Evaxion Biotech A/S

Fourth Quarter and Full Year 2021 Earnings Call

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CORPORATE PARTICIPANTS

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

CONFERENCE CALL PARTICIPANTS

Kevin DeGeeter, *Oppenheimer*

Thomas Flaten, *Lake Street Capital* Markets

Ahu Demir, *Ladenburg Thalmann*

PRESENTATION

Operator

Greetings, and welcome to the Evaxion Biotech Fourth Quarter and Full Year 2021 Earnings Call.

As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Mr. Corey Davis.

Thank you, sir. Please go ahead.

Corey Davis

Thanks, Donna.

Hello, everyone. Thanks for joining us.

Let me quickly remind you that today's 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.

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 call over to Lars Wegner, the Company's President and CEO.

Go ahead, Lars.

Lars Wegner

Thank you, Corey.

Good morning, everyone. Thank you for joining us for this Evaxion Biotech Q4 Earnings Call.

I'm Lars Wegner, the Chief Executive Officer of Evaxion. With me today is Evaxion's Co-Founder and Chief Business Officer, Niels Moeller, who is currently the Interim Chief Financial Officer. We'll give you a short presentation on our business and results and then open the call up for any questions you may have.

Let me begin by saying Evaxion continues to demonstrate exciting clinical momentum in the fourth quarter of 2021 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 discovery and develop potential effective drug candidates to improve the lives of patients with cancer and infectious diseases. We believe that our AI models allow us to identify unique drug targets which may translate into a higher likelihood of clinical success.

In October 2021, we announced a clinical trial collaboration and supply agreement with Merck, one of the world leading immuno-oncology companies, to evaluate the combinations of Evaxion's cancer immune therapy EVX-01 in combination with Merck's KEYTRUDA in a Phase 2b clinical trial in patients with metastatic melanoma.

In January 2022, we received regulatory clearance to initiate this Phase 2b trial of EVX-01 with KEYTRUDA. We plan to have the first patient's first visit for EVX-01 in the first half of 2022.

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 for EVX-01/03 in patients with resectable melanoma by the first half of 2022 and have first patient first visit by second half of 2022.

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

In other development areas outside cancer, we remain on track on the lead candidate on our EDEN platform, which generates vaccines against bacterial diseases. This 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 first half of 2022. We plan to select the first viral candidate from our RAVEN platform in the second half of 2022.

Outside of the clinic, we closed our follow-on public offering in November 2021, raising net proceeds of US$24.9 million.

Evaxion also received the 2021 Enabling Technology Leadership Award in the artificial intelligence-enabling drug discovery industry by the leading global research and consulting firm Frost & Sullivan. We're 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 U.K. conference which was held in London. One of our senior scientists, 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 updates for Q4 2021.

I will now turn the call over to Niels for news on our follow-on public offering and the 2021 financial review.

Niels Moeller

Thank you, Lars.

As Lars mentioned, we closed our follow-on public offering in Q4, 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, which raised net proceeds of US$24.9 million including underwriting discounts and commissions and other offering expenses. This follow-on is from our IPO in February 2021, which raised net proceeds of US$27.9 million after underwriting discounts and commissions but before offering expenses.

We also completed a drawdown and received our first tranche of €$7 million, approximately US$7.7 million, from the European Investment Bank loan on February 17, 2022.

As of December 31, 2021, cash and cash equivalents were US$32.2 million as compared to US$5.8 million as of December 31, 2020. We expect that the net proceeds from our IPO and our FPO, the proceeds from drawdowns and amounts available under the EIB loan, and our existing cash and cash equivalents 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$19.6 million for the year ended December 31, 2021, as compared to US$10.9 million for the year ended December 31, 2020. The increase was primarily related to the increased spending, net of grant income, for ongoing development on our platforms, preclinical product candidates, and clinical trials. In addition, employee-related costs increased due to the higher headcount.

General and administrative expenses were US$6.3 million for the year ended December 31, 2021, as compared to US$5.7 million for the year ended December 31, 2020. The increase was primarily due to an increase in professional fees related to the expansion of our corporate function for our initial public offering, partially offset by the decrease in employee-related counts.

Net loss was US$24.5 million for the year ended December 31, 2021, or $1.26 loss per basic and diluted share, as compared to US$15 million, or US$0.97 loss per basic and diluted share, for the year ended December 31, 2020.

Lars Wegner

Thank you, Niels.

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

Operator

Thank you. Our first question is coming from Kevin DeGeeter of Oppenheimer. Please go ahead.

Kevin DeGeeter

Hi. Thanks for taking our question.

Can you comment on the recent approval of the first of the LAG-3 antibodies in a fixed combination with a PD-1? Do you sort of see that compound just serving a similar or different patient population relative to one? And just any thoughts how that approval may or may not impact potential patient enrollment for the 01-2b study. Thanks.

Lars Wegner

Thanks, Kevin, and good questions.

We've all been following the development of the combination of checkpoint inhibitors in this field and especially the large trial with LAG-3. It was expected to pan out as we saw. We do see that the landscape in metastatic melanoma is changing. It is an ever-changing landscape that we need to monitor, both for clinical trial and commercial opportunities for your compound. We don't see a big challenge in it. We see that the market space is developing. We see this data as being a decent potential for patients in this space. It's also still actually shown to be pretty toxic, a bit more than I actually expected.

Good efficacy results, but a lot of toxicity still. It will, of course, play a role. I think we have a very unique value proposition with the combination of PD-1 and EVX-01 due to the fact that EVX-01 is a really precise medicine, which means you are truly only targeting the cancer cells. This allows for very clear-cut efficacy, but it also allows for having very limited off-target effect. The majority of the side effects you see, of course, on PD-1 and also LAG-3 is off-target effects. That means we believe we will have effective therapy, but also very well tolerated therapy, almost in the line of monotherapies with checkpoint inhibitors.

We definitely believe there's a huge place for therapies that are this precise with this efficacy and safety profile. Thank you.

Kevin DeGeeter

Great. Thank you for that. And then maybe as our follow-up, I think you called out first half of the year for first patient dosed in the Phase 2b for the EVX-01. Can you comment on number of sites either open or expected to be open in the first half? Any thoughts, even if preliminary, on potential pace of enrollment?

Lars Wegner

Yes. We just got, as we also announced, clearance in Australia where we will set up multiple sites, and that's already in the working. So that will be the place where the first patients will start approving, and then we will down the road receive clearance in EU and the U.S. and start sites there.

It will start in multiple sites in Australia, and that's already in the making. I believe we are on track on that. And then EMA and FDA following that.

Kevin DeGeeter

Thanks for the update.

Lars Wegner

You're welcome.

Operator

Thank you. Our next question is coming from Thomas Flaten of Lake Street Capital Markets. Please go ahead.

Thomas Flaten

Hi, guys. Thanks for taking the question.

Just to follow-on to the prior answer, Lars. Can you give us some sense of timing for the submission to EMA and FDA for clearances in the U.S. and Europe?

Lars Wegner

Yes, I could give an idea. We have not communicated specifically to the market on the timing. We're already in dialogue, and have been for some time, both with EMA and FDA. We do not expect a lot of hiccups in that process, so we believe it will follow as we're currently planning. We're not setting an exact time, but it will be as fast as possible. We're already in dialogue and we see no dark clouds in the horizon. So we're quite happy with our regulatory interactions so far.

Thomas Flaten

Just to go back to the PD-1/LAG-3 combination, given that you're bringing in patients who are on background pembro, do you see any shift in standard of care where ethical considerations could be raised in terms of treating patients with what some would argue would be the older standard of care as opposed to new standard of care, especially here in the U.S. where it'll be on the market first?

Lars Wegner

Yes. If you asked me that question two years from now, we would potentially have decided differently, but first of all, it's not a sure thing that it will be standard of care. There are still other combinations. Right now people are getting either a checkpoint inhibitor as a monotherapy, a checkpoint inhibitor plus a CTLA-4, which is pretty toxic, and now a new one entering with a checkpoint inhibitor, plus LAG-3 that still is quite—I think it's double the rate of people that have to discontinue due to side effects compared to monotherapy. So there are patients in all those groups today, even though they are combos approved.

I believe there will be three groups of patients also in the future, also in two or three years, which is checkpoint inhibitor/monotherapy, then checkpoint inhibitor/LAG-3, and then potential checkpoint inhibitor and IPI, that might fade out with the LAG-3 data. But those patients that cannot tolerate combinations, they will also always be there.

We don't see a huge issue, as we plan to recruit we're rapidly to recruit in the patient population on monotherapy. I don't think the LAG-3 will enter into the other markets. Even when it has entered, we're pretty confident there'll still be a large pool of patients. It's still quite a large pool of patients getting monotherapy, and that pool will remain there.

And then the next question comes in the planning of a future Phase 2, should we consider triple therapy. That's definitely something that every company in this space should be considering if they have a therapy that is well tolerated as ours. But right now, we don't see any major issues in the recruitment, as we will be recruiting over next year.

Thomas Flaten

And then just one final one if I may. On EVX-02/03, you said you're going straight to regulatory filing following on the completion of enrollment in the study. What data will you be taking to the regulatory agencies, and is there any interim data that you'll be sharing with them that we won't see on any success you've had in the 02 study so far?

Lars Wegner

Yes, we have not announced. We have more data as the program has matured, and that will be shared with the regulatory authorities. We also plan, of course, to share that with the community outside the regulatory authorities. The exact timing of that, we haven't disclosed, but we do expect to be sharing that data later this year, as it is needed for our regulatory processes of our Phase 2b as well.

Thomas Flaten

Excellent. Thanks, guys, for taking the questions.

Lars Wegner

Yes, Thomas. But it will be an interim, because it's an adjuvant melanoma and the full readout will be when we have the full year follow-up on the last patient.

Thomas Flaten

Great. Thank you.

Lars Wegner

Thank you.

Operator

Thank you. Our next question is coming from Ahu Demir of Ladenburg Thalmann. Please go ahead.

Ahu Demir

Hello, Lars, Niels. Thanks for taking my question.

I would like to ask about the AI-DeeP drug response platform. What are the aspects that you use and how it might be implemented in the ongoing and future trials? Also a follow-up question on the same line is, can it be applied to three of the platform aspects, PIONEER, EDEN and RAVEN? Could you comment on that please?

Lars Wegner

Thank you, Ahu. Great questions. Our AI-DeeP is a drug response platform. Based on our current data, it seems that, based on the immunological profiling of the tumor micro environment, we're able to predict which patients are actually responding to immune therapy and which are not. Right now, we're working on validating that in a larger data set, not from our own clinical trials, but from collaborators. When we have that data, we will be developing the AI-DeeP as a drug prediction platform, but it will not be 100% related

just to our programs, because we believe it can actually predict on all immunological active drugs, such as checkpoint inhibitor, LAG-3, etc. We are also developing a business model for that that will be different than our normal drug development path.

It's a super exciting platform. Here in 2022, we will validate it in a large data set. If it pan outs showing the same data as it did on our Phase 1/2a, we definitely have a drug response platform, and when that is validated, we will of course also implement it in our own clinical trial going forward. But right now, we believe it's too early with not enough patients to include it. The only way to include it is actually we are grabbing data from our current trials to actually train the AI system to perform even better.

The AI-DeeP are uniquely for cancer. It is based on biopsies and how the tumor micro environment is actually expressing different genes. That means it's primarily relevant for our PIONEER platform and not so much for EDEN and RAVEN.

I hope that answered the question, Ahu.

Ahu Demir

Yes, that's very helpful. My other question would be on the EDEN platform. What point of the IND-enabling studies are you currently doing for EVX-B1 program as you are preparing for the IND filing in the second half?

Lars Wegner

That's our Staph aureus vaccine program. As many of the callers are aware of, it's a huge medical problem. There are no cures and vaccines approved. The path to the clinic, which is a Phase 1 in healthy volunteers, is of course to finalize the tox package. That's a larger milestone that is ahead of us on EVX-B1.

Ahu Demir

My last question would be about the clinical sites as well. Does the Ukraine war impact? Do you have a site there, and does it impact the expected enrollment by any means for the company?

Lars Wegner

That's another good question. We are all concerned about what's happening in Ukraine. Luckily it does not impact any of our businesses. We don't have collaborators. We don't have sites. We don't plan to have sites. So we don't expect that at its current stage will influence our programs. Just as we were, in the last couple of years, been battling COVID, we were able to actually successfully run our clinical trials. We're confident that we can also do that. Of course, all depending if the situation develops into another direction. But currently as things are, we don't expect any direct impact on Company performance.

Ahu Demir

Thank you.

Lars Wegner

Perfect. Back to you, Donna.

Operator

Thank you.

Ladies and gentlemen, this concludes today's question-and-answer session and today's event. You may disconnect your lines at this time. I'll log off the webcast. We thank you for your participation, and enjoy the rest of your day.