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AVXL.OQ - Full Year 2020 Anavex Life Sciences Corp Earnings Call

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PRESENTATION

Operator

Good afternoon. My name is Vanessa, and I'll be your conference call operator today. Welcome to the Anavex Life Sciences Fiscal 2020 Year-End and Fourth Quarter Conference Call. As a remainder, this conference call is being recorded. I would now like introduce your host of 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 fiscal 2020 year 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'll 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, the risks inherent in 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 would like to turn the call over to Dr. Missling.

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

Thank you, Clint. We appreciate everyone joining us today conference call to review our financial results and clinical updates.

First, I would like to provide new key clinical updates, given the very encouraging data of the U.S. Rett syndrome study. We plan to advance the AVATAR adult Rett syndrome study into a pivotal Phase II/III clinical trial.

In December 2020, Anavex announced top line results from a U.S. Phase II controlled trial of ANAVEX 2-73 in adult female patients with Rett syndrome. Primary safety, pharmacokinetics and secondary efficacy endpoints were met with statistically significant and clinically meaningful, consistent improvement in Rett Syndrome Behavior Questionnaire, RSBQ; and Clinical Global Impression Improvement, CGI-I score.

Improvements in RSBQ Total scores were correlated with decrease, improvements, in plasma glutamate. Based on these results, we are planning to meet with the FDA to discuss an accelerated approval pathway.

Further, we are planning a pipeline extension for 2-73 using gene biomarkers of response and applying precision medicine for neurological disorders with unmet medical need. This includes a planned initiation of a pivotal Phase II/III study in Fragile X Syndrome, the most frequent genetic cause of autism spectrum disorder, for which we have convincing preclinical data.

We also are planning to initiate a Phase II/III clinical trial for the treatment of a new rare disease indication, ANAVEX 3-71, an orally administered small molecule targeting sigma-1 and M1 muscarinic receptors that is designed to be beneficial for neurodegenerative diseases is currently in a Phase I clinical trial and on track with top line data anticipated in the first half of 2021.

Lastly, we plan to initiate a ANAVEX 2-73 imaging-focused Parkinson's disease clinical study in 2021.

Since our last conference call, we reported top line data of another clinical trial program. Data was presented in November at the CTAD 2020 Conference, reporting top line results from the proof-of-concept Phase II placebo-controlled trial, with primary objective of safety, tolerability and efficacy in cognition of ANAVEX 2-73 in patients with Parkinson's disease dementia compared to placebo. Both primary objectives of the study were met.

The results show clinically meaningful, dose-dependent and statistically significant improvements in the Cognitive Drug Research, CDR, computerized assessment system analysis. The study confirmed the precision medicine approach of targeting SIGMAR1 as a genetic biomarker in response to ANAVEX 2-73. And we are planning a pivotal trial of ANAVEX 2-73 in Parkinson's disease dementia after submitting the results of the study to the FDA to obtain regulatory guidance.

Lastly, in November 2020, Anavex received a Notice of Allowance from the United States Patent and Trademark Office, USPTO, for its patent application number 16/717,921 expected to remain in force at least until 2037, expanding coverage of treatment methods using its lead drug candidate 2-73 as well as drug candidate 1-41 for treating a range of neurodevelopmental disorders, including Rett syndrome, autism spectrum disorder, Angelman syndrome, cerebral palsy and multiple sclerosis, among other indications.

While 2020 was marked by the outbreak of COVID-19, which has temporarily slowed down activities in many countries in which our trials are taking place, our ongoing clinical trials were able to continue largely uninterrupted in compliance with local regulations and policies, including the enrollment of the Phase IIb/III ANAVEX 2-73 Alzheimer's disease study, which currently reached over 80% enrollment with complete enrollment expected in early 2021.

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 continued fiscally responsible activities with a net loss of $26.3 million or $0.45 per share for the 2020 fiscal year as compared to $26.3 million or $0.54 per share in the comparable 2019 fiscal year.

General and administrative expenses fell by approximately $1 million as a result of a reduction in noncash compensation charges.

Research and development expenses were $25.2 million for fiscal 2020, an increase of $2.9 million over the comparable 2019 fiscal year. This increase is a result of increased clinical trial activities and the continued advancement of our existing clinical trials.

We reported an increase in other income to $4.8 million for fiscal 2020 related to research and development incentive income in connection with our Australian clinical trial activity.

Our cash position at September 30, 2020, was $29.2 million compared to $22.2 million at September 30, 2019. We are also reporting today, our cash position has increased to $47.6 million as of today, which gives us sufficient cash for approximately the next 24 months.

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, despite all of the new challenges, 2020 was an extraordinary year for Anavex, with significant progress across our portfolio.

We look forward to building on this momentum with key milestones expected from multiple programs, including data on the ongoing late-stage Rett syndrome trials, AVATAR and EXCELLENCE; expanding the clinical biomarker-driven 2-73 rare disease program into additional late-stage studies with high unmet medical needs; completing the late-stage 2-73 Phase IIb/III Alzheimer's disease trial; and advancing 2-73 into clinical disease-modifying testing in Parkinson's disease.

At this point, I would like to thank the patients, the doctors, and entire Anavex team who made all of this progress possible. We look forward to providing 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 Charles Duncan from Cantor Fitzgerald.

Charles Cliff Duncan - *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

Happy holidays. And Christopher, all the great progress recently, congratulations. Had a couple of quick questions regarding the Rett program. In AVATAR versus the recent adult study, you mentioned that you are going to move forward with AVATAR as a pivotal. I'm kind of wondering what has changed, what will change in moving that forward?

And then when you consider the, I guess, characteristics of the cohort that was included in the sample and the recently read out adult study, how is that different in any way with the AVATAR study? And then I have a follow-up question.

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

Right. So the AVATAR study is designed as a Phase II right now, with the safety as a primary endpoint. So what we're doing, we are switching the secondary endpoint, which is the efficacy measure of RSBQ and CGI-I to a primary endpoint. So that's a change, which you can do in our ongoing studies without being blinded.

And the difference to the U.S. study, the AVATAR study is on average higher drug exposure profile. So the doses are higher than the U.S. study was. So this is why we also think we can capture a very important element, which the FDA is looking for, which is dose response.

Charles Cliff Duncan - *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

Okay. And then when you think about the efficacy measures that were made and efficacy seen in the U.S. adult study, how do you feel about the sample size or the planned effect size or the hope for effect size out of AVATAR? Is there going to be a change in the sample size that you plan to enroll in that study?

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

Yes. Excellent question. Right now, we don't have any need to change the number of patients in the AVATAR study. But it could well be that we will make an adjustment, not to increase the size, but maybe just to increase additional regions in that regard. But still it's not completed the enrollment that might not require any change of numbers.

But we want to basically let this discussion then -- the final discussion come out, out of the discussion with the FDA before making a change on that level at this point.

Charles Cliff Duncan - *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

Okay. So you do plan to meet with the FDA. You're going to perhaps request a meeting here soon or have you done so? And then the outcome of that meeting will possibly impact the design and conduct and sizing of AVATAR?

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

Right. I mean we have very good strong effect size of the U.S. study, knowing that it was even a low dose, we expect the high dose to be even stronger in effect size. So right now, we don't have an immediate need to change the design of the study other than switching the primary and secondary endpoints.

But what I want to point out is that ultimately, we want to discuss with the FDA, because we also want to make this as the final pivot study. And if there are additional changes the FDA, the agency recommends, we certainly will be open to that.

Charles Cliff Duncan - *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

Yes, that makes sense. It seems prudent. Last question on this is regarding the Rett study that read out recently, but also the Parkinson's disease cognition or dementia study that you alluded to, when would you anticipate being able to present the data from those 2 studies in a peer reviewed form?

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

Yes. So we want to be very transparent, and we will. You have to appreciate that the co-primary endpoint of both studies and secondary, the efficacy endpoints, we're also looking at a genetic outcome of the patient's genetic background of the patients, and that requires a bit more time than usually analysis of studies. That's why we have to basically go through this before we can basically submit this to a publication.

But we mentioned it, we will submit to a publication, the PDD studies and/or present probably over the course of early 2021 more details about the PDD study as well as the Rett study.

Charles Cliff Duncan - *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

Okay. Last question, then I'll hop back in the queue, regarding the pipeline. And sorry for taking up all this time. But regarding the pipeline, you mentioned another rare disorder. And I guess, I'm wondering if you had mentioned it actually in the IP discussion that you alluded to, for example, Angelman or could that be inclusive of Huntington type indication or an indication beyond, say, a neuropsych rare disorder?

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

Yes, excellent question. We didn't want to not mention it, because we don't want to prevent knowledge about it. It's just because the drug has shown now in addition to infantile spasm and Angelman syndrome, in addition to Rett syndrome, which we have in the clinical trial. But we have infantile spasm clinical -- preclinical data as well as Angelman presented already in the past.

In the meantime, we were able to get additional preclinical data of confirmation of efficacy in models of diseases, which are rare and developmental in nature, which are basically on top of those I just mentioned. And since this is our also now strategic discussion with regulatory as well as with clinical design, so which study would be quicker to perform versus others, how does the competitive landscape look like for these rare diseases, we just want to do that homework first before we engage into mentioning what it is.

But it will be one new indication, which I not have yet -- we don't have yet mentioned in the slides presented so far.

Charles Cliff Duncan - *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

More color in 2021, you suspect?

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

Exactly. Definitely, more colors coming 2021. And again, it's a rare disease. Maybe it's even an ultrarare disease. So this is the really intriguing thing about it that we never stopped finding or engaging in communities, which have an unmet need based on the approach of the drug to be upstream and regulate the downstream features of homeostasis imbalance in the biological system. And that benefits quite a lot of additional indications and among them quite rare diseases. And that's why we want to basically not pass on, on this opportunity for patients to help.

Operator

Our next question comes from Robert LeBoyer from Ladenburg Thalmann.

Robert Michael LeBoyer - *Ladenburg Thalmann & Co. Inc., Research Division - MD Equity Research*

Congratulation on all the recent progress. My question has to do with the Alzheimer's study. And you had mentioned that you expect to complete enrollment early in 2021. And I was wondering when we might see the first cut of the data.

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

So the study is a 48-week study. So it's very simple to add once the last patient has been enrolled then to add 48 weeks. Because last patient enrolled in the study will also determine the last patient finishing the study. And that's basically the simple arithmetic to do, so that will be early 2022.

Robert Michael LeBoyer - *Ladenburg Thalmann & Co. Inc., Research Division - MD Equity Research*

Okay. Great. And there was also -- in addition to the cash balance as of September 30 and the $29.2 million at September 30 and the $47.6 million as of today. And I was wondering where that extra money came from.

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

Yes. So we have 2 programs in place in order to basically be always able to, I would say, strategically and also as least dilutive as possible when the stock price moves up to a higher level to basically utilize the ATM and the purchase agreement. And one of those 2 features we were able to utilize to basically make sure we always have 2 years of cash.

Now that we have 2 years of cash as of today, we obviously will not need to use it anymore going forward in a high frequency. And that's basically the message we want to also send to our shareholders that we always want to make sure we have enough cash and resources, so we don't have any problems executing our activities.

Operator

Our next question comes from Tom Bishop from BI Research.

Tom Bishop - *BI Research*

Can you hear me?

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

Yes.

Tom Bishop - *BI Research*

Okay. I noticed this comment about the planned initiation of ANAVEX 2-73 imaging-focused Parkinson's disease clinical study. I didn't say dementia, and I didn't understand the imaging-focused either. Could you put a little bit more on that?

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

Right. So we have been fortunate, we have been -- received funding previously from Michael Fox for a preclinical study in disease modification for Parkinson's disease, which is not Parkinson's dementia, just movement disorder and that was very successful. And now in the next step, we want to make sure that in Parkinson's patients, so not dementia, we also understand better how the drug works. And this is something we'd like to explore this year.

Tom Bishop - *BI Research*

I don't know why this phone is making this noise. Okay. Getting to the Australia trial, I just want to know why the company had to go to U.S. sites. I would have thought that there would be enough patients in Australia to reach your goal of, what is it, 300? Can you just explain a little bit more? I mean -- and what does that say about the market size in Australia?

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

The -- in the Australian Alzheimer's study, you mean?

Tom Bishop - *BI Research*

Yes.

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

So the Australian Alzheimer's study is now an international study. So we started it in Australia. And the Phase IIb/III is actually now enrolling in Germany, Netherlands, U.K. and Canada in addition to Australia. And so what we started in Australia has been now expanded in 3 continents overall. And so we just want to make sure that an international study has advantages. And so there was not that we were limited in Australia, but it's always an advantage to have sites running of this proportion in many different places.

Tom Bishop - *BI Research*

Okay. And also, is there any thought being given to some interim analysis of the Alzheimer's study that's not unusual? Or have we got to wait until 2022?

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

The option is there, because the protocol allows for an interim analysis. It is explicitly mentioned that it can be used for interim analysis. And we have seen that interim analysis could be misleading, as shown in another company. So we don't know if we want to use that at this point in time, but the chances are there. So there's a possibility that there's data before 2022 for the Alzheimer's study.

Tom Bishop - *BI Research*

Okay. And with regards to AVATAR and the adult Rett syndrome study moving on to Phase II/III, I kind of thought that, that was initially just a study so that you could advance into the adolescent market, which I thought was your primary market. But are you going 2-pronged, you're going to test all the way through the adult?

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

So the adult population -- right. Sorry for interrupting. So the adult population is a little bit a population which has not received much attention. Mostly trials go for younger patients, pediatric patients, because the expectation is that the brain is more plastic and has a higher potential response than if the patients already advanced in age, and therefore, the brain doesn't respond anymore as much to an intervention.

We have seen a very strong response in an older population in Rett syndrome, which is very favorable to be interpreted, because that makes us even more excited to see the data when we go to younger patients.

But ultimately, we want to capture the entire market, right? So it's not limited to one age group. But it's just often -- the signal often is stronger in younger patients. So -- but we capture -- we are aiming with the AVATAR and the EXCELLENCE study exactly to capture both age groups, the adults above 18 years old and the age group below 18 years of age.

Tom Bishop - *BI Research*

Is the EXCELLENCE study now enrolling?

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

Yes. It's enrolling very nicely. That's the case.

Operator

Thank you. There are no further questions at this time. This concludes today's call. Thank you, ladies and gentlemen. You may now disconnect.
