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Transcript of
Inovio Pharmaceuticals, Inc.
First Quarter 2017 Financial Results Conference Call
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Participants

Bernie Hertel - Vice President-Investor Relations & Communications
J. Joseph Kim - Chief Executive Officer
Peter Kies - Chief Financial Officer

Analysts

Sarah Weber – Piper Jaffray
Susan Lee – Maxim Group
Yi Chen - H.C. Wainwright

Presentation

Operator
Greetings, and welcome to the Inovio Pharmaceuticals Inc. First Quarter 2017 Financial Results Conference Call. At this time all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator instructions.] As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Bernie Hertel, Vice President of Investor Relations & Communications. Thank you, Mr. Hertel. You may begin.

Bernie Hertel - Vice President-Investor Relations & Communications
Thank you. Good afternoon, ladies and gentlemen, thank you for joining us today. Today's call may contain certain forward-looking statements relating to our business, including our plans to develop DNA immunotherapies and electroporation-based delivery technologies, products and product candidates as well as our capital resources all of which involves certain assumptions, risks and uncertainties that are beyond our control, and could cause actual results to differ materially from these statements. A description of these risks can be found in the latest SEC disclosure documents and recent press releases. These statements speak only as of today's date and we undertake no duty to update or revise them.

Presenting today are Dr. J. Joseph Kim, Inovio's President and CEO; and Peter Kies, our CFO. I will now pass the call over to Joseph.

J. Joseph Kim - Chief Executive Officer
Good afternoon, everyone. Investors are obviously interested in the status of our clinical hold. Let me get straight to the point for you. Inovio has submitted its complete response regarding the device related questions and comments that were part of the VGX-3100 phase 3 program, clinical hold imposed by the U.S. FDA.

The FDA is now reviewing our submission. While we cannot predict the outcome of the review, we have conducted an extensive effort to address the FDA's information request. Based on our experience designing, testing and manufacturing CELLECTRA delivery devices and the favorable safety profile accumulated in over 1400 human subjects and 4000 separate immunizations, I unequivocally state that our CELLECTRA 5PSP device does perform as intended to facilitate the delivery of our novel DNA-based immunotherapies.

We remain optimistic that we can meet our objective of having the clinical listed and start our Phase 3 in the first half of the year as we had previously communicated. If the FDA does seek further clarification, I have every confidence we will be able to address additional questions or comments in a satisfactory manner.

Apart from the Phase 3, we have stated our 2017 goal to initiate three additional studies with a Phase 2 element in them. In an expansion of our HPV product franchise, we recently started our Phase 2 study of VGX-3100 for HPV-related vulvar neoplasia, an indication with orphan status potential.

In our recently announced joint development agreement with Regeneron Pharmaceuticals, we are combining our multi-antigen INO-5401 immunotherapy with Regeneron's PD-1 checkpoint inhibitor REGN2810 to fight newly-diagnosed glioblastoma, a devastating brain cancer. We expect this Phase1/2 Study to start enrolling in the second half of the year. We are pleased to establish this first collaboration to study INO-5401 in combination with the checkpoint inhibitor.

We are also pleased that MedImmune will start their planned trial combining MEDI0457, this is previously known as INO-3112, our HPV related cancer immunotherapy, with durvalumab, MedImmune's PD-L1 checkpoint inhibitor. This study which we expect to begin enrolling patients in the second quarter will address this combination in patients with metastatic HPV-related squamous cell carcinoma of the head & neck. HPV related head & neck cancer, the most rapidly growing cancer in men in the developed world, represents a significant unmet need. Importantly, this study and all other ongoing developmental work for MEDI0457 is fully funded by MedImmune.

Both of these combination studies are designed to assess efficacy and safety and to generate valuable data with a relatively small size and in an optimal timeframe. These studies are both expected to enroll about 50 patients with disease.

While checkpoint inhibitors targeting PD-1 or PD-L1 receptors play a vital role to unleash T cells from cancer cells breaking mechanism, an important missing link is the ability to generate significant killer T cells in the tumor in the first place. Activating these T cells is what Inovio's immunotherapies do best. So these first two studies will now place Inovio in the middle of the cancer map as a prospectively pivotal component of many future immuno-oncology combinations targeting notable unmet needs and market opportunities.

The numerous checkpoint inhibitors developed by multiple life science companies represent an array of possible combinations with Inovio products that could take patient response rates to a new level. Apart from these initial programs with Regeneron and MedImmune, we will continue to pursue relationships that enable us to study differentiated combinations.

With respect to our relationship strategy, larger strategic alliances including license agreements, such as our partnership with MedImmune for MEDI0457, are attractive to help facilitate the development and commercialization of Inovio products. We will continue to pursue this type of licensing and partnership deal with our pipeline products.

We do not, however, want to license all our products at an earlier stage of development. That would not maximize our long-term value. It is important to note that our goal is to retain and build some products through later stages of development. This will allow us to generate potentially validating data, discharge risk and have the option to partner later in development or independently pursue commercialization.

This is the case with INO-5401. The broad applicability of INO-5401 to potentially treat multiple cancer types position this immunotherapy with blockbuster potential. We aim to complete well designed clinical studies for multiple cancer indications with leading collaborators such as Regeneron.

The bottom line is we will continue to pursue such clinical collaborations as an approach to early clinical validation of novel combination regimens in addition to exploring longer term strategic alliances for select pipeline assets.

That's my update on our primary efforts at Inovio. We can discuss other areas of interest in our Q&A. Peter?

Peter Kies - Chief Financial Officer
Thanks, Joseph. As of March 31, 2017 we had $89.7 million in cash, cash equivalents and short term investments. With respect to our marketing collaboration established with ApolloBio Corporation in February, they are awaiting approval of the agreement by the Chinese regulatory bodies. Upon regulatory approval of this agreement, Apollo will pay Inovio $3 million with another $12 million payment tied to the lifting of the clinical hold, and up to $35 million in equity investments also tied to the lifting of the clinical hold.

I also want to note that a key contributor to the change in our net loss year-over-year was due to a significant change in the value of our investment in GeneOne Life Sciences. These fluctuations in fair market value occur on a regular basis. Thank you. Joseph, back to you.

J. Joseph Kim - Chief Executive Officer
Thanks Peter. When we look back on 2017, we will see many new data sets, as we already have with our Ebola, MERS and Zika programs, with more to come from our prostate cancer and hepatitis B studies this year. To date, across all our pipeline clinical studies, we have demonstrated robust and consistent antigen-specific immune responses in almost 1000 subjects and patients while maintaining a favorable safety profile. This is a feat unmatched by other novel immunotherapy and vaccine platforms. We will also see multiple steps in initiating important new studies, including four studies with efficacy endpoints along with multiple new major corporate partnerships and collaborations.

We look forward to completing an accomplished year. Thank you for your attention. And I will take any questions from the analysts on this call.

Operator
Thank you. At this time, we will be conducting a question-and-answer session for analysts on the call. [Operator instructions.] Our first question comes from the line of Charles Duncan with Piper Jaffray. Please proceed with your question.

Q: Hi, this is Sarah on for Charles. Thanks for taking the questions. So first one is just around the cervical dysplasia program. I saw the update in the PR, but can you describe what's the new update there and how confident you are that the trial can get kicked off this quarter versus next?

J. Joseph Kim - Chief Executive Officer
Yes, Sarah, thank you for the question. So as we stated in our release and in the prepared remarks, we have submitted a complete response to the FDA regarding the device related clinical hold on our Phase 3 program. Currently FDA is reviewing our submission and they will get back to us in the second quarter. So if, and of course we can't predict how the FDA is going to rule, but if we do satisfy their requirements as I have very strong confidence in, we will be able to launch our Phase 3 study for cervical dysplasia as planned during the second quarter of this year.

Q: Okay. Great, thanks for the added detail.

J. Joseph Kim - Chief Executive Officer
Thank you.

Operator
Our next question comes from the line of Jason McCarthy with Maxim Group. Please proceed with your question.

Q: Hi, guys. This is Susan Lee calling up on behalf of Jason McCarthy. Thanks for taking my question. Hello.

J. Joseph Kim - Chief Executive Officer
Hi.

Q: Hi, sorry. Can you guys discuss the next steps for INO-4212 and Ebola following completion of the immune data and the expanded trial a few weeks ago?

J. Joseph Kim - Chief Executive Officer
Yes, absolutely. INO-4212 is our vaccine for preventing Ebola infection. We have currently enrolled 200 subjects who have been dosed with our vaccine. And as it was reported a couple weeks ago at the World Vaccine Congress, we had a 95% seroconversion rate in these subject, which is a pretty good, pretty amazing, and we have done multiple challenge studies in nonhuman primates with the pathogenic Ebola virus challenge.

So, our plan is to accumulate all of our safety and immune data in our clinical studies along with our protection and efficacy data from animals, and we plan to hold a meeting with the FDA in the second half of 2017 to really map out a pathway for a licensure or an approval of INO-4212. So, following that meeting which we predict or estimate to be in the second half, we should be in a better position to have a clear path, what we hope to have as an approval pathway for INO-4212.

Q: Perfect. Thank you so much for that.

J. Joseph Kim - Chief Executive Officer
Thank you, Susan.

Operator
Our next question comes from the line of Yi Chen from H.C. Wainwright. Please proceed with your question.

Q: Thank you for taking my question. Could you give us some color when the topline results from the MedImmune and Regeneron collaborations could be recorded?

J. Joseph Kim - Chief Executive Officer
Well, thank you, Yi. And first of all, I have to say we're so excited about these two checkpoint inhibitor combinations studies for MEDI0457 which is getting started now and along with our INO-5401 with Regeneron's PD-1 inhibitor against GBM. These two studies are very exciting for us and for the immunotherapy field in general because that it's combining in Inovio's T-cell generating products with a PD-1, PD-L1 checkpoint inhibitor.

So we feel that we can have this perfect one-two punch between T cells and knocking down the braking mechanisms of the cancer. Each of these will enroll approximately 50 patients. While we can't really predict and speak for MedImmune, they are expanding extensive efforts in launching and enrolling these patients. So, we will be able to communicate once they become more based on MEDI's communications.

What I can't speak on our 5401 is that we're going to look forward to starting the study. We expect to open approximately 30 different sites to efficiently enroll the patients with newly diagnosed glioblastoma multiforme as expediently as possible. But I do want to comment is GBM is one of the deadliest cancers with 5-year survival being rated at low single digit percentages with median survival for these patients around 15 months.

So what's unfortunate for the patients is an opportunity for this trial to establish the signals of efficacy in a timely manner. So we are very excited, and I can speak for Regeneron that they're very excited to get this study started.

Q: Since you control the speed of Regeneron collaboration of Phase 1/2 trial, would you say first half of 2018 the topline results from this GBM trial could be readable?

J. Joseph Kim - Chief Executive Officer
So, you are correct in that we are controlling it and we are executing the preparation, and once we start the enrollment of these patients we will be able to communicate in more detail when the projected data points could be. But I have to reiterate that this is one of our most exciting programs because we're combining three of our top cancer antigens anchored by our hTERT antigen INO-1400 along with PSMA and WT1. So you can think of this as Inovio really striking and swinging for the distance with this very potent combination of cancer antigens.

And then you throw in REGN2810 which we're very bullish about as a PD-1 inhibitor, I think what you have is a combination of products that can—what we hope it will make a huge impact in this important disease.

Q: Thank you. Could you also give us a clinical status update for PENNVAX-GP?

J. Joseph Kim - Chief Executive Officer
Yes. I'm very happy to. So late last year in 2016, our HIV vaccine trials network collaborator who is actually conducting the Phase 1 study, 94 subject Phase 1 study for PENNVAX-GP was able to complete the enrollment, and I am pleased to say that the data will be presented at the HVTN National Conference later in May during one of the plenary talks. So while we have not publicized the PENNVAX-GP's progress because sometimes some of these studies get lost with some of our other more catalytic studies, what we are hoping is to show strong immunogenicity and safety in this 94-subject study.

In addition to this study – I think we've done a release on this earlier – we received along with our collaborators at UCSF and the Wistar Institute and elsewhere an NIH grant that lets us test PENNVAX-GP along with the checkpoint inhibitor in HIV-infected patients with the goal of clearing or curing these patients with HIV.

So that study should be starting in the fourth quarter or this year or the first quarter of 2018, and that study is very exciting for us, because we have the potential of using our immunotherapy, throw in a checkpoint inhibitor, and to my knowledge this will be the first therapeutic vaccine with a checkpoint inhibitor in an HIV setting and getting the NIH funding to do so with the PI from UCSF, Steven Deeks, one of the top experts in the field. We couldn't be more excited about this program going forward.

Q: Okay. Thank you.

J. Joseph Kim - Chief Executive Officer
Thank you, Yi.

Operator
We have a follow-up question from the line of Charles Duncan from Piper Jaffray. Please proceed with your question.

Q: Thanks for taking the second question. Sorry if I've missed this, but it seems like your focus for 3112 is now completely on head and neck, and is there any update in cervical cancer for this one?

J. Joseph Kim - Chief Executive Officer
Yes. Thank you, Sarah. So, 3112 or now more properly named under MEDI code MEDI0457, we're starting or MEDI is starting the combo study in the metastatic head and neck cancer patients first. I can tell you that the overall approach is to expand into cervical and other anogenital cancers caused by HPV, and we will communicate those additional studies when the details become available by MEDI.

From our Phase 1 studies that we had initiated and are being completed for MEDI0457 as a monotherapy, those Phase 1 studies are ongoing, one for head and neck with 20 plus subjects, they have a cervical cancer study with ten patients as well. So those studies are ongoing and wrapping up. We actually have a poster at ASCO providing additional data from our monotherapy Phase 1 study of MEDI0457. So please stay tuned.

Q: Will do. Thanks.

J. Joseph Kim - Chief Executive Officer
Thank you, Sarah.

Operator
There are no further questions in the queue. At this time, I'd like to hand a call back over to management for closing comments.

J. Joseph Kim - Chief Executive Officer
Thank you. In summary, really we are making a lot of progress in all fronts. We have submitted our complete response for our Phase 3 clinical hold comments by the FDA. And we have full confidence that we will be able to get the nod to start the Phase 3 study in the second quarter.

We also have three other Phase 2 studies that we look for to executing and launching in 2017 with many other data points including our prostate cancer study as well as our hepatitis B therapy study which will report data in 2017. So we're very excited about what's to come in the remainder of this year and going forward. Thank you very much.

Operator
Ladies and gentlemen, this does conclude today's teleconference. Thank you for you participation. You may disconnect your lines at this time, and have a wonderful day.