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# Evaxion Biotech A/S

## Second Quarter 2021 Earnings Call

## August 12, 2021

## CORPORATE PARTICIPANTS

**Corey Davis**, *Investor Relations, LifeSci Advisors LLC*

**Lars Wegner,** *Chief Executive Officer*

**Glenn S. Vraniak**, *Chief Financial Officer*

## CONFERENCE CALL PARTICIPANTS

**Kevin DeGeeter,** *Oppenheimer*

**Thomas Flaten,** *Lake Street Capital* Markets

**Ahu Demir,** *Ladenburg Thalmann*

## PRESENTATION

**Operator**

Greetings. Welcome to the Evaxion Biotech Second Quarter 2021 Earnings Call.

As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host, Corey Davis from LifeSci Advisors.

**Corey Davis**

Thank, Joe. Good morning, everyone. Welcome to the Evaxion Biotech conference call to discuss second quarter results.

Earlier today, we issued a press release, which is available on Evaxion's website.

During this call, Lars Wegner, CEO of Evaxion, will provide a brief corporate update, after which Glenn Vraniak, the CFO, will review the financial results. After the prepared remarks, we will open up the call for Q&A, where Lars and Glenn will be available to answer your questions.

Before we begin, I'd like to remind everyone that statements made during this call, relating to Evaxion's expected future performance, future business prospects or future events or plans, may include forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995. All such forward-looking statements are intended to be subject to the Safe Harbor protection provided by the Reform Act. Actual outcomes and results could differ materially from these forecasts, due to the impact of many factors beyond the control of Evaxion. Evaxion expressly disclaims any duty to provide updates to its forward-looking statements, whether as a result of new information, future events or otherwise. Participants are

directed to the risk factors set forth in Evaxion's Form-20F for the year ended December 30, 2020 and our other reports filed with or submitted to the U.S. Securities and Exchange Commission.

With that said, I will now turn the call over to Lars.

**Lars Wegner**

Thanks, Cory. Good morning, everyone. I'm Lars Wegner, Chief Executive Officer of Evaxion. With me today is Glenn S. Vraniak, our Chief Financial Officer.

We're going to give you a short presentation on our business and results.

Let me begin by saying Evaxion has made some very exciting progress in the same quarter of 2021 towards our goal of becoming the world leader in AI-driven immunotherapies. As many of you know, Evaxion specializes in decoding the human immune system and use the data to rapidly discover and develop drug candidates. We believe using our AI models, the drug discovery and development translate into a higher likelihood of clinical success and ultimately improve lives of patients with cancer and infectious diseases.

In July, we reported data which support advancing both our lead cancer therapy programs, EVX-01 and EVX-02 into Phase 2b trials. These Phase 1/2a results of our EVX-01 program showed a robust anti-tumor effect in combination with anti-PD-1 treatment for metastatic melanoma and demonstrated that 67% of the patients benefited from the combination therapy with EVX-01 compared to historical data showing that only 40% benefit from anti-PD-1 checkpoint inhibitor treatment alone. Based on this exciting data, we now plan to begin the Phase 2b trial for EVX-01 in metastatic melanoma in December of this year, 2021.

We've also seen promising preliminary clinical data for our second lead program, EVX-02, demonstrating EVX-02 induced T-cell activation in adjuvant melanoma patients and the treatment was well tolerated. We expect to initiate a Phase 2b trial of EVX-01 in combination with our third program, EVX-03, in adjuvant melanoma patients in Q3 of 2022.

The EVX-01, 02 and 03 product candidates are derived from our pioneer AI platform which identifies neoepitopes for our patient-specific cancer immunotherapies.

In Q2 2021, we also reported preclinical proof-of-concept data for our AICoV program using our RAVEN AI platform for vaccine design and development for viral infections. Early data demonstrate that RAVEN identifies novel immunogenic T-cell epitopes outside the spike protein. This is an improvement of our first generation COVID-19 vaccine which was solely focused on generation of a T-cell response. Activation of T cells may help broaden the immune system's response to coronavirus and protect against viral mutations. This proof-of-concept data shows RAVEN's potential to rapidly support the design of novel COVID-19 vaccines capable of tackling newly emerging coronavirus variants.

We believe that the RAVEN platform has the potential to make significant contribution in addressing corona and other viral infections. We expect the first vaccine candidate selection for RAVEN in Q1 of next year, 2022.

In other developments, the lead candidate for our EDEN platform, which generate vaccines against bacterial diseases, is progressing well through preclinical development. EVX-B1 is a vaccine for the prevention of Staphylococcus aureus including MRSA. We expect a regulatory filing for clinical trial in the second half of next year, 2022. Our cash reserve of $18.8 million will allow us to fund this key clinical program into next year.

I also want to mention a presentation by Evaxion's Director in Genomic Immuno-Oncology, Dr. Jens Kringelum, entitled "AI in Personalized Cancer Medicine," and delivered at the 4th Neoantigen Summit Europe in April. Dr. Kringelum presented a presentation describing Evaxion's recent improvement in determining cancer neoepitopes through measurement and predictions of peptide-MHC complex stability, which we believe is an important advancement in how we can train the AI system to make drug development more efficient.

Evaxion also had a scientific paper accepted by the International Conference on Machine Learning. This paper was authored by Evaxion personnel in collaboration with the probabilistic programming group with the University of Copenhagen. This paper describes BIFROST, a novel predictive system based on deep probabilistic programming that enables the rapid conversion of sequence data into structural information on protein fragments. It's an exciting development, which we believe may be useful for drug and vaccine design.

This concludes our business and operational update for Q2 2021. I'll now turn the call over to Glenn for the financial review.

**Glenn S. Vraniak**

Thank you, Lars.

As of June 30, 2021, cash and cash equivalents were $18.8 million compared to $5.8 million as of December 31, 2020. As Lars mentioned, Evaxion's current cash position of US$18.8 is expected to be sufficient to fund key clinical programs into 2022.

On February 9, 2021, we closed our IPO, raising net proceeds of $27.9 million after underwriting discounts and commissions but before offering expenses.

Our research and development expenses were $5.1 million for the quarter ended June 30, 2021, as compared to $2.6 million for the same period in 2020. The increase of $2.5 million was primarily related to increased spending, net of grant income, for ongoing development utilizing our AI platforms, preclinical product candidates, and clinical trials. In addition, employee-related costs increased due to higher headcount.

General and administrative expenses were US$1.9 million for the quarter ended June 30, 2021, as compared to $1.4 million for the same period in 2020. The increase of $0.5 million was primarily related to increases in overhead and professional fees related to the expansion of our corporate function.

Net loss was $6.8 million for the quarter ended June 30, 2021, or a $0.36 loss per basic and diluted share, as compared to $3.6 million, or a $0.24 loss per basic and diluted share, for the same period in 2020.

I'll turn it back over to you, Lars.

**Lars Wegner**

Thank you, Glenn. This concludes our presentation today. It is now time to open up the call for any questions.

**Operator**

Our first question is from Kevin DeGeeter with Oppenheimer. Please proceed.

**Kevin DeGeeter**

Hey guys. Thanks for taking my question. Maybe, Lars, just to start off, I mean, appreciate the update on the oncology portfolio in terms of specific programs, but maybe you can take a moment this morning or today and reset us as to kind of your strategic rationale of the combinations or specific patient populations you're looking at for these upcoming trials that could cost (phon)—I mean, the Company has a limited amount of bandwidth in terms of both personnel and capital and I think maybe a little bit of a biologic strategic rationale would be helpful for us to appreciate the investments you've chosen to make here.

**Lars Wegner**

Thank you, Kevin. Excellent question. So, we have for very obvious reasons chosen to focus on melanoma, both in the metastatic setting and the adjuvant setting. As most of you are aware of, our neoepitope therapies that are based on the pioneer platform are capable actually of creating therapies towards the majority of major tumors that has a certain mutational burden.

So, why did we choose, of course, melanoma? There are three main drivers for that. Number one is that melanoma is a high mutational cancer, so the likelihood of clinical success is high in that population. Secondly, as we're given and harnessing the power of patients' immune system, we want to be early in the therapy and not be in third or fourth line where our patients' immune system are pretty much suffering due to the general state of the patient. And that means that melanoma is also a good choice because the first line therapy and the gold standard is checkpoint inhibitor, and that means that we can be in first line metastatic. And the same actually goes for adjuvant for our EVX-02 and 03 trial that adjuvant as the standard of care is also checkpoint inhibitor.

And then, why do we see the combination with checkpoint inhibitor? That's because we don't believe that checkpoint inhibitors is only additive towards a neoepitope specific therapy, we also believe it's quite synergenic (phon), right. The checkpoint inhibitors are removing kind of the break (phon) of the immune system and we are creating the specific T-cells that actually do the tumor killing, and as most of you are aware of, with checkpoint inhibitors, there's actually also the T-cells that has the effect directly on the tumor cells when you look at checkpoint inhibitors.

So that's kind of the rationale for being on that. Of course, down the road, we are looking at a lot of other interesting patient populations. I'm just going to mention a few. We have not made the decision or communicating any decisions on what could be a potential second or third indication, but diseases like non-small-cell lung cancer, bladder cancer are, of course, also very interesting indications for neoepitopes therapy.

I hope that answered the question, Kevin.

**Kevin DeGeeter**

It's very helpful. So, maybe two more from us this morning. In terms of for the balance of this year at oncology-oriented medical needs, are there currently sort of incremental updates on either 01 or 02? And then just gaining (phon) steps to get the first of the RAVEN product candidates into further development early next year, what needs—what are the execution steps to be able to deliver on that timeline?

**Lars Wegner**

Yes. Good question. So, we plan to share EVX-01 data with the scientific community down the road. We haven't settled for the exact time and place yet, but we'll of course share that. We will settle for that but data results will also be shared for EVX-01.

For RAVEN, right now, we are, of course, validating the AI approach that we're using to find strong candidates for viral diseases. As some of you know, we received a non-dilutive grant to actually develop the RAVEN platform and we're using COVID-19 as a test case for a broader platform because RAVEN is not just built to tackle a potential future in curing COVID-19 outbreaks, it's also built to tackle any viral diseases to find the right targets for vaccine design.

Right now, we are doing validation in preclinical models and, of course, doing a bioinformatic and AI validation of the algorithms. The minute we have that solidified and we are happy with it, we will, of course, choose a candidate for the RAVEN platform, which could be COVID-19 related. But it could also be a novel virus which we are looking at, such as HIV, where you have the opportunity of actually creating personal therapies that together with antiviral therapy could actually potentially cure HIV patients so we have the T-cells knocking out the last infected cells.

So, that's our current thinking and right now, the team's working hard on validating in preclinical models.

**Kevin DeGeeter**

Thank you for taking my questions.

**Lars Wegner**

Thank you.

**Operator**

Our next question is from Thomas Flaten with Lake Street Capital Markets. Please proceed.

**Thomas Flaten**

Great. Thanks for taking my questions. Lars, just a quick clarification on the EVX-01 Phase 2b. The designation of a checkpoint inhibitor in combination, I just want to clarify, and I know you want to try and minimize noise. So is that—could that be pembro, nivo or ipi or are you allowing the nivo/ipi combination in? I know you want to minimize noise. I'm just trying to see if you're trying to restrict patients based on CPI.

**Lars Wegner**

Yes, it's a very good question. That's something we've been discussing a lot, especially in nivo/pembro, which (inaudible) in, at least in the clinics, it is pretty similar. We think there's a risk on not being extremely clear-cut selective. So we're going to go with one single checkpoint inhibitor and then the same checkpoint inhibitor plus our therapy. Of course, the downside to that is you need a bit more work on the recruitment but you are actually potentially removing a lot of noise.

With ipi, the toxicity of the combination with ipi and nivo is not an attractive alternative for also testing a new therapy as the first larger trial. So that's why we're actually not including ipi in the trial. But, of course, as most of you can imagine, when we have data on the combination in a Phase 2b and it looks good, all the combinations will of course be explored, including ipi and nivo, etc., etc. But for the first step to prove that EVX-01 gives a clear-cut benefit to patients, we want as little noise as possible.

**Thomas Flaten**

And then sticking with 01 for my last question, how are you thinking about regional sequencing of not just regulatory submissions but also standing up sites and recruitment?

**Lars Wegner**

So, what is—normally if we look—it's different when you're running a clinical trial or how we think about it commercially. Commercially, there will be a lot of flexibility because most of the larger hospitals these days will have high quality NGS machines that you can run on. But again, for clinical trials to have as little noise in the data set as possible, we are sequencing everything at the same place at the same kind of machine, and that's basically to make sure there's no noise in the data set. That's not the commercial solution. They will be a bit more flexible. But for the clinical trial, one machine, one collaborator, all the sequencing in one place.

**Thomas Flaten**

And then which territories do you expect to start or initiate the study? Is it going to be U.S. first or would it be more like the EU or Australia?

**Lars Wegner**

So, we expect to start up in Europe, Australia, in Italy and then the U.S. right after. The (inaudible) will be run in Europe, Australia and the U.S., and probably even distributed between U.S. and Europe/Australia.

**Thomas Flaten**

Got it. I appreciate you taking the questions. Thank you.

**Lars Wegner**

Thank you, Thomas.

**Operator**

Our next question is from Ahu Demir with Noble Capital. Please proceed.

**Ahu Demir**

Hello. Good morning. Thanks for taking my question. I'm actually joining from Ladenburg. Hi Lars. I will also follow-up on the Phase 2 study as well. Would you be able to elaborate more on the design of the trial, how large it might be and is it going to be open label, placebo-controlled? So a bit more color on the trial will be helpful.

**Lars Wegner**

Thank you, Ahu. Yes, of course, Yes, the design of the study will be a two-arm study. It will be randomized. It will not be blinded, but it will be randomized and in the two arms. Number one arm, the active arm, will be checkpoint inhibitor plus EVX-01. In the standard of care arm, it will be checkpoint inhibitor alone, and it will be a one-to-one design in the study.

**Ahu Demir**

Okay, that was helpful, Lars. My follow-up, another question I have is about maybe data readout. Do you plan to have any data update? Are there any conferences that you plan to present maybe in the next nine months?

**Lars Wegner**

Yes, not something we have shared yet, but yes we do plan to share the EVX-01 data on upcoming conferences and, of course, when we talk about our new study, there we plan to do interim that will also be shared on an ongoing basis. The timing and how many interims, we have not settled for yet, but the minute we have settled that we will, of course, share what people can expect from the new study as well.

**Ahu Demir**

My last question will be on the EVX-B1 program. So, what activities have you done on the IND-enabling study? What stage are you at? So a bit more granularity would be helpful.

**Lars Wegner**

Yes. So, it's a multi-component protein-based Staph aureus vaccine. Currently, we are manufacturing the multi-components, (inaudible) level for doing the tox and the tox will start very soon. All the preclinical validation and efficacy is completed. So that means ahead of us is manufacturing and toxicity studies. We do not expect to have any tox issue with this product, but, of course, we need to do the regulatory tox as planned. And then we'll start with a Phase 1 in healthy (phon) for safety and immunogenicity, and then after that, quickly after that we're going to move into a Phase 2b efficacy study probably in skin infections with Staph aureus, and probably in collaboration with the U.S. military, where they have a lot of Staph aureus infection, which means you can run a very efficient clinical trial that benefits the army personnel and (inaudible) readouts.

So that's a bit more granularity on the EVX-B1 program.

**Ahu Demir**

Great. Thank you so much, Lars. Thanks for taking my questions.

**Lars Wegner**

You're welcome.

**Operator**

Thank you. There are no further questions at this time. I would like to turn the call back to Lars Wegner for closing remarks.

**Lars Wegner**

Thank you, and thank you all for your questions and your interest in Evaxion.

So, in summary, we have made some exciting clinical progress in the same quarter of 2021, with data supporting the advancements of both our lead cancer programs into Phase 2b clinical trials, and encouraging preclinical proof-of-concept data for our RAVEN AI platform.

Our cash reserves provide a solid financial foundation and will facilitate the continued development of these programs into 2022.

This concludes this call on our Q2 2021 results, and we look forward to speaking again next time. Thank you, everyone.

**Operator**

You may disconnect your lines at this time. Thank you very much for your participation, and have a great day.