ISSUERDIRECT
Trading Under the Symbol: ISDR

Transcript of
Inovio Pharmaceuticals, Inc.
Third Quarter 2016 Financial Results
November 9, 2016

Participants

Jeff Richardson - Senior Director, External Relations
Joseph Kim - President and CEO
Peter Kies - CFO

Analysts

Thomas Shrader - Stifel
Sarah Weber - Piper Jaffray
Yi Chen - Rodman & Renshaw
Jason Wittes - Aegis Capital
Jason McCarthy - Maxim Group

Presentation

Operator
Greetings and welcome to the Inovio Pharmaceuticals Incorporated Third Quarter 2016 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, Jeff Richardson of Inovio. Thank you. You may begin.

Jeff Richardson - Senior Director, External Relations
Good morning and 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 involve 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 our 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 to you today are Dr. J. Joseph Kim, Inovio's President and CEO; and Peter Kies, our CFO. Now Dr. Kim.

Joseph Kim - President and CEO
Good morning, everyone, thank you for joining us. I want to start by saying that every quarter the sheer volume of work that our team at Inovio is completing grows significantly. Our workplace mantra is "patients are waiting!" With an expanded team of motivated leaders and specialists, we are continuously progressing toward our goal to bring important new medicines to these patients.

At the same time, our goal is to build the value of the company. We believe we have the right focus and strategy to achieve this goal. We also know that while we can set the direction of the company and the application of our capital and human resources to achieve our vision over the long term, there will often be detours with extra steps

to take as is the case with every journey, every company. Last month, we faced such a circumstance. We announced the delay of an important program with the clinical hold on our pending Phase III clinical program for VGX-3100. Clearly, investors are disappointed and we share that disappointment.

But let's put the situation in perspective, we did not announce a safety issue in a study that is already enrolling and treating patients. This is a request for further information prior to the initiation of our Phase III program. And this delay at the beginning may not necessarily affect our approval timeline at the end. Also, this hold or questions about this Phase III device have no effect, I will say it again, no effect on any of Inovio's other ongoing clinical studies.

Here is where we are. Of all the Phase III preparations we had to complete, the final step was submitting to the FDA our clinical or immunotherapy product and new device package for the Phase III program. We submitted this comprehensive package in September on time with the goal to initiate the Phase III in November and we were fully prepared to do so.

In this clinical submission, we included a protocol for shelf-life testing of the single-use disposable unit of the newly designed CELLECTRA® 5PSP immunotherapy delivery device and its packaging. This disposable unit contains the injection needle to administer the immunotherapy and needle array that applies electroporation pulses that are part of Inovio's proprietary immunization process. We also included our plan to submit the shelf-life data subsequent to the initial filing in September.

Questions and answers between the FDA and a trial sponsor ahead of a proposed study is a usual and expected process. In this case, in their initial response the FDA requested that shelf-life data be submitted prior to initiating the Phase III program.

The FDA has 30 days to provide their formal letter, and while we do not have all the details of their requests yet, shelf-life testing does involve standard processes and measurements. Such testing is conducted on an accelerated basis to achieve a desired shelf-life equivalency.

Here is the process now we envision. When we receive the formal letter, we will ensure our current and additional data will fulfill the shelf-life data requests. We expect that there will be additional questions in the letter which we also plan to address fully. We plan to submit to the FDA a single response letter which will start a new 30-day count for FDA review. If the FDA has no further questions and we have satisfied all informational requests, we would then be clear to initiate our Phase III program. We expect these steps to take us at least into the first quarter of next year.

During the clinical hold, all interactions with trial site institutional review boards related to the Phase III program is halted; we cannot ship products and there is no dosing. We can conduct other organizational and logistical work and it is therefore possible that this pause will not extend the potential overall timeline to submit for marketing approval.

You may ask, will there be an interim update regarding this information request? The answer is no, unless there is a material impact on this Phase III program and/or timeline to launch in the first half of 2017.

As a footnote, we now expect the total size of our Phase III program to slightly increase from our previously stated 350 participants to about 400 subjects.

Let's move on to our other programs. In conjunction with initiating the 3100, VGX-3100 Phase III cervical pre-cancer study, we continue to prepare for a start of a Phase II study next year for VGX-3100 in the treatment of vulvar neoplasia or VIN which has very limited treatment alternatives.

Turning to our cancer programs, we are progressing on many fronts. With enrollment of our INO-3112 Phase I/IIa head and neck cancer study completed, we are conducting the follow-up monitoring steps on the last patients and immunology analysis on the earlier patients. We will be presenting a poster with the new interim outcomes at a cancer conference that is just around the corner and will highlight key points in a news release. This product has been licensed to MedImmune in 2015 and future planning and timelines related to the development of this program, especially regarding the combination study of INO-3112 with one of their immuno-oncology products, are in their hands. They are preparing to start this study which we now expect in the first quarter.

In our prostate cancer immunotherapy, INO-5150 program, we previously noted we completed enrollment of the 60 subject Phase I study. We are going through the follow-up period and have started assaying the early immune data. It can be beneficial to release this type of data at a prominent medical conference and we aim to present the first immunogenicity data in the first half of next year.

Regarding our hTERT program, we couldn't be more enthusiastic about the potential of this antigen. Presented in roughly 85% of cancers, we expect this antigen to play a lead role in multiple cancer indications we intend to target over time.

When we started the hTERT study, we targeted three advanced cancer types in lung, breast, and pancreatic and started with a single trial site. Given the broad potential of this antigen and with the purpose of increasing the enrollment rate, in recent quarters we decided to increase the number of tumor types in the study to nine types including ovarian, head and neck, and hepatocellular carcinoma. We now have five sites to recruit our target for a total of 54 subjects.

With these steps, we have substantially increased enrollment in the study. Again, the follow-up and assay process is time-consuming. We expect to report the first interim data in 2017 with potentially multiple reports throughout the year. While the final readout will not be available until 2018, this timeline does not preclude us from initiating the next planned study incorporating hTERT and we envision overlapping studies.

On this note, we are finalizing the various pieces of clinical program for INO-5401, our new cancer product combining hTERT with two other antigen targets and a checkpoint inhibitor. We aim to unveil this new program by the first quarter.

Finally, the highlights in our infectious disease efforts:

Our INO-1800 hepatitis B therapy program is enrolling well. We now expect full enrollment of 90 patients in the first quarter and continue to target the second half of 2017 for preliminary safety and immune data.

With positive immune responses and safety data in hand, we expanded our DARPA funded Phase I study for our Ebola vaccine to 200 total subjects. There have been no safety issues today. The additional 125 subjects have been fully enrolled in the second stage of this trial and will permit the evaluation of different variables for this intradermal vaccine regimen. We will have antibody data available for the second stage in the first quarter. T cell and antibody responses were already observed in the first 75 subjects of this Ebola vaccine study, and we anticipate a publication to be published on this initial data in 2017.

We also completed the enrollment of MERS vaccine study with 75 total subjects and expect interim safety and immune response data by the year end.

In Zika, we expect to report interim data from our first 40 subject study by the year-end as well. Inovio also initiated a second Zika vaccine clinical study in Puerto Rico. Given the CDC's estimate of 25% of Puerto Rican

population being infected with Zika by the end of this year, we initiated a placebo-controlled double-blind trial involving 160 healthy adult volunteers divided into two groups receiving either vaccine or placebo. The study will evaluate safety, tolerability and immunogenicity of GLS-5700 administered with Inovio's CELLECTRA® 3P device. We will also access differences in Zika infection rates between the placebo and vaccine groups as part of an exploratory endpoint to look for early signals of efficacy. We look forward to data from this program in 2017.

Now, we'll have an update from our CFO, Peter Kies.

Peter Kies - CFO
Thanks, Joseph. First, let me touch on two corporate development steps since our last quarterly report.

As you know Inovio's technology platform has potential utility across many applications and diseases. We cannot pursue all opportunities at once but we are willing to leverage and monetize assets through partnerships and other structures. This quarter, we licensed a veterinarian vaccine for foot and mouth disease to Plumbline Life Sciences, an animal health company headquartered in South Korea. Plumbline will fund all development activities and pay Inovio milestone payments and royalties on product sales in exchange for commercial rights in Asia, excluding Japan. In 2014, Inovio sold other animal health assets to Plumbline for cash and a significant equity position in the company.

Second, we incorporated a 100% owned subsidiary, GENEOS Therapeutics, Inc., to develop and commercialize neo-antigen based personalized cancer therapies. While Inovio's product universally targets cancer and infectious diseases, GENEOS' focus will be on making single cancer immunotherapies for specific patients. You can read further details in our release distributed this morning.

The gist is that there is a potential value opportunity in personalized therapies and a need for well suited technology. We believe our DNA immunotherapy technology is ideally suited for this opportunity. But it is a different business model and it is outside Inovio's core focus. So while Inovio continues to focus on DNA immunotherapies and vaccines with a universal antigen approach, GENEOS will advance personalized neo-antigen focused strategy. This will be complementary and a value-add to Inovio. I want to emphasize that while Inovio has gotten the ball rolling, GENEOS plans to build its own team and independently secure operating capital, it will not use Inovio's resources.

On the financial front, we had an increase in year-over-year quarterly R&D expenses from $16.1 million to $27 million. The increase in operating expenses shows our commitment and activity level in advancing all our programs, including our partnerships and collaborations. Receiving a one-time upfront payment from MedImmune in the third quarter of 2015 resulted in a comparative drop in revenue this year.

In the third quarter through our ATM facility, the company sold 448,848 shares of its common stock at an average price of $9.45 per share for net proceeds of $4.2 million. As of September 30th, we had $119.7 million in cash and short-term investments.

Joseph, back to you.

Joseph Kim - President and CEO
Thank you, Peter. During the course of this year, we have continued to expand our team of experienced and motivated experts. The talented individuals in our company have expertise to drive our products forward and through regulatory approval as they have been demonstrated at other companies. We are a small company, but expect our growing pipeline will provide us a broad cross-section of important immune data from many different cancers and infectious diseases.

Furthermore, we believe that even in our currently running early stage clinical studies, some of these products can provide important potential indicators of their ability to break tolerance in cancers or impact anti-viral immune responses in infectious diseases. This enviable critical mass gives us a strong foundation with important value creation potential, and with which we can plan and initiate multiple next-step studies, independently and in partnerships in 2017 and beyond.

Thank you very much for your attention and now, we're ready for your questions.

Operator
[Operator instructions]. Our first question is coming from Thomas Shrader of Stifel. Please proceed with your questions.

Q: Good morning. Quite a day to hold a call, but thanks for doing this. A couple of things. So AZ and MedImmune have made some comments about their immuno-oncology drugs. Does that affect you any? Do you have to think harder about your additions and do you have any insight into that question yet?

Joseph Kim - President and CEO
Just with respect to INO-3112, MedImmune is expecting to combine with their checkpoint inhibitor. Our relationship and partnership with MedImmune and AZ is very strong, and we expect our partnership to continue that way.

Q: So they haven't seen enough that they wanted to reexamine or do any more pre-clinical testing. Do you think they're still comfortable with the plans you have?

Joseph Kim - President and CEO
No. In fact, as I mentioned in the prepared comments, we have new data from INO-3112 where we will be presenting a poster later this week.

Q: Okay, perfect. And then on the Zika front, there seems to be relatively little visibility, some money has been turned loose or earmarked, but it's relatively unclear at least to, I think, us how you would apply for that money, what the avenues are, which of the pots of money are appropriate for vaccines. Do you have any insight or can you provide any clarity there as well as maybe timelines as to when you can apply things like that?

Joseph Kim - President and CEO
Well, there's nothing I can comment on now, but I can tell you that our vaccine, Zika vaccine, studies are garnering a lot of attention from the funders and we are in early discussions with them. As we prepare and present the interim immune and safety data from our 40-subject study from North America, I would expect there will be an additional interest in that regard.

Q: So it is clear to you who to apply to. Do you think your choice to front end some of the clinical trials will be essential to getting money?

Joseph Kim - President and CEO
Well, we felt that it was very important for us to respond to this infection as rapidly as possible and as the data that's coming out from the field, the causes of microcephaly and other neurodegenerative diseases by this virus in infants and adults is quite significant. So we feel that we did the right thing in taking the leadership role in this important outbreak, and we expect to have the first clinical data from the vaccine studies. We will continue to lead this field going forward.

Operator
Thank you. Our next question is coming from Charles Duncan of Piper Jaffray. Please proceed with your questions.

Q: Good morning. This is Sarah on for Charles. So two questions, first I guess on the Zika program. What's the next update we should look for and will that be coming in the first half of next year?

Joseph Kim - President and CEO
The next updates, we will expect our preclinical data to be published in this quarter, and by the year end, we expect to have clinical immune and safety readouts from early results from our 40-subject US and Canada healthy volunteers study. So we will be able to update on the early readouts of the safety and the anti-body immune responses we're regenerating against Zika virus by the end of this year.

Q: Great. Thanks. And what about the study in Puerto Rico?

Joseph Kim - President and CEO
So the study in Puerto Rico is enrolling as planned and we expect to have updates in 2017.

Q: Great. And then just a second question, sorry if I missed this, had a couple of calls this morning. So have you begun any of the shelf life testing for the Cellectra device in anticipation of the FDA's request? Are there any other information or any—

Joseph Kim - President and CEO
Based on the initial communications and we are still waiting on the formal letter, but based on the initial communications, we have proactively prepared much of the data and we'll also have additional readouts that will come out in the coming weeks. So we expect to, barring any surprises, we expect to have a full response back to the FDA by the end of this year, and that is our plan.

Operator
Thank you. And our next question is coming from Yi Chen of Rodman & Renshaw. Please proceed with your questions.

Q: Hi. Thank you for taking my questions. So regarding GENEOS, is that a subsidiary that will eventually be a separately listed public company? And what are the candidates that are currently being developed under that umbrella and in what timeframe that we can expect to see those candidates to enter clinic?

Joseph Kim - President and CEO
So we have separately set up a 100% owned subsidiary, GENEOS. And we will be building out the business independently of Inovio, but leveraging on our DNA-based immunotherapy product and delivery platform. As Peter mentioned in the comments that GENEOS will focus on personalized patient-based cancer neo-antigen, which are new antigens that derives out of the cancers as they mutate, specific therapies. And that's a burgeoning newly establishing field, as you know, that Inovio and the newly established GENEOS can go after.

Inovio Pharmaceuticals will continue to focus on our main core business, which is universal antigen-based vaccines and immunotherapies. So everything that we're doing is staying at Inovio and continue to advance as we have been doing and GENEOS will focus on personalized medicine application of our platform.

So to re-envision as part of your question a separately listed company, that's far down the line. We are focused on building out the business and really bringing the next set of clinical programs under the GENEOS umbrella as

rapidly as possible. So it's too early to comment on now, but we expect this subsidiary to grow on its own resources and staff in the coming months.

Q: Thanks. Second question, I think you mentioned in the prepared remarks that the number of patients that are likely to be enrolled in the Phase III trial of VGX-3100 has increased from 350 to 400. Is that a decision by Inovio itself or that's a decision after discussion with the FDA? Thank you.

Joseph Kim - President and CEO
That's based on our discussions with the FDA and we've been projecting on the low side of 350 and high side of 400 already. We just wanted to give a transparent projection at this time. And once we are off clinical hold, which we expect in early first half next year, assuming we satisfy all the comments and all the requests, once we launch our Phase III program, we will share the details of our design, our protocol and our trial's design and other information at that time.

Operator
Thank you. Our next question is coming from Jason Wittes of Aegis Capital. Please proceed with your question.

Q: Hi. Thanks for taking the questions. Just maybe to follow-up on the delay in 3100, you mentioned I think the main issue is stability and you actually gave quite a bit of detail already. Just curious if the FDA is looking for a specific lens of time for stability and whether that's something that you can address on an accelerated timeline?

Joseph Kim - President and CEO
Yes. We will address an accelerated timeline, there's an established industry practice to simulate the aging process. So you can, in a validated way, accelerate the aging process and the stability and so on. So we are doing the most expedient path to get the trial started. Overall, once the product is acceptable and launched at the commercial level, we expect to have at least three years of shelf-life dating for all of our disposable units, but that work can be done concurrently as our trial is ongoing

Q: Right. And just if you could remind me again the initial stability testing required to start the trial, that's something you said you think you could address by year-end. Did I hear that correctly?

Joseph Kim - President and CEO
Yes.

Q: Okay, great. And then for GENEOS, do you have a sense of what the regulatory pathway might be for that division at this point.

Joseph Kim - President and CEO
So we have a sense, but it's a regulatory pathway that is evolving through both the personalized new antigen vaccine approaches, which is, time wise, behind the CAR-T, personalized cancer therapy approach. So I believe companies like Juno and Kite and others, Novartis are blazing the trail of how to get personalized medicine, value lifesaving medicines approved through a non-conventional pathway. So it's something that we will be able to blaze through, as we develop the GENEOS Therapeutics company and build out the organization and develop the clinical programs going forward.

Q: And then you mentioned requirement for external funding, you're going to look to basically fully externally fund that. Do you have a sense will that be your corporate sponsor? Is that something that you're going to go to the public markets to do? Is there a specific timing in terms of when we would expect to get more clarity on the plans on that front?

Joseph Kim - President and CEO
I can't project specific timelines at this point, but once these significant events occur, we will communicate as transparently and expediently as possible.

Q: Okay. And then just a question about just really the next 12 months, assuming when you start 3100, I assume the burn rate will increase. Do you have a sense of what the burn rate might look like next year and also if you can maybe just map out sort of how you think milestone payments work out maybe over the next 12 months as best you can at this point?

Joseph Kim - President and CEO
So, first, the burn rate, although it wasn't asked specifically, our annualized net burn for 2016, the net burn annualized by the end of this year is approximately $60 million. For 2017, we expect to only go up by about 10% net. I said net, because we have lots of revenues from DARPA and partners offsetting, grants and partners offsetting the total gross spend.

As far as the milestones, our next milestone from MedImmune is for starting a Phase II portion of the combination studies for INO-3112 and we expect that to be sometime in 2017.

Operator
Thank you. Our next question is coming from Jason McCarthy of Maxim Group. Please proceed with your questions.

Q: Hi, Joe. I just want to jump back to the Ebola vaccine. Once you get past the additional 125 subjects and you get that immune data, would you approach regulators about an emergency use authorization as you continue to look towards larger trials down the road? We've seen other groups like Janssen recently get that approval. And I was wondering if Inovio, if you're thinking about going for that as well.

Joseph Kim - President and CEO
Yes. In 2017, we plan to approach both the US FDA and other regulators for the possibility of getting clarity on getting our Ebola vaccine approved for emergency use. As I mentioned before, the path for Ebola vaccine will likely involve the use of animal rule and we will look to get the clarity, armed with our 200-patient study data, in 2017.

Operator
Thank you. At this time, I'd like to turn the floor back over to management for any additional or closing comments.

Joseph Kim - President and CEO
Thank you, all, for listening to this conference call. We're advancing on many fronts in cancer and infection and we will have multiple data points in the next quarters for us to really build out our programs in this company. Thank you very much.