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AVXL - Q4 2019 Anavex Life Sciences Corp Earnings Call

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PRESENTATION

Operator

Good afternoon. My name is Hilda, and I'll be your conference call operator today. Welcome to the Anavex Life Sciences to Announce Fiscal 2019 Fourth Quarter Financial Results Conference Call. As a reminder, this conference call is being recorded.

I would now like to introduce your host for today's conference, Clint Tomlinson. Please go ahead.

Clint Tomlinson - *Anavex Life Sciences Corp. - Executive*

Thank you, and good afternoon, everyone. We appreciate you joining us today for Anavex Life Sciences' conference call and webcast. Our agenda is to review the company's financial results for fiscal 2019 and provide a clinical study update. A taped replay of this call will be available approximately 2 hours after the call's conclusion and will remain available for 1 month. The call will also be available for replay on Anavex' website, www.anavex.com.

With us today is Dr. Christopher Missling, President and Chief Executive Officer; and Sandra Boenisch, Principal Financial Officer. Dr. Missling and Ms. Boenisch will make prepared remarks, and then we will take questions from equity analysts.

Before we begin, please note that during this conference call, the company will make some projections and forward-looking statements regarding future events. 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 those 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 U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

Thank you. I'd like to thank everyone for joining us today's conference call to review our fiscal 2019 financial results and share with you our clinical updates for ANAVEX 2-73, or also called blarcamesine.

First, in the U.S. -- first, The U.S. Food and Drug Administration, FDA, granted the Rare Pediatric Disease, RPD, designation for ANAVEX 2-73 for the treatment of Rett syndrome. The RPD designation provides the opportunity or the award of a pediatric review voucher at the time of marketing approval.

In a recent peer-review journal, preclinical data of ANAVEX 2-73 in Rett syndrome in a study entitled ANAVEX 2-73 blarcamesine, a sigma-1 receptor agonist, ameliorates neurological impairments in a mouse model Rett syndrome confirmed with a proof-of-concept the ongoing Phase II clinical studies.

To offer all participants access to ANAVEX 2-73, after completion of the ANAVEX 2-73 U.S. Phase II Rett syndrome study and the AVATAR Rett syndrome study, 12-week and 48-week open-label extension studies, respectively, were initiated. Currently, 90% and 100% of eligible participants have continued into the corresponding extension studies.

The International EXCELLENCE Rett syndrome study of ANAVEX 2-73 in pediatric patients was approved by the Australian Human Research Ethics Committee and is scheduled to initiate early 2020. Anavex Life Sciences presented data at the 12th clinical trials of Alzheimer's Disease CTAD 2019 Conference, reporting baseline matched real-world external control data of Anavex (sic) [Alzheimer's] Disease Neuroimaging Initiative, ADNI, with ANAVEX 2-73 Phase IIa clinical data, demonstrating a significantly lower cognitive decline of the sufficiently dosed ANAVEX 2-73 Phase IIa study cohort compared to the ADNI control cohort at the interim 2-year, which is a 104-week time point. Separately, abundance of 2 relevant families of bacteria were identified as potential biomarkers of response from the 2-year study interim clinical data analysis of ANAVEX 2-73.

Enrollment for the Phase IIb/III ANAVEX 2-73 Alzheimer's disease study is nearly 50% recruited. To offer all participants of the study access to ANAVEX 2-73, a voluntary 96-week open-label extension study called ATTENTION-AD was initiated, and currently 95% of eligible participants have opted into the extension study. Enrollment for the Phase II ANAVEX 2-73 Parkinson's disease dementia study is expected to be completed by the end of December 2019, with top line data expected mid-2020. To offer all participants of the study access to ANAVEX 2-73, a voluntary 48-week open-label extension study, including microbiome assessment was initiated, and currently 100% of eligible participants have opted into the extension study.

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 - *Anavex Life Sciences Corp. - Principal Financial Officer & Treasurer*

Thank you, Christopher. Good afternoon, everyone. During fiscal 2019, we made significant progress in the advancement of clinical studies for ANAVEX 2-73, as Christopher has just described. We were able to continue to advance with fiscal responsibility by utilizing nondilutive grant from the Rett foundation and the Australian government third-party support in order to fund our operational objectives beyond next 24 months.

Our operating expenses for fiscal 2019 increased to $29.1 million from $19.3 million in fiscal 2018. However, these operating expenses do include approximately $6.4 million in noncash accounting charges. The increase in operating expenses is attributable to an increase in research and development expenses of $9 million in 2019 from $13.3 million in fiscal 2018 to $22.3 million in fiscal 2019.

We reported net other income of $2.9 million, which includes Australian research and development incentive income of $2.2 million.

During fiscal 2019, we utilized cash of $18.5 million to fund our operations compared to $12.6 million during fiscal 2018, and our cash position at September 30, 2019, was $22.2 million.

Thank you. And now I will turn the call back over to Christopher.

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

Thank you, Sandra. In summary, we continue to make steady progress towards reaching several important milestones, and we are poised for an exciting 2020 with multiple data readouts. We look forward to provide further updates as advancements continue.

I would now like to open the call for questions. Operator, please go ahead.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Raghuram Selvaraju from H.C. Wainwright.

Edward Dean Marks - *H.C. Wainwright & Co, LLC, Research Division - Equity Research Associate*

This is Edward Marks on for Ram. I appreciate taking our questions. What do you scope and design of the pediatric Rett syndrome trial? And are the efficacy endpoint similar to those used in the adult trials?

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

It's a very good question, indeed. So the endpoints are similar to the Rett adult study and the period of the study is a 12-week period study with an additional extension period. And the extension will be open label, but the randomized controlled part will be 12-week long.

Edward Dean Marks - *H.C. Wainwright & Co, LLC, Research Division - Equity Research Associate*

Perfect. And then looking at the CTAD presentation, what's the pathological significance of those 2 bacterial families in Alzheimer's patients? And is there an indication that these would also be implicated in Parkinson's disease? And what micro biomarkers might be in Parkinson's context?

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

So they are very relevant for 2 reasons. There is a data -- evidence of data showing that microbiota is corresponding with the brain and vice versa. And it looks like there is a increased -- there is increase of variations of gut microbiota in healthy subjects compared to patients, both Alzheimer and Parkinson, but the question is related also to Parkinson's. And the goal is now to find out if these could be used as biomarker. And to answer that question, we included in the Parkinson's study also microbiota assessment before and after. And that is one of the data points, which we did from the phased way was only at one point, so we still have to confirm that this effect is corelated with an impact on the drug, which we believe because it correlates with the concentration of the drug administered to the patients and the respective response. But ultimately, what we need at this point in time is a before and after measurement of this gut microbiota, and that's what we are now doing in the Parkinson's study. So eventually, we will be able to answer that question, how and what relevance this microbiota variations have in patients -- in Parkinson's and also in Alzheimer's disease.

Edward Dean Marks - *H.C. Wainwright & Co, LLC, Research Division - Equity Research Associate*

All right. And sticking with Alzheimer's, one of the Phase IIb/III Alzheimer's trial likely to reach full enrollment, and would you say that the enrollment pace is speeding up static or currently slowing down?

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

So we expect actually an increased in enrollment because we're adding sites. We have to appreciate that so far, the enrollment has been exclusively in Australia. And I understand that we have reached the highest enrollment in Australia ever in the history of a Alzheimer's study enrollment in terms of numbers, recruited for Alzheimer patients. So now we're expanding to additional territories. And this will allow, what we believe, in addition to the existing sites in Australia, an uptick in enrollment speed for the Alzheimer study. We have not yet set a target when we are completing

enrollment, but we will communicate that as soon as we have that available, and we can make that confirmation when the study will be fully enrolled.

Edward Dean Marks - *H.C. Wainwright & Co, LLC, Research Division - Equity Research Associate*

Got it. Looking forward to it. And then on a broader level, assuming positive data in the Parkinson's study with blarcamesine, sorry, what would next step look like for the drug in this indication?

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

We would probably share this with regulatory authorities and seek guidance how this data could be then leading to moving this forward towards approval since Parkinson's disease dementia has not received yet a drug which seems to be utilized in the community. There's only 1 drug approved, which, however, does not get used because of significant side effects, that will be the next step.

Operator

(Operator Instructions) Our next question comes from Yun Zhong from Janney.

Yun Zhong - *Janney Montgomery Scott LLC, Research Division - Equity Research Analyst & Director of Biotechnology Research*

So 2 questions on the Rett syndrome program. Are you waiting for initial data from the Phase II Rett study and Australian study before you will initiate the pediatric study? If not, and -- what will be the rate-limiting steps that you will have to complete before you will be able to initiate the pediatric study?

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

So we are not really waiting for that, but there's certainly a chance that this will overlap a little bit. So -- but it's not like a dependency -- a directly correlated dependency.

Yun Zhong - *Janney Montgomery Scott LLC, Research Division - Equity Research Analyst & Director of Biotechnology Research*

Okay. And then given that this is the third study, was quite meaningful number of patients close to 70 patients for an organization, what's the potential to assume that the data are positive? What's the potential for the study to serve as a pivotal study?

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

Which one, if I may ask?

Yun Zhong - *Janney Montgomery Scott LLC, Research Division - Equity Research Analyst & Director of Biotechnology Research*

The pediatric study.

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

Yes. So we are planning in this still to be confirmed, but given that we have knowledge about design for this indication, we're planning to power the study. So this could become and could be sufficiently as a pivotal study and the 2 additional studies in adult Rett syndrome would be obviously also utilized as supportive for that strategy.

Yun Zhong - *Janney Montgomery Scott LLC, Research Division - Equity Research Analyst & Director of Biotechnology Research*

Okay. And last question on the dose that is currently valued in the Parkinson's dementia study, can you remind us how do they compare to the higher concentration and low concentration that you achieved in the Alzheimer's study?

Christopher U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

Yes. So the dose is actually very similar to the dose in the Alzheimer's Phase IIa study where we have -- we are aiming for a high dose and a medium dose. And we believe both doses have potential to be efficacious, both the medium dose as well as the high dose.

Operator

At this moment, we show no further questions. Mr. Tomlinson, do you have any final remarks?

Clint Tomlinson - *Anavex Life Sciences Corp. - Executive*

We'd like to thank for all participants in today's conference call. I hope that based on the described development today, you're looking forward to 2020 as much as we are. Should you need additional information or have any questions, please visit our website at www.anavex.com or call or e-mail us. This concludes our remarks for today, operator.

Operator

Thank you. Ladies and gentlemen, this concludes our call today. You may now disconnect.
