Evaxion business update and second quarter 2024 financial results
August 18, 2024

Corporate speakers:

- Christian Kanstrup; Evaxion Biotech; Chief Executive Officer
- Mads Kronborg; Evaxion Biotech; Vice President of Investor Relations and Communications
- Birgitte Rono; Evaxion Biotech; Chief Scientific Officer
- Jesper Nyegaard Nissen; Evaxion Biotech; Chief Operating Officer, Chief Financial Officer

Corporate participants:

- Yi Chen; HC Wainwright; Analyst
- Thomas Flaten; Lake Street Capital Markets; Analyst
- Unidentified Participant; Ladenburg; Analyst

Presentation

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

Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your first speaker today, Christian Kanstrup, CEO.

Please go ahead.

Christian Kanstrup^ Good morning. And good afternoon, everyone. And a very warm welcome to this Evaxion business update conference call on the back of our Q2 results.

I'm Christian Kanstrup, CEO of Evaxion.

With me today I have Birgitte Rono, our CSO. I have Jesper Nyegaard Nissen, our COO and CFO. And I also have a new joiner with me today, which is Mads Kronborg, VP, Investor Relations and Communications.

And I would actually like just to start out handing briefly over to Mads for a brief introduction to who we are.

This is the first time you are attending the call here.

Mads Kronborg^ Thank you, Christian. And thank you for the opportunity. And just for a brief introduction, I have some 15 years of experience in corporate communications and investor relations from the pharmaceutical and biotech industries, having earlier held

positions like Head of Corporate Communications at Lundbeck and Head of IR and Communications at Zealand Pharma.

I'm glad to join Evaxion at this very interesting time for the company with a number of milestones lying ahead. And I'm looking forward to help communicate our progress and facilitate the dialogue with you as investors, analysts and journalists.

You will find my contact information on the Investors section of our website, and are of course always welcome to get in touch.

Christian Kanstrup^ I am pleased to have Mads on board so we can provide even better service and support to all of you.

So it's great to have you on board, Mads.

Then let's jump to the next slide and look at the agenda for today.

I'm going to do a brief introduction, then I'll hand over to Birgitte for an R&D business update. Jesper will be covering our financial results.

I will conclude before we head into the Q&A part.

But before we get going for real, let's just direct our attention to Slide 3, which is a forward-looking statement.

As you know we will be talking about the future, and that do entail uncertainty. Hence, please read this one carefully.

So with that, let's look at some of the key achievements since last business update.

As you know one of the key elements in our strategy is to create value via a multi-partner approach. And here, I'm super pleased to see that we have been advancing our partnering discussions since our last update.

We are seeing a solid interest from external parties, both in our AI-Immunology platform and pipeline candidates, and we do have several partnerships discussions ongoing. And this is, of course, key to execute upon our multi-partner strategy that we see these discussions advancing.

What I'm also pleased about is that we are seeing progress on the EVX-01 program.

We did present positive and validating Phase II immune data at ASCO this year.

We also presented our Phase I results in a leading medical journal including the 67% objective response rate from the Phase I trial, which I'm very proud about. And very importantly, we are on track for a key milestone for Evaxion, our 1-year clinical data

readout, which will be presented at the ESMO Congress in September, so very nice progress on the EVX-01 program.

In addition to this, an important element is, of course, to continue strengthening our AI-Immunology platform and our capabilities, and that we have also progressed upon over the past quarter. Among other things, we did get the positive feedback on a patent application for an AI-based novel target identification method which is based on the endogenous retroviruses. And of course, creating a strong IP portfolio around our platform and around our pipeline assets is important for us.

So getting this positive feedback is a major milestone for the continued strengthening of our platform.

Finally, I think worth mentioning is the fact that we did present at the computational biology conference not too long ago an improved performance on one of the building blocks of AI-Immunology. And as you might remember then, AI-Immunology has a quite unique modular structure where we have a number of building blocks used across the different AI models. And that means improving the performance of one of these will improve the performance of those AI models where it's used.

So having the opportunity of showcasing what we do to increase the predictive capabilities, which we'll get back to later, is a major element in strengthening and improving our AI-Immunology platform.

So I would say it has been quite busy with several important parts of our strategy advancing since our last update.

And I would also just, on the next slide, quickly recap on our strategy.

Our strategy is unchanged.

As you know we have a 3-pronged business model, which is based upon AI-Immunology.

So the core of our strategy, that's AI-Immunology, and then we have the multi-partner approach towards value realization, then the three prongs, its targets, its pipeline and its responders.

Within the target path, that is about a multi-partner approach focusing around either single or multiple vaccine target discovery, design and development agreements.

And of course, the collaboration we have with MSD around EVX-B3 is a great example of what we want to achieve here. Pipeline, that's taking select, high-value programs forward ourselves, bringing these to key value inflection points. And again, that's why we are super excited about having the readout of the 1-year clinical data from the Phase II on

EVX-01 in September at the ESMO conference. This is going to be a key milestone for Evaxion.

Finally, the responder part, that's really about taking the core capabilities we have, data, predictive analysis, and developing responder models.

So the 3-pronged business model remains in place, multi-partner approach towards value realization.

And then, before handing over to Birgitte, I just want to look a little bit forward because we have a number of important milestones to report shortly.

In September, at the ECCB conference, we will be launching the upgraded version of EDEN model 5, or version 5.0, that we are looking very much forward to. And that, of course, links into the continuous strengthening of our AI-Immunology platform.

Also in September, at the 18th Vaccine Congress, we will be reporting out on the milestone for EVX-B2 in an mRNA version where we have been pursuing preclinical proof of concept.

I already mentioned ESMO, September, 1-year readout on EVX-01.

So a number of important milestones reporting out shortly.

For the latter part of the year, we are still on track with our collaborations with MSD around EVX-B3, where the first phase is going to conclude in the second half.

We are on track with our ERV-based precision cancer vaccine where we are pursuing the preclinical proof of concept that will also report out later on in the year. And then finally, we have the ambition of generating business development income equal to our 2024 cash burn, excluding financing activities. That also remains.

The only thing here is the attentive reader will see we have updated this wording here to say business development income or cash-in. And that reflects the fact that, of course, now we are relatively later on in the year. Hence, if we get to the $14 million, the -- it is uncertain if the accounting impact of an upfront milestone will lead to full accounting for this in this year, or that will be leading into next year.

So from an income point of view, it might be divided over '24 and '25.

But from a cash point of view, we clearly have the ambition, which remains intact, of generating business development income of $14 million.

But as you, of course, know any business development activity is uncertain, so this remains an ambition.

But as I also started out saying, we are seeing a very nice traction on our business development activities with several discussions ongoing.

Also pleased to say that we are seeing new potential partners approaching us on a regular basis, so strong activity around our business development activities, and we are having the ambition of generating the $14 million this year.

But of course, uncertainty remains.

And with that, I will hand over to Birgitte for giving an update on the exciting R&D activities that have taken place over the past quarter.

Birgitte Rono^ Thank you, Christian.

It has indeed been a very active and busy time during the last quarter. And today, I'll focus on the data from the Phase II study of EVX-01 presented at ASCO in June and on the improvement of this central building block in our AI-Immunology platform that we call EvaxMHC. And that building block is key for designing effective vaccines. The improvement of performance of this building block was presented at the computational biology conference called Intelligent Systems for Molecular Biology in July.

So our EVX-01 lead product candidate is a personalized cancer vaccine designed to engage the patient's own immune system to fight the cancer. And EVX-01 is currently in Phase II in a global multi-center trial in first-line advanced melanoma.

So the patients enrolled in the Phase II trial received standard of care. That is the checkpoint inhibitor from (inaudible) called KEYTRUDA. And they receive it according to label in combination with six initial EVX-01 primary doses followed four additional extra doses.

So EVX-01 consists of 10 AI-Immunology-identified new antigens, and new antigens are these short sequences that are exclusively found in tumors. And when administered to a patient, they will induce a specific T-cell response with a tumor-killing potential.

So in June, we presented encouraging immune data from the first 12 patients at ASCO. And what the data demonstrated was that we profiled EVX-01 induced T-cell responses in all of these evaluated patients. And the graph to the right displays the EVX-01-induced immune response over time.

Week one represents baseline, where the patients have not received any study therapy.

Week 12 is where the patients have been dosed with KERYTRUDA.

And at Week 18, that is during the EVX-01 primary phase, whereas -- which that is after primary, but before the patient has received any booster immunization.

So in all evaluated patients, we do see an increase in the T-cell response upon vaccination with EVX-01.

So further analysis also demonstrated that the T-cell responses were mediated by [CD4] and CD8 T-cell responses are not included in the data here, but they were presented at ASCO. And there is currently a lot of debate about the roles of CD8 and CD4. And we have also talked a lot about this, and we believe that it's very important that there is a balance between these two T-cell types.

We also saw that (inaudible) we could maintain the response in the patients, and we believe that this is critical for obtaining a doable clinical response.

What is also important, that is to look at the [single new] antigens and their ability to induce a specific immune response.

And regards to the left, it depicts also the response to the individual new antigens in the vaccine over time. And at Week 30, we could see that we had 64 out of the administered 90 antigens giving rise to a specific immune response, leaving us with 71% positive hits. And that, we believe, also compares favorably to what we have seen others communicating.

[Now], we correlated the AI-Immunology prediction scores and new antigen T-cell responses, and that is depicted on the graph to the right. And that demonstrated the significant positive correlation, also underlining the precision and predictive power of our AI-Immunology platform.

So just to summarize the ASCO data, we demonstrated EVX-01-induced T-cell responses in all trial patients. The responses were mediated predominantly by CD4 T-cells, but also by CD8 T-cells.

We saw that 71% of the new antigens induce an immune response and AI-Immunology new antigen qualities were correlated with immune responses. And in general, we believe that these early immune data are very encouraging, and we are looking so much forward to presenting the 1-year clinical readout at ESMO in September, as Christian alluded to.

So changing focus a little bit, we are continuously working on improving our AI-Immunology platform. And one key feature is -- in developing effective vaccine is the ability to actively predict these small segments, known as peptides, stemming from pathogens and cancer cells that are displayed on the surface of this. And this allows the immune system to recognize and eliminate the threat.

So we have worked on improving one of these two key building blocks in AI-Immunology, the one called EvaxMHC. And that actually predicts which peptides that are most likely to be displayed on the surface of those and thereby the most [clinically] relevant vaccine targets.

So with this improvement, we have used a state-of-the-art, novel, deep-learning framework, and we have also trained the models on publicly and proprietary data. And we saw that, when we compare to publicly available [source], there was an improved performance of this building block.

So with these improvements, we anticipate to further enhance the ability to accurately predict vaccine targets, and we also envision that these updated versions of EvaxMHC will lead to an improved design of our vaccines.

So just to sum up, in June, at ASCO, we presented encouraging new data from our EVX-01 Phase II cancer study, and we are on track for this exciting upcoming 1-year data presentation at ESMO. Further, we have shown, with this improved performance of our key building blocks, that we potentially can improve the design of both cancer and infectious disease vaccines.

Christian Kanstrup^ Thank you, Birgitte.

I think it's fair to say it's truly exciting to see the EVX-01 data continuing to unfold, so looking forward to September. And now over to you, Jesper, to see how the Q2 numbers have been unfolding.

Jesper Nyegaard Nissen^ Thank you, Christian.

I will focus my comments on the financial results for the first half year of 2024 compared to the first half year of 2023. All the numbers that I will review will be approximate for easy sharing during the call.

For additional information regarding our first half year results and period comparisons, please refer to the business update on second quarter two021 financial results press release and the Form 6-Ks we have filed this morning.

Starting with our financial highlights for the first half year of 2024, mainly we are seeing the effects of the 2023 cash spend optimization and organizational slimming in the financial results. This is linked to the continued implementation of the focused company strategy with intensified focus on value realization we are partnering as we shared at rear calls.

As of June 30, 2024, cash and cash equivalents were USD 8 million.

We expect that our existing cash and cash equivalents will be sufficient to fund our operation expenses and capital expenditure requirements into February 2025.

If all prefunded warrants included in the public offering in February 2024 are exercised, we expect necessary funding will be in place into March 2025.

As shared earlier, the company received, May 7, 2024, a NASDAQ equity deficiency letter as a result of our equity being below $2.5 million.

Our plans to regain compliance have been shared with and accepted by NASDAQ, providing the company until November 4, 2024 to evidence compliance.

Looking at our expenses for the period, research and development expenses were $5.6 million for the six months ended June 30, 2024. The decrease of $1.2 million versus the same period in 2023 was primarily due to a decrease in employee-related costs counterbalanced by a small increase in costs related to clinical trials.

General and administrative expenses were $3.6 million for the six months ended June 30. The decrease of $1.7 million versus the same period in 2023 was primarily due to reduced external costs related to professional fees as well as reduced employee costs for the period.

Finance income and expenses for the first six months of 2024 are primarily impacted by effects from the remeasurement of the derivative liability related to investor warrants from the public offering in February 2024 as well as the [private] placement in December 2023. These effects have been eliminated going forward as the investor models have had the exercise currency change from USD to DKK during Q2, moving them from being recognized as financial instruments to equity instruments.

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

Christian Kanstrup^ Thank you so much, Jesper, and thanks for the update on the numbers. Let me just quickly provide a few conclusive remarks before we jump into the Q&A part.

I think it's fair to say that we are seeing a solid progress on our 3-pronged business model and very good traction along the different parts.

Importantly, also, we are having a strong focus on advancing ongoing business development discussions, which, of course, is a key milestone for us this year as well that we will be focusing on value generation via a multi-partner approach.

Again, the data Birgitte presented shows that EVX-01 continues to deliver solid data, and we do have a major milestone coming up here at ESMO in September. And in addition to that, it is going to be a busy time ahead with several of our other 2024 milestones going to report out just as we are on track for delivering on remaining milestones during the second half of the year.

So all in all, I would say I am very pleased with the progress we are seeing, a strong focus upon execution and bringing our strategy forward.

So with that, I would very much like to open for the Q&A session, so please just join the Q&A session.

Questions and answers

Operator^ (Operator Instructions) And the first question comes from the line of Yi Chen from HC Wainwright.

Yi Chen^ Christian, congratulations on this great quarter.

I have a couple of questions.

First, do we expect any update between the ESMO data and the final data in 2025 in regards to EVX-01?

Birgitte Rono^ I can answer that.

So we are continuously generating more data also on the biomarker side. And yes, we do expect to -- in early '25, to present some more of that work.

Yi Chen^ Excellent. And another question I have is regarding to EVX-B2 vaccine.

Can you give us a sense of what could be the potential scenario for the next step with development or with the collaboration with Afrigen?

Christian Kanstrup^ Yes.

I think, if we take B2 in general, right, you can say that's, of course, at the preclinical stage. And it's, I think, [especially] one of the assets where we are looking for partnering to bring it forward broadly.

So the next steps on B2 in general would be the partnership discussions.

For the Afrigen collaboration, in particular, which, of course, is for an mRNA-based version for low and middle-income countries, there, the next step is establishing the preclinical proof of concept, which will be presented at this 18th Vaccine Congress in September.

And then next steps beyond that, that would depend on, you can say, the data as well.

But primarily, this is a research collaboration focusing on establishing the proof of concept for use of the two B2 antigens in an mRNA construct.

Yi Chen^ Got it. Maybe if I can squeeze in my last question.

Can you give us a sense of the current status of the ERV platform, what kind of preclinical data you're generating? When do we see the data published or being announced?

Christian Kanstrup^ Are you thinking in particular for the precision-based vaccine, which we -- where we have the milestone, or are you thinking about ERVs in general?

Yi Chen^ I think you said -- stated the updated timeline is second half '24.

Christian Kanstrup^ Yes. Yes.

Yi Chen^ Yes. That's the one I'm talking about.

Christian Kanstrup^ Yes.

Birgitte Rono^ So the milestone in later this year is -- or related to the precision version of the vaccine, so meaning that we are currently developing a vaccine that fits a broader subset of patients with a certain indication, so not personalized as such.

We are currently doing a lot of design studies and also preclinical evaluation of these designs to be ready for our presentation at the conference later this year.

Christian Kanstrup^ And I would say, personally, I'm super excited about the whole -- first of all, ERV as a novel cancer target, but also the concept of developing a precision vaccine where you have the opportunity of reaching new patients which you might not be able to reach with standard immunotherapy and/or with the personalized cancer vaccine due to a lower tumor mutational burden.

So we are looking forward to seeing the data here later on this year.

Yi Chen^ Looking forward to the data.

Operator^ Thank you.

We will now take our next question.

Please stand by. And the next question comes from the line of Thomas Flaten from Lake Street Capital Markets.

Thomas Flaten^ Christian, I was wondering if you could maybe characterize the partnership discussions that you mentioned in the press release that are ongoing. Are they infectious disease-focused, like cancer-focused, maybe across the board? How advanced are those conversations? Just a little bit more color there would be super helpful.

Christian Kanstrup^ No. I would say, Thomas, without, of course, being able to go into a whole lot of detail, it's across the board. And that's also what I tried to say here.

We are seeing interest both in AI-Immunology, i.e. in, you could say, new target discovery collaborations like the one we have with MSD, but we're definitely also seeing interest in our pipeline assets, which is both from the cancer side and from the infectious disease side. And I would say some of these discussions are fairly advanced, which they also need to be, given that we keep the milestone of the USD 14 million in [BD] income this year because it, of course, takes time to get deals done.

So I would say we have a good mix of things which are quite advanced and across the board as well as new things coming in, which would probably more likely be 2025 deals.

So I think, given the fact that we only really started very active in our [BD] efforts in, say, towards the end of the first quarter, then I am very pleased with where we are now in the pipeline of deals and seeing that it is a broad-based interest.

Thomas Flaten^ And then given where your spending was, particularly in R&D, for the second quarter, can you help us think through how we should model spending, particularly in R&D, for the second half of the year, given where you are with cash and the cash runway you've laid out?

Christian Kanstrup^ Yes.

I think you should be looking at a slightly lower R&D spend in the second half of the year. And actually, the same goes for G&A.

So we will be having a lower second half spend than the first half. And also, you can say, from a cash-out point of view, I mean we are paying insurance.

We are paying employee bonus, et cetera, in Q1.

So the cash flow is also skewed towards the first half of the year, so definitely looking at lower R&D as well as G&A in the second half and also lower cash-out.

Thomas Flaten^ Excellent.

Operator^ (Operator Instructions) We will now take our next question. And the next question comes from the line of Chung Yu from Ladenburg.

Unidentified Participant^ Well this is [Theresa Aquavaneer].

We have a question regarding the upcoming results at ESMO.

So could you please give us more color on what we will expect to see? And besides the (inaudible) data, are we also expecting to see the update [ORR] on the [PMS] or [OS]?

Birgitte Rono^ So we will present 1-year clinical readout from the Phase II study, and we will also present more biomarker analysis including a few more cases of patients that have been boosted. The exact data, the exact clinical data, we cannot say that yet, exactly what it's going to be, because we are a little bit reluctant to conclude on the primary endpoint when it's a preliminary readout.

Christian Kanstrup^ But it is going to be clinical data that we will be presenting.

Birgitte Rono^ Clinical data, so of course, this is criteria and the response of the clinical -- their responses, yes.

Unidentified Participant^ And so my next question is, will this Phase II data readout help you advance maybe into the next stage of the partnership discussion in the future?

Christian Kanstrup^ I think the short answer to that is, yes, of course, assuming it's good data, which we hope and expect.

But no, there's no doubt that -- I mean when you are discussing personalized cancer vaccines, I think, given this is a novel concept, then clinical data are important in partnering discussions, and that's also why this is an important milestone for us in that respect.

So yes, it will be very important.

Unidentified Participant^ Okay. And my next question is regarding the EVX-B3.

So can you please provide some updates for that?

Birgitte Rono^ Yes.

So EVX-B3 is a collaboration with MSD on an undisclosed pathogen vaccine. And it's running according to contract, meaning that we have now assigned the antigens.

We have produced them, and we are currently testing them in animal models.

So we are on track with that collaboration.

Christian Kanstrup^ And then that is said to -- you can say this first phase on the testing is set to conclude during the second half here. And then we will be discussing with MSD the next phase, which would be a more traditional license and collaboration structure, of course, assuming that the data looks promising.

Unidentified Participant^ And my last question is, so what is the difference of the EDEN new model version, like 5.1, from the older version?

Christian Kanstrup^ You can say the overarching objective with the upgrade is, of course, to increase the predictive capabilities of EDEN, making us capable of identifying -- the greater certainty identifying the right antigens but also possibly discovering targets which could not be discovered in other ways.

And we've been doing a couple of things.

We've been expanding the training data set.

What we have done is we have acquired additional training data from public sources using what we call retrieval augmented generation with large language models, and that has been followed by a manual domain expert curation. And this enhanced data set now includes the prediction of bacterial toxins, which is a new feature in EDEN 5.0.

Also we have -- we call it advanced protein feature prediction.

We developed a completely new building block for protein feature prediction, and we have fine-tuned the protein language model, thereby enhancing the model's capability to predict various protein characteristics. And then all of this, I mean is, as I said, about improving the antigen identification.

We have trained a new machine learning model in EDEN specifically designed to identify antigens, improving both the you could say accuracy and the reliability of the antigen prediction.

So I mean in short, improving the predictive capabilities of EDEN, which is a continuous process that we're doing with all our AI models, both by taking a detailed focus on the individual model, but also as Birgitte presented on the EvaxMHC building block, which is used across the models, improving that and hence thereby improving the predictive capabilities of all models together.

So we're definitely looking forward to presenting that in greater detail at the ECCB conference in September.

Unidentified Participant^ And so are you going to apply this new model to any programs?

Christian Kanstrup^ I mean that's, of course, going to be applied to a possible new target collaboration discussions or collaborations with the pharma biotech as well as our own internal programs that we are looking to bring forward.

We have a list of infectious disease targets that we would like to bring forward as well. And of course, there, this EDEN 5.0 will be a great help in quickly advancing new candidates into our internal pipeline, as well as it will be additional value proposition towards external parties when we collaborate with them.

Operator^ Thank you.

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

Christian Kanstrup^ Thank you so much.

I just want to say thank you to all of you either dialing in or joining the webcast. And also thank you so much for the questions.

We also always appreciate a good dialogue, so thank you so much for that.

And now we are looking forward to be reporting on the key milestones ahead in parallel with advancing the different discussions that we have ongoing.

So thank you so much to all of you for listening in.

Operator^ Thank you. This concludes today's conference call. Thank you for participating.

You may now disconnect.