THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

AVXL - Q3 2019 Anavex Life Sciences Corp Earnings Call

EVENT DATE/TIME: AUGUST 07, 2019 / 8:30PM GMT

THOMSON REUTERS

CORPORATE PARTICIPANTS

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

Clint Tomlinson *Anavex Life Sciences Corp. - Executive*

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

CONFERENCE CALL PARTICIPANTS

Anna Vorobyeva *Roth Capital Partners, LLC, Research Division - Analyst*

Raghuram Selvaraju *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Tom Bishop *BI Research*

PRESENTATION

Operator

Welcome to the Anavex Life Sciences Fiscal 2019 Second Quarter Financial Results and Corporate Update Conference Call. My name is Vanessa, and I will be your operator for today. (Operator Instructions)

I will now turn the call over to your host, Clint Tomlinson.

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 the second quarter of 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 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-Q and 10-K, 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 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. I'd like to thank everyone for joining us on today's conference call to review our financial 2019 second quarter financial results and share with you our clinical updates for ANAVEX 2-73. First, we are very pleased to report that the 120-patient Phase II ANAVEX 2-73 Parkinson's disease dementia study has achieved 70% of the total patient enrollment target to date. Additionally, the study is expanding internationally and expect to add several sites based on interests from investigators in Australia. Enrollment for the 450-patient Phase IIb/III ANAVEX 2-73 Alzheimer's Disease study is also continuing as planned with over 20% of patients enrolled to date.

Regarding our Rett syndrome program, we are pleased to report that for the United States Phase II ANAVEX 2-73 Rett syndrome study, to date, 40% of the patients have been enrolled. Further, we received approval from the Australian Human Research Ethics Committee to initiate the Phase II AVATAR clinical study in Rett syndrome patients. The study will enroll approximately 30 patients and will be double-blind, randomized, placebo-controlled over a 7-week period with safety and efficacy as endpoints. The study is actively enrolling patients and the study details are available at clinicaltrials.gov under the identifier number, NCT03941444.

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. During the second quarter of fiscal 2019, we used $4.3 million in cash to fund operations, while operating expenses for the second quarter of fiscal 2019 were $8.1 million compared to $4.7 million for the comparable quarter in fiscal 2018. The increase in operating expenses is attributable to higher research and development expenses compared to the same period last year.

R&D expenses for the quarter were $6.1 million, up from $3.2 million reported in the second quarter of fiscal 2018. The increase in research and development expenses is a result of expenses incurred in connection with the advancement of clinical studies for ANAVEX 2-73. Operating expenses during the quarter also include an aggregate of $1.9 million in noncash charges. This compares to $1.2 million in noncash charges in fiscal 2018 second quarter.

Net loss for the quarter was $8 million or $0.17 per share as compared to $4.8 million or $0.11 per share in the comparative quarter of fiscal 2018. Our cash resources at March 31 were $19.5 million. We believe that this is sufficient cash resources to fund our objectives for the next 18 months given the cash we have on hand and the support we received from the Australian government and other third parties to fund our ongoing clinical trials.

Thank you, and now I'll turn the call back to Christopher.

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

Thank you, Sandra. In summary, we are actively focused on execution of the current clinical studies for ANAVEX 2-73, and we are pleased with the pace in which these studies are advancing. We look forward to providing further updates as advancements continue.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We have our first question from Ram Selvaraju with H.C. Wainwright.

Raghuram Selvaraju - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Can you hear me?

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

Yes.

Raghuram Selvaraju - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

So firstly, I just wanted to ask if you could go over the principal differences and similarities between the 2 Rett syndrome studies and enumerate for us what the specific objectives are of each study? So the study that is already running. And the one in Australia, the AVATAR study.

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

So thank you for the question. So the difference is the number of patients, the U.S. study has 15 patients and the AVATAR study has 30 patients. The focus on the U.S. study is safety and PK, and the 30-patient study, the AVATAR study is safety and efficacy.

Raghuram Selvaraju - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

And will the AVATAR study be specifically considerable by the FDA? Or once it is completed, assuming the results are encouraging, would you need to recapitulate the AVATAR study in the U.S.? Or would you be able to proceed directly to something more advanced, assuming the AVATAR study yields positive results on the efficacy front?

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

So it will depend on the data and the signal, the strength of the signal, but we don't believe that we have to repeat the same study in the U.S., but however, it's possible that we could increase the study -- the AVATAR study internationally and expand to other -- add other sites beyond the Australian region or territory.

Raghuram Selvaraju - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Okay. And then just two other quick items both on the clinical development front. Can you give us an idea of what the cost differential is for the AVATAR study in terms of running in Australia versus any other territory, including the United States as well as the degree to which you expected to enroll in a timely fashion, given the fact that it is being run in Australia? And in particular, do you think that you would need to potentially expand it to additional territories in order to meet the full 30-patient complement? Or do you feel confident that the entire study can be fully enrolled given the Australian sites that you currently envisage being involved?

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

Yes. So the study is supported and is in collaboration, as you saw this morning, with the Rett Syndrome Association of Australia, RSAA. And they have indicated to us that the number of patients in the AVATAR study is fully able to be fully enrolled in Australia alone, but it is not uncommon to add additional sites internationally if you want to accelerate the enrollment. The other question about the financial, the advantage of a study in Australia is that the government of Australia is giving us a cash-back payment of around 40% -- over 40% for every dollar spent and another element, which is relevant, the Australian dollar is a more -- is a better foreign exchange, it's less expensive than in the U.S. dollar terms. There is another advantage of cost for a U.S. company doing the study in the Australian region from a foreign exchange standpoint as well.

Raghuram Selvaraju - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Okay. And then just the last question -- verification is that, you have given pretty regular updates on the enrollment status of all the ongoing trials. I presume, for each one of them as you reach complete enrollment, you are going to provide us with notification that, that has indeed happened, right?

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

Once we reach complete enrollment, this will be made public. That's correct.

Operator

Our next question comes from Anna Vorobyeva with Ross Capital Partner.

Anna Vorobyeva - *Roth Capital Partners, LLC, Research Division - Analyst*

Just two quick questions. One surrounding the sigma-1 receptor variant carriers and whether or not they will also be enrolled? Is that part of the criteria to be enrolled? Or will the wild types and the variant carriers be enrolled in both AVATAR and the U.S. study?

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

The answer to this question is, in both studies, in Rett syndrome, both the U.S. and the AVATAR study, we both will enroll patients with those genetic variants and this will allow to prespecify. They are still having been in this protocol -- in each protocol prespecified in regards to their genetic background. Each patient has been prespecified with a genetic background, nevertheless.

Anna Vorobyeva - *Roth Capital Partners, LLC, Research Division - Analyst*

Right. And will they be balanced between the arm?

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

The balance is not something which we do because it will delay the enrollment rate. And we do know that there is a average of patients with a variant, which we expect this will balance out by itself in the study. And even if so it will not be the case, there are in statistical analysis way to allocate or correct for, like you do in studies for gender imbalances. And so that can be also done in that case for an analysis.

Anna Vorobyeva - *Roth Capital Partners, LLC, Research Division - Analyst*

Okay. Great. And my second question has to do with sort of similar topic around sigma-1 receptor in Alzheimer's. Just wondering if you can provide some color on whether or not you're going to continue to conduct the studies in Alzheimer's? Or whether your thesis on sigma-1 has changed in terms of Alzheimer's given all the recent readouts about amyloid?

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

So the advantage of the sigma-1 activation is the analogy of the cancer-immune stimulation, where the oncology field has moved away from targeting and blocking but rather activating the body to help to reduce the cancer infiltration. And in the analogies, we're doing the same. We're asking the body to help the patient to help himself. So we're activating the sigma-1 receptor. And we have seen that when you look at the landscape

of the Alzheimer's alternatives to amyloid better, which we never doubted is a part of the pathology, but it's not the entire story alone, we have seen that with ANAVEX 2-73, we were able to reduce tau hyperphosphorylation, but also calcium imbalance and inflammation as well as mitochondrial dysfunction, and all these elements I just mentioned have been now more and more confirmed that they are co-aggregators or responsible within the pathology of Alzheimer's, in addition to a better aggregation. And we believe for that reason that this approach might be having more merits to address the complexity of this disease by not limiting it to only 1 phenotype, like, for example, a better aggregation.

Operator

We have our next question from Tom Bishop with BI Research.

Tom Bishop - *BI Research*

I had a question on the cash used of $4.3 million. And that was that -- you mentioned the loss of $8.1 million, and some of that was noncash expenses, which gets you to a little over $6 million use of cash, but the company said they used $4.3 million of cash in the quarter. So I'm wondering what that difference is.

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

Difference is an accrual of accounts payables.

Tom Bishop - *BI Research*

Okay. Another question is on -- back on the Rett syndrome trials, isn't one of the differences also age? I thought I saw on the clinical site, the FDA site that there was an age limit on the Rett trial in the U.S. and no age limit in Australia, but maybe you can just clarify both.

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

Yes. The age is actually in both very same. It's 18 years and older. And as we continue, the plan is according to our Rett syndrome program to also add patients with younger age to the study as we continue.

Tom Bishop - *BI Research*

So in other words, initially of the 30 patients in Australia, you'll start with 18 years and older and then within the 30 go below 18?

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

No, the plan is to start a study separately with younger patients. So 18 and older will stay the AVATAR study and younger patients will be enrolled in a separate study. And that's why we refer to the...

Tom Bishop - *BI Research*

So yet another II study coming up? So that's yet another Phase II study coming up?

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

That is the plan to move forward into younger patient population. That's correct.

Operator

It seems we have no further questions in queue at this time. I will now turn the call over to Christopher 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 you are as excited as we are about the recent progress at Anavex and our prospects for the remainder of 2019. Should you need any 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, please.

Operator

Thank you. Thank you, ladies and gentlemen. This concludes our conference call. We thank you for participating. You may now disconnect.
