Evaxion Biotech A/S

Second Quarter 2022 Earnings Call

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CORPORATE PARTICIPANTS

Corey Davis, *Investor Relations*

Lars Wegner, *President and Chief Executive Officer*

Bo Karmark, *Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Thomas Flaten, *Lake Street Capital Markets*

PRESENTATION

Operator

Good morning, and welcome to the Evaxion Biotech Second Quarter 2022 Earnings Call.

I would now like to turn the conference over to Corey Davis. Please go ahead.

Corey Davis

Thanks, Joe, and hello, everyone. Thanks for joining us this morning.

Let me quickly 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're 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 20-F filed on March 31, 2022, and the company's current and future reports filed with or submitted to the Securities and Exchange Commission.

At this time, I'm pleased to turn the call over to Lars Wegner, the company's President and CEO.

Lars, take it away.

Lars Wegner

Thank you, Corey. Good morning, everyone. So thank you for joining us for this Evaxion Biotech Q2 Earnings Call. I'm Lars Wegner, the Chief Executive Officer of Evaxion, and with me today is Evaxion's Chief Financial Officer, Bo Karmark. We'll give you a short presentation on our business and results and then open the call up for your questions.

Let me begin by saying that Evaxion announced multiple exciting milestones in the second quarter of 2022.

Starting with our oncology program. In May 2022, we announced a successful production using our PIONEER AI platform of all batches of personalized cancer immunotherapy for all patients enrolled in our Phase I/IIa clinical trial of our EVX-02 product candidate for resectable melanoma, demonstrating once

again that Evaxion runs a feasible and efficient production chain and that we will successfully manage to provide a truly unique and personalized therapies within this critical time window. The ongoing clinical trial is expected to be finalized according to plan with a full clinical readout in the first half of 2023.

In June 2022, we announced the expansion of our third cancer immunotherapy program, EVX-03, into a new indication, non-small cell lung cancer, due to encouraging data in preclinical studies. We intend to submit regulatory filing for our Phase I/IIa clinical trial in the second half of 2022.

In addition, we plan—as planned, we expect to begin the Phase IIb combining EVX-01 with Merck's KEYTRUDA for the treatment of patients with metastatic melanoma in the second half of 2022.

We believe that these significant steps, including the progression of our clinical programs and the successful manufacturing of our EVX-02 personalized cancer therapy, highlight the potential for our existing pipeline of cancer therapies to improve the treatment landscape in melanoma, non-small cell lung cancer and eventually other cancers.

In our bacteria program. In June 2022, we announced gonorrhea as the second bacteria target for treatment with our EVX-B2 product candidate that we developed using our EDEN platform. We plan to select our first viral candidate from our RAVEN platform in the second half of 2022. As you may know, Evaxion's business model is to develop our programs through Phase II before seeking to out-license them. We are actively discussing potential partnership with multiple pharmaceutical and biotechnology companies.

Outside of the clinic, we also hosted a key opinion leader webinar with acclaimed experts on metastatic melanoma and personalized cancer immunotherapies.

As of June 30, 2022, our cash reserve totaled USD 25.3 million. We expect these funds, including a use of financing facilities, to support our product development efforts for the next 12 months. The Company also entered into an equity financing arrangement for up to $40 million with Lincoln Park Capital Fund, LLC, to further strengthen our financial resilience.

This concludes our business and operational update for Q2 2022. I will now turn the call over to Bo for our second quarter 2022 financial review.

Bo Karmark

Thank you.

As Lars mentioned, in the second quarter of 2022, we entered into an equity financing agreement for up to USD 40 million with Lincoln Park Capital Fund. As of June 30, 2022, cash and cash equivalents were USD 25.3 million as compared to USD 32.2 million as of December 31, 2021. The decrease in cash and cash equivalents during the first six months of 2022 was primarily related to our operating expenses for the first six months of 2022, partly offset by proceeds received from the first tranche of our loan from the European Investment Bank. We expect our expected cash and cash equivalents, including use of financing facilities, will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months.

Research and development expenses were USD 4.1 million for the three months ending June 30, 2022. This is compared to $5.1 million for the same period in 2021. The decrease was primarily due to lower external costs related to the clinical trials. General and administrative expenses were USD 2.1 million for the three months ending June 30, 2022, as compared to USD 1.9 million for the same period in 2021. The slight increase was primarily due to an increase in fees associated with the expansion of our business as a listed company. Net loss was USD 4.8 million for the three months ended June 30, 2022, or $0.2 loss per basic and diluted shares compared to USD 6.8 million or $0.36 loss per basic and diluted shares for the three months ended June 30, 2021.

Lars Wegner

Thank you, Bo.

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

Operator

Our first question will come from Thomas Flaten with Lake Street Capital Markets. Please go ahead.

Thomas Flaten

Good morning, guys. I appreciate you taking the questions.

Lars, I was curious if you could comment on the ongoing delay in first patient in for the Phase IIb EVX-01 study. It's been a while since you guys got clearance. I know you were screening patients actively, but I was just hoping you could provide some color around that.

Lars Wegner

Yes. And good question, and thank you for that. So we actually had the first initiation of the first site actually today. We plan to open 25 sites, and we have patients being screened as we speak. So we are expecting actually the first patient to be starting very, very soon. We had a smaller delay compared to what we actually announced earlier this year, which was primarily due to logistics and planning. We expect to be able to actually get that delay kind of cut back during the next couple of months so it will not influence any of the readout of EVX-01. But we are actually quite happy that the initiation of the first site was actually today. And then we are, of course, opening up additional 24 sites to have a fast recruitment so we will expect to have the readout as planned.

Thomas Flaten

Any updates on the regulatory submissions in the EU and U.S. for EVX-01?

Lars Wegner

Yes. That's actually moving according with plan. We start the first five sites actually in Australia, and then we plan to open up in Europe. We will, of course, also announce when we have the first sites up and running in Europe and U.S. But that is moving according with the plan. But the first five sites will be opened in Australia, where we have actually also a lot of experience in running our previous trial such as EVX-02 and where we also have a very, very broad KOL network with people like Georgina Long.

Thomas Flaten

One kind of nonclinical question. Any—I know it's only been a few weeks since your transition was announced, but any updates on timing of transition from the old company to the new company, etc., for the incoming CEO?

Lars Wegner

We expect to be able to announce the exact date within a matter of weeks as, of course, our new CEO, Per, will have to arrange that with his current company. So I will expect to have a firm date within a matter of weeks. And of course, we hope he will start soon so we can have a very, very solid transition. But regardless of how and when he's starting, I am not—so I probably also mentioned earlier, leaving for another company, so I will be there to help out as long as needed.

Thomas Flaten

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

Lars Wegner

Thank you.

Operator

Our next question will come from Ahu Demir with Ladenburg Thalmann. Please go ahead.

Male Speaker

Hello, everyone. Thank you for taking my question. This is (Inaudible) for Ahu Demir. I have two questions.

Can you please give us more details on the EVX-03 in non-small cell cancer in terms of the patient population, treatment regimens and time line? And my second question is, could you please give us some information on the data from the platform AI-DeeP to predict responders and nonresponders? When can we see the data and in what format?

Lars Wegner

Thank you, and very good questions. So let's start with the first one, on non-small cell lung cancer. So right now, of course, we are in the midst of preparing for that trial. And we are targeting first-line metastatic non-small cell lung cancer in combination with checkpoint inhibitors. We have also announced that we expect to do our regulatory filing in the second half of '22, and we expect to be able to deliver on that. More details on the different time lines we will be sharing in the upcoming months as we progress on the submission. But we expect to be able to deliver on the time line that was also previously communicated when we launched the program.

AI-DeeP, which is a truly interesting platform that is able to predict who will respond to immune therapy in general, not just our immune therapy but also checkpoint inhibitors, we had some very interesting data when we have basically run all our patients through it. And it was very precise in being able to predict who responds to a combination therapy. Right now, we are actually gathering additional data to validate it on a data set from other studies. And as soon as we have that data and have run through AI-DeeP, we will be sharing that data. We don't have an exact time line for that, but our expectation is we'll be able to share data around the year shifting from '22 to '23 with a lot more patients and there—and that setting, of course, also what is our business model for this new platform.

Male Speaker

Okay, that’s really great. Thank you very much for taking my question.

Lars Wegner

You are welcome.

Operator

This will conclude our question-and-answer session. I'd like to turn the conference back over to Lars Wegner for any closing remarks.

Lars Wegner

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

Operator

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect your lines.