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Evaxion Biotech A/S

First Quarter 2022 Earnings Call

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CORPORATE PARTICIPANTS

Corey Davis, *LifeSci Advisors, LLC*

Lars Wegner, *Chief Executive Officer*

Jesper Nyegaard Nissen, *Chief Operating Officer & Interim Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Kevin DeGeeter, *Oppenheimer*

Ahu Demir, *Ladenburg Thalmann*

Thomas Flaten, *Lake Street Capital* Markets

PRESENTATION

Operator

Greetings, and welcome to the Evaxion Biotech First Quarter 2022 Earnings Call.

As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host Corey Davis of LifeSci Advisors. Please go ahead, sir.

Corey Davis

Thanks, Peter. Hello, everyone, and thanks for joining us.

I'd like to remind everyone that the following discussion contains certain statements that are considered forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. Because forward-looking statements involve risks and uncertainties, they are not guarantees of future performance and actual results may differ materially from those expressed or implied by these forward-looking statements due to a variety of factors, including those risk factors discussed in the Company's prospectus filed on November 5, 2021, and the Company's current and future reports filed with or submitted to the Securities and Exchange Commission.

At this time, I'd like to turn the conference call over to Lars Wegner, the Company's President and CEO. Please go ahead, Lars.

Lars Wegner

Thank you, Corey, and good morning to everyone. So, thank you for joining us for this Evaxion Biotech's Q1 earnings call. I'm Lars Wegner, Chief Executive Officer of Evaxion. With me today is Evaxion's Chief Operating Officer, Jesper Nyegaard Nissen, who is currently Interim Chief Financial Officer. We'll give you a short presentation on our business and results, and then open the call for your questions.

Let me begin by saying Evaxion continues exciting clinical momentum in the first quarter of 2022, progressing our lead cancer therapy towards a new Phase 2b clinical trial. The upcoming trial will combine EVX-01 with Merck's KEYTRUDA, for treatment of patients with metastatic melanoma, a condition for which there is significant unmet medical need. We also completed recruitment for the Phase 1/2a clinical trial for our second cancer therapy, EVX-02, and we are advancing this product candidate into a dedicated Phase 2b clinical trial in patients with resectable melanoma.

We believe that these are significant steps forward for Evaxion in our pursuit to use our existing pipeline of cancer therapies to improve the treatment landscape in melanoma and possible other cancers as well. We are also actively discussing potential partnerships with pharmaceutical and biotech companies, and we are optimistic about achieving solid progress on this during 2022.

In January 2022, we received regulatory clearance to initiate our Phase 2b trial of EVX-01 with Merck's KEYTRUDA. We plan to have the first patient, first visit for EVX-01 in the first half of '22. Also in January '22, we completed recruitment for our Phase 1/2a clinical trial for EVX-02, advancing into a dedicated Phase 2b clinical adjuvant trial in patients with resectable melanoma. We plan to file for regulatory clearance in patients with resectable melanoma by the first half of 2022 and have first patient, first visit in by the second half of 2022. The EVX-01, EVX-02 and EVX-03 products all come from our PIONEER AI platform which generates patient-specific cancer immune therapies.

We believe that our AI models allow us to identify unique drug targets which may translate into a higher likelihood of clinical success. We are also progressing on our lead candidate on the EDEN platform, which generates vaccines against bacteria diseases. The program, EVX-B1, is a vaccine for the prevention of Staph aureus in skin and soft tissue infections. We also plan to select our second bacteria product candidate in the second half of 2022.

Furthermore, we plan to select the first viral candidate from our RAVEN platform in the second half of '22. Outside of the clinic, we announced publications on personalized therapy with EVX-01 in patients with metastatic melanoma in the open-access, peer-reviewed medical science journal *OncoImmunology*. Evaxion also hosted a key opinion leader webinar, which acclaimed expert on the metastatic melanoma and personalized cancer immune therapies.

This concludes our business and operation update for Q1 2022. I will now turn the call over to Jesper for our first quarter 2022 financial review.

Jesper Nyegaard Nissen

Thank you, Lars.

In the first quarter of 2022, we completed a drawdown and received our first tranche of €7 million or US$7.8 million gross proceeds from our European Investment Bank loan. As of March 31, 2022, cash and cash equivalents were US$31.4 million as compared to US$32.2 million as of December 31, 2021. We expect our existing cash and cash equivalents combined with funds from the draws on amount available under our EIB loan will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months.

Research and development expenses were US$4.8 million for the quarter ended March 31, 2022 as compared to US$3.9 million for the quarter ended March 31, 2021. The increase was primarily due to an increase in employee-related cost as a result of a higher headcount.

General and administrative expenses were US$1.6 million for the quarter ended March 31, 2022 as compared to US$1.3 million for the quarter ended March 31, 2021. The increase was primarily due to an increase in external costs.

Net loss was US$5.8 million for the quarter ended March 31, 2022 or a US$0.25 loss per basic and diluted share as compared to US$4.1 million, or US$0.23 loss per basic and diluted share for the quarter ended March 31, 2021.

Back to you, Lars.

Lars Wegner

Thank you, Jesper. That concludes our presentation today. Now it's time to open up the call for any questions and I hand it over to the Operator to facilitate this.

Operator

Thank you. Our first question is from the line of Kevin DeGeeter with Oppenheimer. Please go ahead.

Kevin DeGeeter

Okay, great. Appreciate the update today. I guess three questions from us. First, Lars, how should we think about a potential timing for an update on the Phase 2a EVX-01, specifically in the context of durability of response for the patients previously dosed? Thanks.

Lars Wegner

Thank you, Kevin. So, as you know, we presented the first data readout on our EVX-01 Phase 1/2a in July of '21 and we were very happy with the results. We are of course continuously following up on these patients and we will be looking at the durability of the response. We would be expecting within the next half to nine months to actually have that data available. But since of course it's durability, it will take time. Of course we can't predict that timing as we have had some patients in that study that had very, very durable responses. And of course we want to follow them for a significant time period.

I hope that answered the question, Kevin.

Kevin DeGeeter

Yes. Then our second question, really is around the initiation of the EVX-01 Phase 2b study. How should we think about number of sites being opened initially for that study and some of the earlier metrics or targets for pace of enrollment?

Lars Wegner

Yes. Good question. So, we are already very far as you can probably see from our announcement with the Australian authorities. We have experienced running melanoma trials there as our EVX-02 trials run there. We're working with the lead sites in Australia. We expect that we'll be starting the recruitment in this first half of 2022. And we'll start out in Australia with multiple sites and then we'll build on as we achieve

regulatory clearance in Europe and U.S. to open up multiple sites. We're targeting to open up more than 10 to 12 global sites, but we are aiming to work with the larger site, such as we are doing in Australia with the National Institute of Melanoma, basically sites that has large patient recruitment base. So, we expect around 10 to 12 in total of sites across the globe to be able to recruit for our Phase 2b trial and everything is moving according with plan.

Kevin DeGeeter

No. Great. Then just lastly from us and then we'll join the queue. Can you provide an update on EVX-03 particularly in the light of the comments that you're advancing EVX-02 into 2b study? How should we think about future investment into EVX-03?

Lars Wegner

Yes, both are based on our DNA technology, and to be pretty clear, they are both DNA based on the PIONEER platform and we are currently getting data on both programs. Our EVX-02 just finalized recruitment and we also recently, actually, yesterday, announced that all manufacturing process actually run according to plan, which is quite an achievement for a company making personalized medicine and unique products for each patient. We are thinking about if we want to speed up EVX-03 in the light of the EVX-02 data, and we are receiving data on both of these program on a continuous basis. So, as soon as the final design is finalized for the Phase 2b, we will be sharing that with the market. But we are quite happy actually with the progress of EVX-03 in our preclinical model, it seems to be even more powerful than EVX-02.

Kevin DeGeeter

Thanks for taking our questions.

Lars Wegner

Anytime.

Operator

Thank you. Our next question is from Ahu Demir with Ladenburg. Please go ahead.

Ahu Demir

Good morning. Thank you very much for taking my questions. I have two questions. First one, yesterday you announced the production of EVX-02 update. Could you provide more color on what was achieved? What is the production timeline? Maybe you could update us on EVX-03 as well?

Lars Wegner

Thank you, Ahu. Excellent question. Yes. EVX-02—so maybe on this call are probably aware is our DNA technology. We already successfully set up personalized manufacturing process for our peptide technology in EVX-01. EVX-02 is a different process. We are actually already now capable of manufacturing dedicated and personalized medicine in 10 to 12 weeks with the DNA in our first trial. We expect that we will continuously improve the speed. This is of course super important in the planning of our EVX-02 and EVX-03 future trials, because the manufacturing process needs to be controlled and fast to have a high likelihood of success in the clinic. So, we are very happy with actually being able to manufacture for all patients in our

trial. So, it basically creates a foundation and experience to be able to execute well on a Phase 2b with the both EVX-02 and potentially EVX-03.

Ahu Demir

Very helpful. My second question is on the Personalis' ImmunoID NeXT Platform. I know you claim to implement that. When are we expecting to see data, and maybe a bit more color, what it would include would be very helpful?

Lars Wegner

So, just to clarify around the AI-DeeP platform, our prediction platform, right, did I hear correct?

Ahu Demir

ImmunoID, I think that's for the biomarker part. That's what I understand.

Lars Wegner

Yes. So, as we also shared previously with the market, based on the micro environment, and expression (phon) profiles around the immune system, our AI system is actually capable of selecting which patient will actually react to immune therapy, both our and checkpoint inhibitors. That's what we've seen with the data we have had available from our current clinical trial. That's of course not a huge number of patients. So, what we're doing now to validate this, because if we can validate this, we definitely have a product that the world has been looking for for a very long time. That's basically our plan. It's quite simple.

So, first of all, we will, of course be collecting data for our existing trials and future Phase 2b, but we're also working with different groups that are already running clinical trial, where we could get a lot faster access to that data already and that we expect to materialize during this year. So, that means we have enough data to validate this on a larger external database. It's of course something we're looking very much forward to both publish, but also share with the world as a lot of diagnostic companies have been looking for technologies like this.

Ahu Demir

Sounds great. Thank you very much for taking my questions.

Lars Wegner

You're welcome.

Operator

Thank you. Our next question is from Thomas Flaten with Lake Street. Please go ahead.

Thomas Flaten

Hey, good morning. Thanks for taking the questions. Just two for me. Now that the enrollment is complete in EVX-02, optimistically, when do you think would be the first time we could see a data readout on that?

Lars Wegner

So, that we expect to be able to share next year. As you know, this is in the adjuvant melanoma setting, which really means we are looking for relapses, right? That's people that actually after operation and receiving our therapy together with the standard of care. How many actually relapse? That do take some time in this setting. So, we will have to follow the patients for a number of months before we start getting events.

So, we can share interesting clinical data, what we will be sharing and already have been sharing and also will share more data around, will be the safety, immunological profiling, etc., and are people actually reacting to the therapy by creating a strong T-cell response, which we've seen in patients so far. But we still of course have patients that are going in and getting the therapy. So, in '22 more immunological safety data, clinical efficacy, we expect to be able to share that on this cohort of patients in '23.

Thomas Flaten

Great. Then with respect to the regulatory submissions for EVX-01 in the EU and the U.S., could you just give us some sense of which one will be first and when we might expect those?

Lars Wegner

Yes. So, we're not guiding on the exit (phon) dates for it. But I can share with everyone that the process is moving according with what we planned. We are expecting first in EMA and started up in Europe and then FDA and high level timelines would be one of these for basically each quarter. So, two to three months apart, we'll start up the new sites and new jurisdictions for that trial.

Thomas Flaten

Then finally the legal proceeding with SSI around CAF09. Could you just maybe provide some color around that if there's any material risk to the conduct of the studies?

Lars Wegner

No, there's not. So, this is a minor part of one of our programs, our EVX-01 program, which consists of the PIONEER platform, our peptides, and then we use CAF09 as adjuvant for this therapy. The only discussion we currently have around SSI, we already have a license to CAF09. So, it's not really something that will block any of our (inaudible) regardless of how this actually ends up. What we are not agreeing on is who has the inventorship (phon) on using CAF09 broadly in high dose.

So, it's a small part of that. We are a bit surprised that they went in that direction. But of course, we are also happy that our inventions are so attractive that other people wants to grab it. But, it will have no impact on our EVX-01, no previous collaboration on the Phase 2b, or our possibility to utilize this commercially, regardless of the outcome as we have a license to CAF09 already with SSI.

Thomas Flaten

I appreciate you taking the questions. Thank you so much.

Lars Wegner

No problem. Thank you. I think this concludes the Q&A session for today. I'll hand it over to the Operator and want to thank everyone for your time.

Operator

Thank you. This concludes today's conference. You may disconnect your lines at this time. Thank you for your participation.