Evaxion Biotech A/S

Third Quarter 2021 Earnings Call

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CORPORATE PARTICIPANTS

Corey Davis, *Investor Relations, LifeSci Advisors LLC*

Lars Wegner, *Chief Executive Officer*

Niels Moeller, *Co-Founder, Chief Business Officer & Interim Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Kevin DeGeeter, *Oppenheimer*

Thomas Flaten, *Lake Street Capital* Markets

Ahu Demir, *Ladenburg Thalmann*

PRESENTATION

Operator

Greetings. Welcome to Evaxion Biotech Third Quarter 2021 Earnings conference call.

As a reminder, this conference is being recorded.

I would now like to turn this conference over to your host, Mr. Corey Davis from LifeSci Advisors. Thank you, sir. You may begin.

Corey Davis

Thank, Lauren. Hello, everyone. Thanks for joining us.

Let me quickly remind you that the following discussion contain 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 annual report on Form 20F for the fiscal year ended December 31, 2020 as filed with the SEC on April 7 '21 and in the Company's subsequently filed SEC reports.

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, Cory. Good morning, everyone. Thank you for joining us for this Evaxion Biotech Q3 Earnings call. I'm Lars Wegner, Chief Executive Officer of Evaxion. With me today is Evaxion's Co-Founder and Chief Business Officer, Niels Moeller, who is currently Interim Chief Financial Officer.

We'll give you a short presentation on our business and results and then open up the call for your questions.

Let me begin by saying Evaxion has continued to make very encouraging clinical progress in the third quarter of '21 towards our goal of becoming a world leader in AI-driven immune therapies. As many of you know, Evaxion specializes in decoding the human immune system and using the data to rapidly discover and develop potential effective drug candidates to improve the life of patients with cancer and infectious disease. We believe that our AI models allow us to identify unique drug targets which may translate into a higher likelihood of clinical success.

In July of this year, '21, we reported data which supported advancing two of our lead cancer vaccine programs into Phase 2b clinical trials. The Phase 1/2a result of our EVX-01 program showed that 67% of the patients benefited from EVX-01 in combination with anti-PD-1 for the treatment of metastatic melanoma compared to historical data of only 40% benefitting from the checkpoint inhibitor alone. We also observed a complete response rate of 22% compared to the historical data of only 7% benefiting from checkpoint inhibitor alone. The Phase 2b clinical trial of EVX-01 in melanoma is planned to start at the end of 2021.

Last month, we announced a clinical trial and supply agreement with subsidiaries of Merck, one of the world's leading immuno-oncology companies, to supply anti-PD-1 therapy KEYTRUDA in this trial, as well as collaborating on the trial design.

In addition, EVX-02 showed T-cell activation in adjuvant melanoma and appear to be well tolerated. We intend to submit a regulatory filing for a Phase 2b clinical trial of EVX-02 in combination with EVX-03, our novel patient-specific therapy for multiple cancer indications, as a combination therapy with anti-PD-1 in adjuvant melanoma in the first half of '22.

The EVX-01, 02 and 03 products all come from our PIONEER AI platform which generate patient-specific cancer immune therapies.

In other clinical developments, we remain on track for a regulatory filing for a clinical trial in the second half of '22 for the lead candidate on our EDEN platform, which generate vaccines against bacterial diseases. This program EVX-B1, is a vaccine for the prevention of S. aureus and skin and soft tissue infections. We also expect to select the first viable candidate from our RAVEN platform in the second half of '22.

Outside of the clinic, Evaxion received this year's Enabling Technology Leadership Award in the artificial intelligence-enabled drug discovery industry by leading global research and consulting firm, Frost & Sullivan. We are honored to receive the award and I'm very proud of the hard work and commitment of the whole Evaxion team in advancing our vision for better global health.

Evaxion also gave a presentation at the Immuno UK conference, which was held in London last month. One of our senior scientists, Dr. Emma Christine Jappe, introduced Evaxion's AI immunological core technology and detailed how the Company is using AI to decode the human immune system. She focused on PIONEER and demonstrated how Evaxion is continuously working to improve the platform through immunological data generation and the development of optimized AI models.

This concludes our business and operational update for Q3 2021. I will now turn the call over to Niels for news of our follow-on public offering and the Q3 financial review.

Niels Moeller

Thank you, Lars.

I'll begin with the news that later today we expect to close our follow-on public offering, which was multiple times over subscribed and which included the full exercise of the underwriter's overallotment option, for which we announced the pricing on November 4, 2021, and which we expect will raise gross proceeds of approximately US$27.6 million before underwriting discounts and commissions and other offering expenses. This follows on from our IPO in February 2021, which raised net proceeds of US$27.9 million after underwriting discounts and commissions but before offering expenses.

As of September 30, 2021, cash and cash equivalents were US$11.9 million compared to US$5.8 million as of December 31, 2020. We expect the net proceeds from our FPO and our IPO, along with our existing cash reserve will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from September 30, 2021.

Research and development expenses were US$4.4 million for the quarter ended September 30, 2021, compared to US$3.0 million for the same period in 2020. The increase of US$1.4 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 the higher headcount.

General and administrative expenses were US$1.5 million for the quarter ended September 30, 2021, compared to US$1.7 million for the same period in 2020. The decrease of US$0.2 million was primarily related to the higher share-based compensation in the period ended September 30, 2020 due to accelerated vesting period and sign-on warrants issued associated with the IPO.

Net loss was US$5.3 million for the quarter ended September 30, 2021 or $0.27 loss per basic and diluted share, compared to US$4.0 million, or $0.26 loss per basic and diluted share, for the same period in 2020.

Lars Wegner

Thank you, Niels. That concludes our presentation today. Now it's time to open up the call for any questions.

Operator

Our first question comes from the line of Kevin DeGeeter with Oppenheimer. You may proceed with your question.

Kevin DeGeeter

Hey guys. Thanks for taking my questions. Maybe two or three from us. First, with regards to the Phase 2b study of EVX-01, can you just comment on general study design, specifically how you're thinking about any interim analysis and recognizing—so still very early days but a potential timeline to and interim analysis on the 2b study? Thanks.

Lars Wegner

Thank you, Kevin. I think this is a really relevant question. We expect our study to have its regulatory filing this year and in the first patient next year. We are recruiting a hundred patients and we expect we'll be able to do that pretty rapidly. We're going to open up centers in the U.S., Europe and Australia, and this allows us already to have the first interim in '23 and then a full year readout on all patients already in "24.

I hope that answers your question.

Kevin DeGeeter

And then with regards to—it does. Super helpful. And then with regard to patients that were previously enrolled on EVX-01 or EVX-02 in the Phase 2 (inaudible) studies, are any of those patients still on therapy or on active follow-up? And I guess, sort of as we're waiting for this 2b data on EVX-01 to mature, what additional clinical updates can we hope to get from previously enrolled patients?

Lars Wegner

Yes. On EVX-01, we still have patients in the study and we expect to look at the data again in the second half of next year. So we'll be able to have more data out of our Phase 1/2a in EVX-01, of course. EVX-02 is still ongoing and we expect to have the readout by '23, probably first half of '23. We also expect that EVX-02 will finalize recruitment already this year. And that's in adjuvant melanoma.

Kevin DeGeeter

Right. And then just lastly, maybe more of a general question. The (inaudible) meeting will be ongoing later in the week. I think many of those abstracts are now available. I guess, on a more general level, how do you see the competitive landscape currently, specifically in melanoma, and perhaps you can position the 2a data on EVX-01 in the context of what's a continually evolving competitive landscape? Thank you for taking our questions.

Lars Wegner

Yes, good question. We're extremely happy with the data coming out of our EVX-01 and 02 trial. We saw a more than 50% increase in the (inaudible) response rate, something we expect that we'll be able to mirror in our Phase 2b study. That's a very competitive product compared to other combination studies that are ongoing. Of course, we are looking also forward to seeing some of the new checkpoint inhibitor combination trials, such as with LAC2 (phon) and see the details of those data, but so far we have not seen all those details so we can compare. We do believe we have a large competitive edge towards all these combination therapies, combining two monoclones as the safety profile of EVX-01 appears to be extremely favorable compared to checkpoint inhibitors. One of the main reasons for people not receiving combos is that safety profile of these combined therapies are not favorable.

Kevin DeGeeter

Thanks for taking our questions.

Lars Wegner

You're welcome.

Operator

Our next question comes from the line of Thomas Flaten with Lake Street Capital Markets. You may proceed with your question.

Thomas Flaten

Great, thank you. Good morning guys and thanks for taking the questions. Lars, mechanically, on the regulatory filings we'll see, will you do all three regions this quarter or is there going to be some staggering effect where you might see, let's say the EU file this year, then an IND next year? Can you just walk us through some of the details on that?

Lars Wegner

Yes, it's a very relevant question. We expect to start out in Denmark, EU, Australia as a first step. It depends on if it's EVX-01 or 02. But for EVX-01, we expect to file in a staggered approach. So it will be EU to start with, then Australia and U.S. following right after. For EVX-02, it will start when we start the combination trial. It will start in Australia and then right after we're going to file in Europe and the U.S. probably at the same time, and shortly thereafter within months.

Thomas Flaten

Got it. And then I was curious, it looks like there's a bit of a delay in selection of the first candidate from RAVEN. I was wondering if you could comment on that.

Lars Wegner

Yes. We like to be guided by data and we are generating data in the preclinic right now. We're developing the RAVEN technology to be broadly applicable across all viruses but right now we're of course working on COVID-19 due to the non-dilutive funding we have received based on that data, but also on data and evaluation of other viral candidates. We want some data before we make that decision and that will be first ready in around Q2 of next year, and then we'll make the decision of which one is going to be wrapped up and put into the clinic.

Thomas Flaten

And then finally, you mentioned there was going to be some collaboration with Merck on the clinical study design. I don't know if you can comment on that but I'm curious to hear what kind of input you've received from them with respect to the design you laid out back in July.

Lars Wegner

Yes, I'm not going to share Merck and what they share with us, unfortunately, on this call, but, of course, we are working with their team. They have excellent team of clinicians. They also understand this first line metastatic setting, I think, better than most. They are one of the market leaders in that indication and they have access to a lot of interesting data that basically guides Phase 2b designs. They also recently actually published this data in a very, very nice publication on their two pivotal trials in metastatic melanoma, KEYNOTE 001 and 006, and that data, I think, was a bit surprising to many and many clinicians when they looked at it because there was still high medical need, but there was also some clear documentation on how you design a good Phase 2b, and that's what we've been working on and have finalized here a few weeks ago.

Thomas Flaten

Excellent. I appreciate you taking the questions. Thank you.

Lars Wegner

Thank you.

Operator

Our next question comes from the line of Ahu Demir with Ladenburg Thalmann. You may proceed with your question.

Ahu Demir

Hello, everyone. Thanks for taking my question, Lars, Niels. Congrats on the recent development. It has been a dynamic couple of weeks for the Company. My first question is on Phase 2b trial of EVX-02 and 03. Could you maybe comment on the clinical trial design? Do we expand to see interim results? And lastly, on that question is, do we expect the clinical collaboration with Merck? Are there any discussions around that?

Lars Wegner

Thank you. Good question. The design, we are combining our two DNA technologies into a three-arm study in adjuvant melanoma with people with high risk of recurrence, and that's because then you can get a fast readout after already a year. And that means it's going to have three arms with 75 patients in each; one arm getting checkpoint inhibitor, one arm getting checkpoint inhibitor plus EVX-02, and one arm getting checkpoint inhibitor plus EVX-03. We look very much forward to starting this trial because there is a high unmet need in this group. More than 30% of the patients even on checkpoint inhibitor relapse within one year after their operation.

So, we're looking very much forward to that study. Of course, we are discussing with all the relevant parties that have checkpoint inhibitors in this indication if it makes sense to collaborate on a study like this. There are two products approved on that indication and that is Merck's product, KEYTRUDA and Opdivo from BMS. Our plan in this setting will be only to include our product with the market leaders that are approved in that indication. So that gives us basically two groups to discuss with, which we are, of course, always discussing with on an ongoing basis.

I hope that answered the question.

Ahu Demir

Yes, it did, definitely. My second question is on EVX-B1. Can you maybe comment on what stage of (inaudible)? What are we expecting to see maybe prior to the IND filing?

Lars Wegner

We have, of course, now prepared the product for tox (phon), so it's really in the preclinic. We will be sharing the data update on the very comprehensive preclinical data package on our staph program in the upcoming three quarters. The final time has not been decided, but we'll be looking forward to sharing that data on that program as the preclinical package is very impressive, if you ask us.

So, it will be basically doing the tox and setting up the manufacturing that is currently driving it and then an IND filing by the end of next year.

Ahu Demir

That sounds great. And my last question will be on the capital raise, probably to Niels. How long did you extend your cash runway with this capital raise?

Niels Moeller

Yes, right. So what we have communicated is that the expected net proceeds from our IPO and obviously also our FPO combined with our existing cash reserves will be sufficient to fund our operating expenses and also the capital expenditure requirements through at least 12 months from September 30 of this year, 2021.

Ahu Demir

Thank you so much for taking my questions. Thank you.

Lars Wegner

You're welcome.

Operator

Ladies and gentlemen, we have reached the end of today's question-and-answer session. I would like to turn this call back over to Mr. Lars Wegner for closing remarks.

Lars Wegner

Thank you, Laura, and thank you all for your questions and your interest in Evaxion. In summary, we believe that we have made some exciting clinical progress in the third quarter of '21 with data supporting the advancements of both our lead cancer programs into Phase 2b clinical trials. Our cash reserves of $11.9 million as of the end of the third quarter combined with the follow-on financing provide a solid financial foundation and will facilitate the continual development of our lead programs.

This concludes this call of our Q3 '21 results, and we look forward to speaking to you all next time. Thank you.

Operator

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