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AVXL - Q1 2020 Anavex Life Sciences Corp Earnings Call

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Clint Tomlinson *Anavex Life Sciences Corp. - Executive*

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

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

Tom Bishop *BI Research*

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

PRESENTATION

Operator

Good afternoon. My name is Anna, and I will be your conference operator today. Welcome to the Anavex Life Sciences to announce fiscal 2020 first 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 its first quarter of fiscal 2020 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's website at 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 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 U. Missling - *Anavex Life Sciences Corp. - Chairman, President, CEO & Secretary*

Thank you. I'd like to thank everyone for joining us on today's conference call to review our first quarter financial results and share with you some clinical updates for ANAVEX 2-73 or blarcamesine.

We were pleased to announce earlier this week that the U.S. Food and Drug Administration, FDA, has granted Fast Track designation for the ANAVEX 2-73 clinical development program for the treatment of Rett syndrome. FDA Fast Track is a program designed to facilitate and expedite the development and review of a new drug to address unmet medical need in the treatment of a serious and life-threatening condition for which it demonstrates the potential to address unmet medical needs for such a disease or condition. The purpose of the program is to get important new

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therapies to the patients earlier in order to address the unmet medical need in the treatment of serious and life-threatening diseases. Our clinical Rett Syndrome Program, RS-001 and RS-002, AVATAR, are on track with continued enrollment.

We continue to strengthen our patent position as well. During the quarter, we were granted another U.S. patent to support Anavex' leading drug candidate, ANAVEX 2-73, for the treatment of neurodevelopmental disorders, including Rett syndrome and multiple sclerosis. This patent is expected to remain enforced at least until 2037, not including any patent term extensions. It covers methods of treatment for neurodevelopmental disorders, including Rett syndrome, autism spectrum disorder, Angelman syndrome and cerebral palsy, among others, and also treatment for multiple sclerosis using ANAVEX 2-73.

Regarding the ANAVEX 2-73 Parkinson's disease dementia study, we were pleased to report that we met our enrollment target for the study, the study enrollment over 100 patients at 20 sites across Spain and 3 sites in Australia. We expect to announce top line results from this study by mid-2020.

Enrollment for the Phase IIb/III ANAVEX 2-73 Alzheimer's disease study is 50% complete. Recruitment is expected to accelerate given the anticipated international expansion of the study, which will increase the total number of sites from 15 to approximately 45 in 2020.

We are reporting advancement of another pipeline compound. We have successfully completed IND-enabling toxicology studies and drug product manufacturing for ANAVEX 3-71. ANAVEX 3-71 previously received Orphan Drug Designation from the U.S. FDA for frontotemporal dementia, FTD, and initiation of the first Phase I clinical trial of ANAVEX 3-71 is expected in 2020.

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, and good afternoon, everyone.

We reported a net loss of $6.6 million or $0.12 per share during the quarter compared to a net loss of $6.9 million or $0.15 per share in the comparable first quarter of fiscal 2019. The decrease in reported net loss is due to increased research and development incentive income.

Research and development expenses were $6.3 million for the first quarter of 2020 as compared to $5.7 million for the comparable period in 2019. This increase was driven by increased clinical development activities related to the advancement of our pipeline.

General and administrative expenses were $1.4 million for the first quarter of 2020 as compared to $1.8 million for the comparable period in 2019. This decrease was primarily due to lower noncash stock-based compensation charges.

During the quarter, our cash position grew to $27.5 million at December 31, 2019, from $22.2 million at our year-end September 30, 2019.

Thank you. And now I will turn the call back over to Christopher. Christopher, please go ahead.

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

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

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

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QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is 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. Quickly, on the clinical side, I'm just wondering what the gating items are before you're able to initiate the pediatric Rett syndrome trial.

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

They are -- thank you for the question. There are no gating items. We did announce that we were able to get approval for starting the study. It is really the customary requirements of site initiation visits and preparing the drug to the sites, and then we can start. So I expect this to be over shortly, and we will make that announcement public.

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

Okay. Good to hear. And you mentioned the recent patent announcement, and I noticed that multiple sclerosis was mentioned multiple times in there. I'm just wondering if you intend to or if other companies have shown interest in rapidly developing blarcamesine for multiple sclerosis. And I noticed that you also mentioned autism and cerebral palsy in there that are covered by the patent. So are these also planning to be pursued in the future?

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

So we did actually had encouraging data for MS from an in vitro study from several investigators, which was also presented at ACTRIMS last year or the year -- and the year before. And we have to be aware that -- or mindful that this is a very exciting indication and -- but however, still requires more preclinical work, like an animal study or other forms of validation. But I think the best way to look at this is once we get clarity on the data of Rett syndrome, we would immediately accelerate that program thereafter, and the same applies for the supranuclear palsy indication as well.

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

Got it. And then my final question, I was just wondering if there's any more detail available regarding the microbial biomarker analysis for Alzheimer's and Parkinson's. And when do you anticipate releasing some of this data?

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

So we did get -- received an initial positive signal from the Phase IIa study in Alzheimer's disease that there was a correlation of the gut microbiota changes with drug exposure, and we added this measure into our Parkinson's disease dementia study extension. So we will be able to report this with the Parkinson's dementia study extension outcome where we will be able to see the level of changes in measures of gut microbiota before drug exposure and after as well as for patients on placebo and then on drug -- active drug. So we will have a very good ability to see if we will be able to confirm the correlation of drug effect with increase of variety of gut microbiota, which is the beneficial effect since healthy volunteers have a higher variety of gut microbiome than diseased patients.

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Operator

Our next question is from Yun Zhong from Janney.

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

So the first question is on the status of the 2 ongoing Rett syndrome studies. I believe I heard you said that the 2 studies are still enrolling patients. And I'm wondering, did you run into any challenges in recruiting patient in addition to the fact that just being an orphan indication with the small prevalence?

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

Sorry. What was the last part of the question?

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

I understand that this is an orphan indication with a small prevalence. But did you run into any additional challenges in recruiting patients into those 2 studies?

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

No, we did not. We just want to make sure that the patients are recruited in a fashion that the right patients are in the study because that study now becomes relevant given that we received Fast Track designation. And so our goal is not to rush the enrollment and make sure we get the right patients into the study. But we did not find any challenges during this -- at this point.

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

Okay. Then about the Parkinson's disease dementia study, so I believe that primary efficacy end point is the continuity of ATTENTION. So I assume that you're reporting where you see positive data by mid-2020. Are you going to approach the FDA to discuss about the next step? And do you think the same primary end point will likely be used in the next study?

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

Yes. So the second question regarding seclusion is a little bit a dialogue with the agency to see if this would be able to be confirmed. But the good news is that the measure you mentioned has been shown to be correlated with a drug, which was approved for Parkinson dementia many years ago. So that is the reason why we picked that measure. And indeed, it's correct to make that assumption. After the data is available, we would sit down with the agency and discuss next steps.

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

Okay. So then the last question about the new compound 3-71, what do you expect will be the indication that you pursue with this compound? And how do you plan to position the new compound as compared to the 2-73 -- sorry, 2-73, yes?

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

So we do have the advantage that ANAVEX 3-71 has already received from the FDA Orphan Drug Designation for frontotemporal dementia, FTD. And we would most likely then advance the Phase I into a Phase II with that indication. That would be our current strategy.

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

Okay. But in terms of mechanism of action, the 2 compounds are the same or quite similar. Is that correct?

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

So there are differences. The molecules are completely different, but there is a similarity that they both activate the sigma-1 receptor, which is the core of our hypothesis. But ANAVEX 3-73 has also an activation mechanism of the M1 sigma muscarinic receptor, which is very strong, and that is slightly different to ANAVEX 2-73. So there are differences in that regard. And we still believe, though, that for that reason, that's intriguing to move forward with 3-71 because we have the ability to demonstrate that the drug has shown very solid reduction in tau, in inflammation and a better aggregation in a triple transgenic animal model. And that basically is the reason why we're very excited about 3-71 as well.

Operator

(Operator Instructions) And we have a question from Tom Bishop from BI Research.

Tom Bishop - *BI Research*

If I'm recalling correctly, has the FDA given A 2-73 for Rett Orphan Drug Designation and rare pediatric disease status and now Fast Track designation? Is my memory correct? Or am I in need of some A 2-73?

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

That is absolutely correct. All 3 designations have been awarded to ANAVEX 2-73 for Rett syndrome.

Tom Bishop - *BI Research*

That's pretty impressive. It sounds like the FDA is really doing its best to speed this along. It is clear that the FDA is in the loop for Rett, but is the FDA as much in the loop here on the Alzheimer's trials, so that the company is working closely with the FDA to assure that the Alzheimer's trial results will be to their liking as well as in Australia?

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

We did -- and we announced it. It was by now several years ago that we had interaction with the FDA in a pre-IND meeting and that was shared the design of the study among them. So the assumption is correct. We do have the interaction with the FDA on the Alzheimer's program as well.

Tom Bishop - *BI Research*

On that Alzheimer's trial, how do you define -- it's for early Alzheimer's, as I understand it. And I was just wondering how the company defines that in terms of MMSE or activities of daily living scores.

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

So the designation of early Alzheimer's is a -- is developed by the consortium, the Alzheimer's consortium, and it basically discriminates to more advanced Alzheimer's. And it's basically the area of dysfunction, which is subsequent mild cognitive impairment. And the next level is early Alzheimer's. And the next level is then mild to moderate Alzheimer's and then followed by severe Alzheimer's. So it's basically sandwiched between mild cognitive impairment and moderate to -- mild to moderate Alzheimer's disease.

Tom Bishop - *BI Research*

But I'm just wondering if there's some cutoff for the MMSE or ADL scores.

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

Yes. That's, in fact, the requirement -- or the scores cutoff is 20 MMSE and higher, so 20 to 28. To remind again, 30 MMSE score is the perfect cognition. And the score decreases with advancing of cognitive impairment. So the inclusion of the trial for early Alzheimer's is in the range of 20 MMSE to 28 MMSE score.

Tom Bishop - *BI Research*

Okay. And just also, I wanted to ask about this acceleration in the number of sites for the Alzheimer's trial, moving it, I guess, offshore -- or opening sites offshore. And to increase the number of sites, like, 200% kind of surprised me a little bit. Seems kind of expensive, but is there some reason for the -- behind the acceleration? And...

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

So the -- it's not going to be actually much more expensive. It's just that we are going to more places to buy, so to speak, something. So we still need 450 patients. We now have 50% enrolled. So it would just accelerate enrollment. It's not more expensive. It just accelerates it. So the -- what remains the -- what cost the money is the number of patients, and that's already in the budget, which is 450 patients. So it's independent from which sites this would be coming.

Tom Bishop - *BI Research*

But is there some reason for the acceleration? I must admit to having read some exciting anecdotal news of patient improvements coming out of Australia. And I was just wondering if...

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

So we are excited about this program. And we already had said previously that the Phase IIa Alzheimer's study gave us the confidence to move forward into this Phase IIb/III study, and that is the basis of now accelerating this because we are realizing that we want to now make sure that the study is finishing sooner than later. And so we were confident so far with the first 50%. And now we are moving to this level of acceleration by increasing the number of sites.

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Tom Bishop - *BI Research*

Okay. Good. And finally, does the company have any thoughts on additional Rett data, when that might be coming out because there's 2 ongoing studies? I don't know how close they are.

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

Yes. So these studies are ongoing, as I mentioned, and we will report when each of the enrollment is completed. And then we will also be able to exactly precisely say when are the top line data of these respective 2 study will be presented.

Operator

And we have no further questions at this time. I will now turn the call over to Dr. Missling for closing remarks.

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

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

Operator

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

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