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Anavex Life Sciences Corp. (AVXL) Q3 2023 Earnings Call Transcript

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Anavex Life Sciences Corp. (NASDAQ:AVXL) Q3 2023 Earnings Conference Call August 8, 2023 8:30 AM ET

Company Participants

Clint Tomlinson - IR

Christopher Missling - President and CEO

Sandra Boenisch - Principal Financial Officer

Conference Call Participants

Soumit Roy - Jones Trading

Operator

Good morning and welcome to the Anavex Life Sciences' Fiscal 2023 Third Quarter Conference Call. My name is Clint Tomlinson, and I will be your host for today's call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session. [Operator Instructions] Please note that this conference is being recorded. The call will also be available for replay on Anavex's website at www.anavex.com.

With us today is Dr. Christopher Missling, President and Chief Executive Officer; and Sandra Boenisch, Principal Financial Officer.

Before we begin, please note that during this conference call, the company will make some projections and forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. We encourage you to review the company's filings with the SEC. This includes, without limitation, the company's Forms 10-K and 10-Q which identify the specific factors that may cause actual results or events to differ materially from those described in these forward-looking statements.

These factors may include, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights.

And with that, I'd like to turn the call over to Dr. Missling.

Christopher Missling

Thank you Clint and good morning everyone. Thank you for being with us today to review our most recently reported financial results and to provide our quarterly business update. We are very excited to be entering an important phase of the company with several key data readouts within the remainder of 2023 for blarcamesine.

First on Rett syndrome, in June we announced the completion of the placebo-controlled EXCELLENCE Phase 2/3 clinical trial RS-003 in pediatric patients with Rett syndrome and we're looking forward to the top-line data of this potentially pivotal clinical trial in the second half of 2023.

On June 12, we announced the publication of a new peer-reviewed study in the American Journal on Intellectual and Developmental Disabilities with relevance to this clinical trial entitled, Rett Syndrome Behaviour Questionnaire in Children and Adults with Rett Syndrome: Psychometric characterization and revised factor structure.

In the EXCELLENCE clinical trial, the Characterized Rett syndrome Behaviour Questionnaire, RSBQ, together with the clinical global impression improvement scale, CGI-

I represents the co-primary efficacy endpoints of the trial. This psychosomatic study is timely and significant as it provides additional support for the use of the RSBQ in children and adults as well as reference values and revised subscales for its improved use. We have also been further encouraged for the results of this upcoming data readout based on recent long-term clinical trial results from the U.S. ANAVEX2-73-RS-001 clinical trial which we announced end of June.

The long-term data demonstrated disease-modifying effect of blarcamesine for adult patients with Rett syndrome. Results from pharmacometric modeling of the full clinical data from baseline of the double blind study to the end of the open-label extension study indicated that the data are best characterized by a combined symptomatic and disease-modifying drug effect model meaning that blarcamesine exhibited both symptomatic and disease-modifying effects in the treatment of Rett syndrome in a clinical setting. Continued improvement from the drug as measured with the RSBQ total score was observed from the start of the double blind study to the end of the open-label extension for patients continuing on blarcamesine.

Additionally, disease progression which is defined as the change in Rett syndrome disease severity with time was also reduced with long-term treatment with blarcamesine. In Alzheimer's disease, we look forward to presenting, including in a scientific journal once available, the complete data set of the recently completed Phase 2/3 Alzheimer's disease trial of blarcamesine. With newly available preliminary efficacy results of surrogate biomarkers, we intend to initiate discussions with regulatory agencies in the context of the on-going clinical development of blarcamesine in this indication. With a goal of providing a much needed treatment for the millions of patients living with Alzheimer's disease in a convenient once-daily oral treatment. We expect to be able to announce this data also within the second half of2023.

Following on the encouraging results of our Parkinson's and dementia clinical trial, including the results of the 48-week open-label extension of this trial, which we announced at the end of March, we tend to use the same endpoints in a forthcoming pivotal study of blarcamesine in Parkinson's disease, which is currently in the planning stages and we look forward to announcing the significant milestones of this clinical trial initiation as they are executed.

Further, the pipeline expansions of the ANAVEX platform using gene biomarkers of

response applying precision medicine for neurological disorders is expected, including a planned initiation of blarcamesine imaging-focused Parkinson's disease clinical trial sponsored by the Michael Fox Foundation, a planned initiation of a potentially pivotal blarcamesine phase 2/3 clinical trial in Fragile X syndrome, and a planned initiation of a phase 2 clinical trial in ANAVEX 3-71in Schizophrenia.

We also are planning an initiation of a potentially pivotal blarcamesine trial phase 2/3 for the treatment of a new rare disease indication, which we announced accordingly. And we continue to expect clinical publications involving ANAVEX2-73, blarcamesine, and ANAVEX 3-71.

In conjunction with these planned clinical developments, we continue to strive to remain at the forefront of innovation. In June, we announced we entered into a strategic partnership with Partex Group to leverage artificial intelligence for drug development and healthcare sales marketing, potentially involving a digital healthcare sales marketing pharma platform with the overall ambition to reshape the future of the biopharma business model.

By combining ANAVEX's innovative small molecule precision medicine drug development platform and Partex's disruptive approach of AI-enabled drug development and healthcare sales marketing, this collaboration is intended to drive efficiency, effectiveness, and innovation across the value chain with patient-centric focused at every step.

Additionally, we continue to expand and strengthen our patent portfolio for blarcamesine with a new U.S. patent awarded expanding ANAVEX patent coverage of certain crystal forms of blarcamesine compositions, process of preparation, and uses thereof.

And now I would like to direct the call to Sandra Boenisch, Principal Financial Officer of ANAVEX, for a brief financial summary of the recently reported quarter.

Sandra Boenisch

Thank you, Christopher, and good morning to everyone. I am pleased to share with you today our third quarter financial results. During our most recent quarter, our general and administrative expenses remained consistent year-over-year at $3.2 million. Our research and development expenses for the quarter were $10.3 million as compared to $9.3 million in the comparable quarter of fiscal 2022. The increase in research and development costs year-over-year was primarily a result of our expanded team as well as a sustained increase

in drug manufacturing activities and development for future clinical and potential market supply.

Overall, we reported a net loss of $11.3 million, which is $0.14 per share, inclusive of $3.9 million in non-cash items. Our cash position at June 30th was $154.8 million. During the quarter, we utilized cash and cash equivalents of $7.7 million to fund operations. At our current cash utilization rate, we believe we have continued to have sufficient cash runway to fund our operations and clinical programs beyond the next four years.

Thank you, and now I will turn it back over to you, Christopher.

Christopher Missling

Thank you, Sandra, and this is a really exciting time for the company, and we remain on track for readouts of completed clinical trials and initiation of additional biomarker-driven precision medicine clinical trials as planned.

I would now like to turn the call back to Clint for Q&A.

Question-and-Answer Session

Operator

Thank you. We will now begin the Q&A session. [Operator Instructions] So our first question is coming from Soumit Roy at Jones Research. You can go ahead and speak, Soumit.

Soumit Roy

Hi. Good morning, everyone, and congratulations on the solid quarter and all the progress. A question on the Alzheimer program. Are the patients continuing on a long-term study and any progress on the confirmatory study to initiate on?

Christopher Missling

Yes. Excellent question. So the patient on the extension study actually was given a name. It's called the ATTENTION-AD Study, and it's going over 96 weeks. We have been heard from KOLs that actually this extension study could be the confirmatory study of the

ANAVEX2-73 Phase 2/3 study itself. So we want to basically put this in context and see how this will progress. Accordingly, so we might already have started this confirmatory study with that open-label study, but it will be determined in discussion with regulatory agencies. But we would, of course, be able to, without a problem, initiate a study, if so required, at any time.

Soumit Roy

I see. Do you have any date in mind when the FDA conversation could happen if this study can translate into a confirmation study?

Christopher Missling

Yes. We are planning to do this once the data is available, which is expected this year. And thereafter, agency is able to address things with data as well. And that's what will happen with data, in presence of data.

Soumit Roy

Okay. And the biomarker study data, could you give us some color on how many patient results are going to present an expectation? Because this is not a targeted agent towards [Indiscernible]. So what should be Street's expectations? And could you refine the timeline? Is it going to be later, like in November timeline, or could be earlier in third quarter?

Christopher Missling

I would say we keep the, we want to surprise the market. So we, it's the second half of this year, and we be able to then provide the data once it's available. And regarding the color, so it will be the entire participants of the trial. And the majority of them have received blood biomarker assessment before and after, as well as MRI assessment. And a smaller sample size has also received CSF samples. So this is right now, the entire population of the trial.

Soumit Roy

Wow. That is really helpful. And one last question on the Rett program. Clearly you are heading towards getting the top-line data from the EXCELLENCE study. How are you thinking path forward? Are you thinking about commercializing yourself, or is it going to be a partnership program? If it's going to be by ANAVEX, the commercialization part, when

should we start thinking about hiring the commercial team?

Christopher Missling

Yes. Excellent question. So with the collaboration with Partex, we already initiated the strategizing on the sales for numbers, the expansion of marketing strategies, but also we received unsolicited interest from across the globe, in all regions of the world, from all regions of the world, to either co-market or to license blarcamesine for Rett syndrome already. So we have multiple options open, and we try to make a decision based on shareholder value. So what will create more shareholder value accordingly? And we will base that decision based on that information once we are able to get terms on the table, which will likely happen after the data is out.

Soumit Roy

Thanks. Well, thank you again for taking all the questions and congratulations on all the progress.

Christopher Missling

Thank you.

Operator

I don't see any other analyst questions, Dr. Missling, if there's anything that you want to add here, you're more than welcome to.

Christopher Missling

Thank you very much. I think the question from Soumit was very comprehensive. Again, we like to very much point out that we're looking forward to a very excited second half of this year. We are very excited about the potential, what we build. We're expecting further publications and of our biomarker-driven precision medicine studies, which have all significant unmet need and economic burden. And we remain focused on execution as we prepare for a pivotal year ahead of us, potentially involving meaningful advances in our new developmental in neurodegenerative precision medicine portfolio. Thank you very much and stay tuned, looking forward.

Operator

Thank you, Dr. Missling. Ladies and gentlemen, that will conclude our call for today. We appreciate your participation and you may now disconnect.

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Comments (20)

Newest

P

Patrick3 10 Aug. 2023

Comments (361)

One Wall St analyst on the call...very poor IR efforts!!!
They're going to need significantly more street juice to break through the amyloid juggernaut!

Like (5)

The Political Economist 09 Aug. 2023

Comments (1.62K)

Missling won't give exact date for AD data drop in H2. Said it will be a surprise. This may have spooked traders who are shorting the stock. I have nothing against shorts as long as they are honest, jfyi.

Like (2)

The Political Economist 09 Aug. 2023

Comments (1.62K)

@The Political Economist My guess would be that they reveal the full data at the Alzheimer's conference, but he mentioned "surprise" so it may be in September instead. Or next week. Yes, it's been a long time, and I assume it's because they had to gather all the biomarker data, which I am guessing too took longer to gather than the ADAS-Cog data.

Like (3)

S

strendic 09 Aug. 2023

Comments (1K)

@The Political Economist Next AAIC conference is on July 28, 2024. The one for this year was already held, see below link :

aaic.alz.org/...

Like (1)

The Political Economist 09 Aug. 2023

Comments (1.62K)

@strendic I am not talking about the Alzheimers Association conference. I have spoken to the chief research scientist there and studied their lobbying efforts. They are all in on the amyloid drugs from Biogen and Lilly. She had very little interest in Anavex, but she said she was open to looking into it after I spoke with her at length.

Like (4)

See More Replies

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Amstragram 08 Aug. 2023

Comments (2.52K)

One analyst … well. 2033 is a long wait :D

Like (1)

S

strendic 09 Aug. 2023

Comments (1K)

@Amstragram This is from the company's press release:

"On track to release top-line data of potentially pivotal ANAVEX®2-73-RS-003 Phase 2/3 EXCELLENCE pediatric clinical trial in the second half of 2023"

"Newly available preliminary efficacy results of surrogate biomarkers from the ANAVEX®2-73-AD-004 study in Alzheimer's disease with convenient oral treatment to be released in the second half of 2023"

Like (3)

Timmy41 09 Aug. 2023

Comments (620)

@strendic Glad they narrowed it down. Based on track record, I would say maybe Rett, and no to AZ.

Like (4)

S

strendic 09 Aug. 2023

Comments (1K)

@Timmy41 I added 100 shares on Monday in anticipation of a good ER. I hope the price spike today will continue... GLTA

Like (3)

preterist 08 Aug. 2023

Comments (367)

2033? I hope he meant 2023. . . .

Like (4)

Timmy41 08 Aug. 2023

Comments (620)

@preterist 2033 sound right.

Like

P

Pharma95410 08 Aug. 2023

Comments (202)

@Timmy41 Never say never, they might be reading this board

Like (2)

Timmy41 08 Aug. 2023

Comments (620)

More waiting.

Like (2)

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