a look at.

And then obviously it depends on the partner, but what is the -- how quickly can this get into the clinic? Or again, it all depends upon how your collaborator is looking at it because this is certainly a very -- I think it's a large unmet need, especially in the surgical wounds.

Christian Kanstrup^ No. There's no doubt.

I mean that's also why we are excited about the data because there is a significant unmet need. And then you can say, exactly when data will be published.

It depends very much on how we are progressing the current discussions and with whom we bring this forward.

But of course, our objective is to progress quickly given the unmet need.

And Birgitte, you can speak a little bit more to how quickly it can be in the clinic.

Of course, it is our most progressed infectious disease assets, right?

Birgitte Rono^ Yes.

So the next step is would be the final IND-enabling activities.

So that includes toxicology studies and also the [CMC] activities. And that is, of course, time-consuming activities.

It will probably take one year, one to 1.5 years to get to the point where clinical trial could be initiated.

Swayampakula Ramakanth^ And the last question for me is on the EDEN version to the new AI model that you're working on.

What's unique about this version compared to the first one?

Christian Kanstrup^ I mean the unique part about the 5.0 that we are looking to launch mid this year is that it incorporates some of the newer building blocks that we also discussed in our R&D Day and thereby, you can say, in short, further increases the predicted capabilities of the EDEN platform, which already is high, but will be even stronger.

So it's allowing for, say, even more effective discovery of novel vaccines towards infectious diseases.

Birgitte Rono^ And we will also expand the training data set significantly and thereby increasing the precision of the model.

Operator^ And the next question comes from the line of Thomas Flaten from Lake Street Capital Markets.

Thomas Flaten^ On the preclinical work you're doing on the ERVs, I was curious if there are any particular tumor models that you're focusing on? Or are you doing more of a basket approach just to refine a future strategy at this point?

Christian Kanstrup^ Birgitte, do you want to take that? That has been discussed.

Birgitte Rono^ Yes.

I can answer that. Yes.

So right now we are looking into several indications for the ERV-based cancer vaccines, and we do see several options, which is very encouraging and very promising.

We haven't selected one single indication yet.

We might run with a few. And therefore, we haven't settled on the animal model of the mouse model for testing this concept. And we do have a huge collection of animal tumor models in-house, and therefore, I think we can move -- once we have decided on the indication, we can move rapidly into the preclinical testing.

And I should also mention that we have done a ERV vaccination in animals before. So we do have experience with these types of antigens in preclinical settings.

Thomas Flaten^ And have you had any interest whether inbound or generated through your efforts in the EVX-03 program?

Christian Kanstrup^ Well I think it's we can't really comment specifically on individual assets.

But as we talked about, there are -- I mean there's discussions in generally around both sides of the business. And I think we share a lot of excitement around EVX-03 and it's, of course, a key asset for us that we also want to move forward in a partnership-based approach.

I mean we did announce that we won't bring it into clinical development ourselves.

But that does definitely not mean that we don't want to bring it forward in a partnership-based approach.

Operator^ And the next question comes from the line of Richard Ramanius from Redeye.

Richard Ramanius^ The first financing question, namely about the prefunded warrants. How many are still outstanding? And how much money do you expect to get from them? And when could you expect to receive that money?

Christian Kanstrup^ Yes. You can say it's around USD 4 million that's still outstanding. And this is related to technicality that the nominal value of the underlying share for the warrant is held in escrow.

So it's around USD 4 million that we haven't received yet, and we will receive that as the prefunded warrants are exercised you can say exactly, when that is going to happen is difficult to predict.

But of course, it is the shares that's paid upfront.

So we would expect that those \$4 million are being released from escrow over time right.

Richard Ramanius^ And also wonder about ERV vaccines and how -- what is your business development model there because you're doing precision vaccines. When do you think it would be possible to do a deal there? What kind of interest do you see for precision vaccines in cancer?

Christian Kanstrup^ But I think there's a lot of excitement in general around the ERV-based concept and also the precision vaccine.

I think question is here, when we want to partner and that also depends on how do the preclinical data that we will be generating when we establish a proof-of-concept during second half, how do they look.

It doesn't make sense to bring these assets further.

And so I would say, right now our focus is on establishing the preclinical proof-of-concept for the precision ERV-based vaccine concept and then decide when is the right time to partner. And as Birgitte said, I mean there are several indications, where it shows a higher promise to have a precision-based approach.

So we'll need to look at the data, compare that to the opportunity and then decide what's the right timing for potential partnering.

Richard Ramanius^ Would you agree that there is a larger interest right now for infectious disease candidates than for cancer?

Christian Kanstrup^ No. I wouldn't say that.

I think there's equally excitement around (inaudible) and then now we added the additional element of not only personalize the vaccines, but also precision-based vaccines within the cancer side of the business, which is a somewhat different approach than having a personalized approach.

So I wouldn't say that there's necessarily more interest in infectious diseases. There's a good level of excitement around both sides. And of course, it's also clear that some of our competitors' data on the personalized vaccine that was announced last year have created additional comfort that this is an exciting area, where it makes sense to focus on.

Richard Ramanius^ Yes. Yes. And I also wanted to ask about the [AI deep] or responder program you have specifically one for checkpoint inhibitors because I was thinking, since in the indications for certain approved uses in various cancers.

It says you need to have a certain level -- certain level of a biomarker for PD-L1 levels.

So if this could be your approach that would be quite disruptive. Would it -- isn't that mean you have to sort of redefine how you make indications for checkpoint inhibitors.

So that's my first question.

My second related is how -- what is your monetization model? How -- I mean how could you earn money on this?

Christian Kanstrup^ Yes. Birgitte, do you want to take the first part and then I can talk about the second part.

Birgitte Rono^ Yes.

I can do that.

So yes, it is correct that PD-L1 tumor expression is yes, a biomarker for some cancer indications including non-small cell lung cancer and some of the other huge cancers. And we have also, in our AID model, we have also included the expression level of PD-L1.

And we see that it is only contributing to a minor part of the whole persistent of the AI model.

It's mainly driven by our PIONEER model and our ObsERV model.

But it is correct that for some indications, the PD-L1 expression is used as a treatment biomodel.

Richard Ramanius^ Just wondering how -- wouldn't you have to change how you treat people if you're -- this checkpoint response prediction to a less approved --

Birgitte Rono^ So what AI team is capable of is to identify the patients that most likely would not benefit from a checkpoint inhibitor treatment.

So we'll not risk of excluding patients that would benefit from checkpoint inhibitors.

Richard Ramanius^ Okay.

I understand.

Christian Kanstrup^ And then to your question around how to monetize on that, I mean that can be done in several ways.

Of course, you can say the most straightforward one is positioning as a companion diagnostics and then it's being sold into other clinical selling or it could also, of course, be of relevant for pharma companies are undertaking clinical trials with checkpoint inhibitors because if you are capable of say, reducing the trial population of a late-stage trial by upfront being able to exclude nonresponders.

That means a significant cost savings.

But I think we're -- our focus is right now is focusing on how we can bring it forward in a clinical setting and help patients get on to the right therapy quicker. And that could be as a companion diagnostic.

Richard Ramanius^ Yes.

I think there's some interesting projects you have? And well my last question was, do you have any policy for takeover bids because it's slips easy to remind when you see the investments that MSD has made logical steps that might be to try to make an acquisition?

Christian Kanstrup^ Yes, of course, we can't comment upon any question like that.

If something relevant is to be communicated, of course, we will communicate that.

Operator^ And the next question comes from the line of Ahu Demir from Ladenburg Thalmann.

Ahu Demir^ I just wanted to ask one more question regarding the outstanding debt.

What is the current debt on the financial front?

Christian Kanstrup^ And I'm very happy Ahu to pass that question straight on to our CFO, but I can say it's an EIB loan.

Jesper Nissen^ Yes.

So basically, our debt structure is pretty similar.

We have an EIB loan, which is of \$7 million, and it has an expiry date of Q1 2028.

Operator^ As there are no further questions, I would like to hand back to Christian Kanstrup for any closing remarks.

Please go ahead.

Christian Kanstrup^ Yes. Thank you so much. And I just want to say thank you to all of you for all the relevant and good questions. And thank you for listening in.

We are excited about what has happened over the past several months here and equally excited about what's to come for 2024. And we are looking forward to keeping you updated on that.

So thank you so much for listening in.