Evaxion business update and third quarter 2024 financial results
October 10, 2024

Corporate speakers:

- Christian Kanstrup; Evaxion Biotech; Chief Executive Officer
- Thomas Schmidt; Evaxion Biotech; Chief Financial Officer
- Birgitte Rono; Evaxion Biotech; Chief Science Officer

Conference call participants:

- Thomas Flaten; Lake Street Capital Markets; Analyst
- Swayampakula Ramakanth; HCW; Analyst

Presentation

Christian Kanstrup^ Thank you so much. And good morning and good afternoon to all of you and a very warm welcome to this Evaxion business update conference call on the back of our Q3 Earnings Release, which has been out earlier on today.

I'm Christian Kanstrup, CEO of Evaxion.

With me today I have: Birgitte Rono, my Chief Science Officer. I have Mads Kronborg, our Head of Investor Relations. Also with me today for the first time I have our new CFO, Thomas Schmidt, who just joined us.

And I would actually like to start out by just handing over to Thomas for a very brief introduction of who you are.

Thomas?

Thomas Schmidt^ Thank you, Christian, and also from my side good morning and good afternoon to everyone on the call.

As mentioned and as written here, my name is Thomas Schmidt and officially will be joining here 1st of November as the CFO of Evaxion, having spent the last few days with handover from Jesper.

I'm an Accountant Auditor by training and education and have spent the past more than 25 years within the life science industry, many different roles within the company of Roche amongst other.

Also Financial Officer in Germany and I've been Group CFO also in Ambu earlier.

So I'm really, really looking forward to now joining Evaxion.

This being my obvious first Business Update conference call and excited to be working together with the team and also with the shareholders.

Christian Kanstrup^ Great to have you on board, Thomas. Let's jump to the agenda, which is very similar to what we normally do.

I will start out with a brief introduction. Birgitte will take an R&D business update.

We will have Thomas go through the financial results.

I will conclude before we jump into the Q&A.

But before we get going, let's also just direct your attention to this slide, the forward-looking statement slide.

As normal, we will be talking about the future.

Of course, when you talk about the future, that does entail uncertainty. Hence, I carefully direct your attention to the forward-looking statement slide, which speaks to the uncertainty about talking about the future.

With that, let's get into the introduction and look at the key achievements since last business update.

I think it's fair to say that I am super proud of the team and proud of what we have achieved during the last quarter.

It has been a very busy quarter, and it has been a quarter with a lot of significant achievements, and we have seen a continued strong strategy execution.

Several milestones have been achieved across the company.

If we start out with our multi-partnering strategy, here, of course, in September, we signed a transformative deal with MSD, the European name for Merck around EVX-B2 and B3.

This is providing a significant financial and strategic value to Evaxion.

Also I'm proud to see that we see a continuously increasing external interest in both our pipeline and our platform, and we have a number of ongoing partnership discussions.

We've also seen a very solid pipeline progress, which Birgitte also will get back to.

We did release a very convincing 1-year clinical data from the Phase II trial with EVX-01.

We did present the proof of concept for our mRNA-based B2 vaccine.

We are also spending a lot of effort in continuously strengthening the platform and the organization.

We launched an upgraded version of EDEN. Birgitte will get back to that as well. And then as we just talked about, Thomas has been appointed as CFO.

So an exciting quarter, a busy quarter, but important, a quarter with a lot of significant achievements.

And let me just start out or go a little bit -- spend a few minutes on the MSD agreement, which is truly transformative for us. Just to remind everyone, it's an optional licensing agreement.

It's covering EVX-B2 and B3, and it is ensuring a fast and effective development of these two vaccines to address a serious unmet need. Let's also remind all of you that no approved vaccines are available for the infectious diseases, that those two vaccines are targeting. This does mean a significant financial and strategic value to us, not only for the short term, but also very importantly so for the long term.

We have received the $3.2 million upfront payment in October.

We are expecting up to $10 million in 2025, contingent upon MSD exercising the options to license either one or both candidates.

In terms of total financials, milestone payments of up to $592 million per product plus royalties on sales. Needless to say, this is providing a potential -- very important source of income and funding for the years ahead.

What's also important when we look beyond the EMEA financials is that this is an important validation of both our AI-Immunology platform, but also our pipeline from a world leader in vaccine development and commercialization.

And I think it's fair to say that, that validation, we see that with an increasing interest in discussing potential partnerships with us from other companies.

So a very important element in our multi-partner strategy that we have a strong validation from a world leader in vaccine development and commercialization. Then let's jump to the next slide and take a look at our milestone overview.

As already said, a busy quarter, we have achieved a number of important '24 milestones, launched the upgraded EDEN, got the preclinical proof of concept on EVX-B2 for mRNA, presented the 1-year readout from the Phase II with EVX-01. And we also have the milestone on EVX-B3 and conclusion of the partner -- or the target discovery and validation work with MSD.

You can say that is now superseded by the optional licensing agreement because next step here will be the expected, hopefully, exercise of the option from MSD in 2025.

We are on track for the preclinical proof of concept with our ERV-based precision vaccine concept, also expected in 2024. And then for the BD ambition of generating BD income or cash in equal to our annual cash burn, I'll have an update on that on the next slide.

For the Business Development ambition, we have, as already mentioned, secured $3.2 million this year, up to $10 million in 2025, contingent upon option exercise, of course, and we are seeing a solid and increasing interest in both pipeline and platform.

What can be said is that certain discussions are moving into 2025.

Business development timing of that is uncertain, and we are seeing, despite the strong interest that certain discussions are taking longer time than anticipated.

Others are being initiated later, meaning that certain things are moving into 2025, which does mean that we will not be meeting our $14 million business development income or cash in 2024 ambition.

What is important, however, this, of course, creates a solid basis for business development income in 2025.

I think it's fair to say we are still having a number of discussions or we're having discussions, which could potentially conclude in 2024 with additional business development income, but timing is, of course, uncertain given that we only have two months left of the year.

One final update I would give before handing over to Birgitte, as also addressed in our release we had out earlier on today is our -- the situation around our NASDAQ deficiency letter, we did in May received notification from NASDAQ that we do not meet our minimum equity requirement.

Actually, even though we did, in fact, meet it by the end of the first quarter, but we ended up not meeting it by the second quarter, that resulted in a notification from NASDAQ based upon which we submitted a plan and got an exemption until November 4.

Our aim is to ensure compliance by a combination of business development income and capital markets activities, and we remain very committed to our NASDAQ listing, but it's also clear that this will not be achieved by November four as a number of factors have impacted timing, and we had to have certain things aligned.

We are, however, in a constructive matter with NASDAQ -- or constructive discussion with NASDAQ on this matter. And of course, we have a plan for how to ensure compliance. The way it works is when we are not meeting the November four deadline

for the extension, we will be receiving a notification or delisting notification from NASDAQ, which we will be appealing and requesting a hearing.

At this hearing, we will be pursuing an additional 180-day exemption in order for us to be able to secure compliance in a balanced way.

Of course, no guarantee of an additional 180-day extension can be given.

But as mentioned, we are in a constructive dialogue with NASDAQ around this matter, and do have a plan in place for how to pursue compliance.

As I said, we remain very committed to our NASDAQ listing and will pursue this very diligently.

So with that, I will hand over to Birgitte for an R&D update.

Birgitte?

Birgitte Rono^ Thank you, Christian.

It has been a very busy and exciting Q3.

So besides the transformative MSD agreement, we have made a significant progress across our R&D pipeline.

So next slide, please.

Today I will be focusing on the milestones achieved in our EVX-01 program, and then I will present the preclinical proof-of-concept data we achieved in our gonorrhea vaccine program with the messenger RNA version of our EVX-B2 vaccine candidate.

And finally, I will present the outcome of our efforts in improving the EDEN model.

So next slide, please.

So at the ESMO Congress in September, we presented the encouraging 1-year clinical data from our ongoing Phase II study investigating the effect of our personalized cancer vaccine, EVX-01 in combination with anti-PD-1 therapy in patients with advanced melanoma.

So we have treated 16 patients with EVX-01, and the current status is that we have 11 patients active in the trials with 10 patients having received all 10 EVX-01 doses and four patients having received the last dose of pembrolizumab. This means that we are well on our way to the 2-year data readout planned for Q3 next year.

So let's dive into the data we presented at ESMO. Next slide, please.

So for the primary analysis, we are looking at the clinical response improvement of patients that do have stable disease or partial response before dosing with EVX-01, so after this 12-week run-in phase of pembrolizumab treatment.

And currently we do have four patients out of the 14 patients included in this primary analysis that have had an improved clinical response upon administration of EVX-01 therapy at Week 12.

So we saw that EVX-01 in combination with pembrolizumab resulted in an overall response rate of 69%, which we believe compares favorably to historical data from pembrolizumab monotherapy trial.

So we are very encouraged with these early data.

We also saw that three out of 16 patients achieved a complete remission of the tumor target lesions. Next slide, please.

If we look at the changes of the target lesions over time at the plot in the top, it is evident that the target lesions are reduced in the first 12 weeks, so -- in this pembrolizumab run-in phase and then further reduced upon introduction of EVX-01 at Week 12.

Also from the spider plot, it is clear the [induced] reduction in -- of the lesions in five -- in 15 out of 16 patients.

If we look at the lower plot, we have zoomed in on the reduction of the tumor target lesions from Week 12, so where we introduced EVX-01. And here, we see that there is a clear further decline of the lesions upon this time point.

We have not reached OS and PFS yet, indicating a durable clinical response.

So overall, we are very pleased with this interim data, and we find it very promising, and we are definitely looking forward to (technical difficulty) in the future. Next slide, please.

So the second of these three milestones achieved in September was our EVX-B2 mRNA program.

So in September last year, we entered into an agreement with Afrigen Biologics to develop a messenger RNA EVX-02 vaccine -- or EVX-B2 vaccine. And in September, we presented the preclinical proof of concept of this messenger RNA vaccine candidate.

We saw that the candidate triggered a targeted immune response in mice shown in the graph in the middle panel with the ability to eliminate several clinically-relevant Neisseria gonorrhea strains. The data provides preclinical proof of concept for the messenger RNA-based version of EVX-02 and it also underlines that the targets that are

identified by AI-Immunology are delivery modality agnostic, as we have seen similar results with our protein-based version of this vaccine candidate.

So next slide, please.

So the third major milestone achieved in September was the launch of a new version of our EDEN model.

We use EDEN to identify protective T cell antigens that are included in our infectious disease vaccine.

So the upgraded EDEN prediction model can now predict toxin antigens, allowing for the development of improved bacterial vaccines.

So as bacterial toxins are often key contributors to disease, their neutralization is essential for developing effective vaccines.

And we strongly believe that this now add to a more efficacious vaccines against various bacterial; and also, to some extent, other infectious diseases.

So overall, very promising progress across the entire R&D pipeline in Q3.

Christian Kanstrup^ Thank you so much, Birgitte. And now I will hand over to Thomas for his first quarterly business update and for Thomas to take you through the numbers. Thomas, will you take it from here?

Thomas Schmidt^ Yes, certainly we will do. And maybe let me jump straight into the Q3 financials, and let me start with the financial highlights.

In Q3, we recorded a revenue of $3 million, which again, to what Christian mentioned earlier, is primarily stemming from the new MSD agreement announced back in September 26. The agreement obviously is well aligned with the financing strategy and the ambition and has also looking forward, the potential to generate substantial future revenue.

We've also been executing well on the earlier and ongoing cost reduction initiatives.

And as a result of that, we are seeing lower spend compared to the same period in 2023. Cash and cash equivalents were $4.6 million as of end of September. The $3.2 million upfront payment from MSD agreement we have received in October, but it is therefore not included in the September or Q3 figures, but obviously will be once we get to Q4. And we expect that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into March 2025. Turning to the profit and loss statement.

And net loss for the quarter was posted of $1.9 million compared to a loss in the same quarter last year of $5.7 million. The improvement is, as just mentioned, primarily driven by the recognized revenue, but also reduced G&A spending. There's a slight reduction in the R&D expenses versus the same quarter last year as the R&D expenses were $2.6 million this year versus $2.8 million last year.

The decrease is primarily related to head count. And on the mentioned G&A expenses, there's $800,000 lower expenditure in Q3 this year versus Q3 last year, and the decrease is mainly due to lower expenses following changes in the executive management team made in 2023.

The balance sheet as end of September 30 shows that our -- that due to capital increase in February '24, the equity has now improved by $4.8 million compared to the year-end last year, while we, at the same time obviously are investing and continuing to invest into pipeline and platforms. Cash and cash equivalents as of September 30 of $4.6 million, as just mentioned again, I just want to stress that does not include the $3.2 million MSD agreement payment, but we expect that this cash will carry us forward from an expense -- operating expense and capital expenditures requirements into again, March 2025.

Therefore, of course, we will continue to work diligently to improve, as Christian mentioned earlier, cash flow through continued business development income and also capital market activities. And with that, I will hand it back over to you, Christian, for some conclusive remarks and following Q&A.

Christian Kanstrup^ Excellent. Thank you so much, Thomas. And just to conclude, I think it's clear from the run-through here that we are seeing a solid execution of strategy and plans.

We had a strong quarter in terms of milestone achievements with a good mix of milestones across different parts of the strategy.

What is also encouraging is the signing of the transformative MSD agreement; and in general, a solid business development pipeline where we have full focus on continuing progressing those discussions and also initiating new discussions with interested parties to continue being able to feed the business development pipeline.

Other top priorities are, of course, the continuation of the EVX-01 Phase II trial. Birgitte mentioned, we are on track for the 2-year readout in Q3 2025, which will be an important milestone for next year as well. And then we have a number of novel preclinical activities ongoing as a basis for expanding our pipeline.

So full focus on executing upon the strategy and strong delivery across all the different parts of the strategy.

So with that, I would like to open for Q&A. And thank you all very much for listening into this first part.

Question and answers

Operator^ (Operator Instructions) We will now take our first question. This is from the line of Thomas Flaten from Lake Street Capital Markets.

Thomas Flaten^ Just a couple for me.

Can you walk us through the specific triggers that are required to generate the up to $10 million from Merck next year?

Christian Kanstrup^ Yes.

I mean you can say the up to $10 million is in case they license or exercise the option for both assets. And the -- if we start with the simple one, EVX-B3, that's finalization of the work that we initiated in September last year. You can say there we set out on target discovery and validation of EVX-B3, which is for an undisclosed infectious disease target.

So that's finalization of that, which is just execution of the plan that has been laid out.

For EVX-B2, MSD is doing some confirmatory preclinical analysis on the asset.

So we are, as such, not involved in the B2 work, and we are more or less wrapping up our involvement or participation in the B3.

What I can say also is that, I mean this next part of the collaboration is well on track and everything is anchored in terms of plans.

Thomas Flaten^ Got it. And then from an ongoing business development perspective, do you -- are you seeing more interest on the oncology side of the business or more on the viral bacterial side or perhaps it's balanced across the?

Christian Kanstrup^ Well I would say over the past couple -- or past months, a couple of months, we have definitely seen a pickup in the interest around the infectious disease side of the business, which, as I also mentioned, partners is related to announcing the Merck agreement, but that pickup in interest actually started also before we announced that.

So that's where we are seeing the increase also around, say, new target discovery and validation partnerships.

So it's tilted towards that.

Of course, with the EVX-01 Phase II 1-year data out, of course, there's also been discussions around those data.

Thomas Flaten^ And then one final one, if I may.

In what format do you expect to release the ERV proof of principle or proof-of-concept data?

Christian Kanstrup^ Birgitte, do you want to answer that?

Birgitte Rono^ Sure, I can -- we are planning to present the data at a conference in December.

Operator^ We'll now move to our next question. This is from the line of Swayampakula Ramakanth from HCW.

Swayampakula Ramakanth^ I have a few questions, but let's start from the pipeline side of things. Birgitte, you were stating that you would have some biomarker data in the first half of '25 from the EVX-01 Phase II study.

Can you just highlight for us what additional biomarkers data would we be seeing that we have not yet seen?

Birgitte Rono^ Yes. Thank you for that question.

So currently, we have not analyzed all samples that we have collected from the patients in the EVX-01 Phase II study.

So it is additional T cell analysis that we will conduct.

We will also do a little bit more on like a general profiling of the immune cells in the patient, so looking for regulatory T cells, other immune suppressive immune components in the PBMCs.

We have also collected serum samples for soluble analytes, and we will, of course, look at some of the standard cancer-related and inflammatory-related soluble analytes.

So an extensive biomarker package is what we are working on at the moment.

Swayampakula Ramakanth^ And then one more question on the pipeline.

Outside of the ERV data that we are expecting later this year, what additional data set or data from your programs could we be seeing over the say, let's say, over the next six months?

Birgitte Rono^ Yes, really good question.

So we are currently looking at prioritizing the pipeline and also defining milestones for the coming year.

So I think we -- it might be a little bit too early to disclose exactly what we are thinking within the early part of our pipeline.

Christian Kanstrup^ But RK, we will -- when we are ready, of course, communicate -- expected, say, key milestones for 2025 and what you can expect both from an R&D, but also, of course, from a general corporate point of view.

So that is currently being discussed.

Swayampakula Ramakanth^ One last question from me, Christian.

We understand that the $14 million or so that you are planning to raise through BD activities during 2024 is not going to be done and some of it will be pushed into '25.

But is there any opportunity for you to close out some sort of a BD transaction over the next two months? Or should we just I assume all of it should be expected in '25.

Christian Kanstrup^ No.

I have potential for closing an agreement -- additional agreement this year.

But of course, two months left, you have Thanksgiving, you have Christmas. That's why I don't -- didn't include specific guidance on I want to conclude another deal, but it could be possible.

But of course, that's a challenge with BD, right?

It takes time. And unfortunately, most often, it takes more time than you expect.

It's very rarely that it goes quicker than expected. That did happen with the MSD deal, but that's also very rare.

So there is potential, but we also only have two months left of the year, which is impacted by, yes, you can say, various vacation and holidays.

Operator^ (Operator Instructions) There are no further questions coming through.

So I will now hand back to the speakers for any closing remarks.

Christian Kanstrup^ Excellent. Thank you so much. And I just want to thank everybody for listening in and for your questions. And we are truly excited about the quarter and are looking very much forward to the time ahead.

So thank you so much for your time and we'll make sure to keep you updated on any developments, of course.

Thank you so much again for calling in.