

Transcript of
Inovio Pharmaceuticals, Inc.
First Quarter 2018 Financial Results Conference Call
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Participants

Ben Matone – Director, Investor Relations
Dr. Joseph Kim - President and Chief Executive Officer
Peter Kies – Chief Financial Officer

Analysts

Greg Renza - RBC
Alex Schwartz - Stifel
Yi Chen - H.C. Wainwright and Company
Joel Beatty, Shawn Egan – Citi

Presentation

Operator

Greetings. And welcome to the Inovio First Quarter 2018 Financial Results Conference Call. At this time, all participants are in a listen-only mode. A brief question and answer session will follow the formal presentation. [Operator instructions]. As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host, Ben Matone. Thank you. Mr. Matone, you may begin.

Ben Matone – Investor Relations

Thank you, operator. Good afternoon, everyone and thank you for joining us today. This call is also being webcast live on our website, ir.inovio.com, and a replay will be available, as indicated in our press release.

As a reminder, we will be making forward-looking statements during this call that relate to our business, which include our plans to develop our ASPIRE immunotherapy platform in combination with our proprietary CELLECTRA delivery devices as well as our capital resources, all of which involve certain assumptions, risks, and uncertainties and could cause actual results to differ materially from these statements.

These statements are based on the beliefs and expectations of management as of today. Our actual results may differ materially from our expectations. Investors should read carefully the risks and certainties described in today's press release, as well as the risk factors included in our filings with the SEC. We assume no obligation to revise or update forward-looking statements, whether as a result of new information, future events, or otherwise.

Joining us on the call from Inovio are Dr. Joseph Kim, President and CEO; and Peter Kies, Chief Financial Officer.

I would now like to turn the call over to Inovio's President and CEO, Dr. Joseph Kim.

Dr. Joseph Kim - President and Chief Executive Officer

Thank you, Ben. Thank you, everyone, for joining us in our First Quarter 2018 Earnings Conference Call. Inovio remains focused on becoming the leader for treating all major HPV-caused diseases, from pre-cancers to cancers. Today, Inovio's evaluating VGX-3100 in a Phase 3 trials treating cervical pre-cancer as well as a Phase

2 trial for HPV-caused vulvar pre-cancer, and HPV-caused head and neck cancer is being targeted in a Phase 2 trial conducted by MedImmune with MEDI0457, which stems from our outlicensing deal that we announced back in 2015.

Our plans to add a Phase 2 study for treating anal dysplasia to our HPV treatment platform in 2018 continues to highlight and complement both the versatility and capabilities of the ASPIRE technology platform as it relates to treating HPV-caused diseases.

We began this year by amending our collaboration agreement with ApolloBio, which we later closed in March, providing ApolloBio with exclusive rights to develop, manufacture, and commercialize VGX-3100 to treat pre-cancers caused by HPV within Greater China.

Inovio received an upfront payment of \$23 million, minus Chinese government taxes, and we remain entitled to receive potential future milestone payments of up to \$20 million as well as to receive double-digit tier royalty payments on sales.

The agreement with ApolloBio is a significant advancement for our company, as Inovio continues to identify opportunities that expand and strengthen our efforts to develop VGX-3100 globally. And just as importantly, as HPV remains the most common sexually transmitted infection in the world and the main cause of cervical cancer, which kills more than 270,000 women every year worldwide, this is very important. This agreement will also help broaden awareness globally on all HPV-related diseases.

So, looking ahead in terms of next steps with ApolloBio, Inovio will rely on ApolloBio's expertise in working with the Chinese regulatory agencies, while we will remain focused on patient recruitment within the U.S. and ex-China for our trials, while providing global data to help accelerate ApolloBio's work, with the goal that ApolloBio can potentially complement international recruitment for the ongoing REVEAL Phase 3 studies and our overall China commercialization efforts.

Speaking of REVEAL trials, as of today we have roughly 60 sites opened and recruiting patients for REVEAL 1, evenly split within the U.S. and internationally, and the enrollment rate remains on track. As a refresher, the REVEAL 1 study is a 2 to 1 randomized, double-blinded, placebo-controlled Phase III trial designed to evaluate VGX-3100 for the treatment of high grade cervical dysplasia caused by HPV 16 or 18 subtypes, where the primary endpoints are regression of high-grade cervical lesions and clearance of HPV 16 or 18 virus in the cervix.

Similar to our Phase 2b study design, REVEAL 1 will have a study follow-up through week 88. REVEAL 2, which we expect the enrollment to initiate in late 2018 or early 2019, will have the same criteria and design as REVEAL 1, with the only exception being a study follow-up through week 40 instead of week 88.

As we have indicated previously, our goal is to have both studies to read out in 2020. While we do not comment on specific patient accrual numbers during this process, I can confidently state that our trial is on track and we have a world-class team dedicated to execute the study as efficiently and effectively as possible.

In addition to our Phase 3 study for treating cervical dysplasia and our Phase 2 study for treating vulvar dysplasia, we recently opened a Phase 2 study for treating HPV caused anal pre-cancers in both men and women.

To provide you with some context, anal dysplasia, if left untreated, may progress to cancer, and it is estimated that there will be over 8,500 new anal cancer cases diagnosed this year, in 2018, and approximately 1,100 persons will die of this cancer in the U.S. Our immunotherapy aims to address an unmet medical need for anal dysplasia by providing a non-surgical immunotherapy and thus avoiding the unwanted effects of surgery.

The other potential benefit is that the response to VGX-3100 is systemic and may clear the underlying HPV infection, which is the root cause of the disease. Accordingly, there is the potential to reduce the risk of recurrence of anal dysplasia. We remain on track to begin enrollment for the Phase 2 study in AIN during the second quarter of this year.

Turning now to our immuno-oncology programs, I'll begin with an update on our collaborations with AstraZeneca/MedImmune. In December, MEDI0457, in combination with durvalumab, durva, as I'll call it from here, advanced to the Phase II efficacy stage of the trial, triggering a milestone payment to Inovio.

MedImmune is evaluating MEDI0457 in combination with durva as an approved PD-L1 checkpoint inhibitor in patients with recurrent metastatic HPV-associated head and neck cancers in a clinical trial with an estimated quota enrollment of 50 patients. And there will be a poster presentation at this year's ASCO on this study, as well as a poster for a Phase 1 monotherapy study of MEDI0457 in the cervical cancer setting.

In addition, we're very pleased to report that MedImmune is expanding the testing of MEDI0457 durva combination therapy to other cancers associated with HPV infection in a separate Phase 2 clinical study.

MedImmune has recently posted on the clinicaltrials.gov its plan to test this combination therapy in a separate open label Phase 2 study in patients with multiple recurrent metastatic HPV-associated cancers, including cervical, anal, penile, vulvar and vaginal cancers.

This trial, which is being sponsored by and conducted at the MD Anderson Cancer Center, is designed to test the efficacy and safety of this combination therapy in cancers related to HPV, which CDC states that there are roughly 40,000 new cases of cancer found in these parts of the body, and a little over 31,000 of these cancers are caused by HPV infections.

While we will not be providing any updates from MEDI on the enrollment and potential milestones associated with this trial at this time, we do anticipate the trial to begin in the second quarter, and we'll provide an update after the study has officially begun enrollment.

Moving now to our bladder cancer program, which is being run in combination of Roche/Genentech's PD-L1 inhibitor, atezolizumab, I'll call it atezo from here, we have also posted the Phase 2 study design on clinicaltrials.gov in April, and we plan to open roughly 25 sites in the U.S. and Spain. The primary endpoints of this Phase 2 study will be ORR, T cell immune responses and safety. We're on schedule to begin enrollment in the second quarter, and we should have interim Phase 2 readouts by 2019.

For our other combination checkpoint inhibitor trial with INO-5401, we also posted the Phase 2 trial design for our GBM study that involves INO-5401 in combination with Regeneron's PD-1 checkpoint inhibitor, cemiplimab, or cemi.

Just to provide some context in terms of when we can expect data readouts in this study, the patient setting are newly diagnosed GBM patients, meaning these patients have little to no residual tumor, and Inovio is providing the alternative to standard-of-care, which is chemo or radiation. We expect to fully enroll approximately 50 patients by June of 2019.

I will preface this, because this is an open label study and we control the data readout we believe that we could see and provide interim readouts before being fully enrolled. We anticipate this trial to begin enrollment in the second quarter as well, and we also plan to open a total of 25 sites.

Before I move to the infectious disease business, I also want to provide just a brief update on our prostate cancer program. We're looking forward to sharing updated data for INO-5150 for treating biochemically relapsed prostate cancer at this year's ASCO as the poster session.

Looking ahead in 2018, we do anticipate further presentations and analyses presented at other cancer conferences later this year, and we're targeting a publication before year end. So, more to come as it pertains to the advancement of INO-5150 for prostate, which we plan to do with a partnership. But I think you'll find expanded publication at ASCO of real interest.

Speaking of presentations and publications, we expect to publish our positive Phase 1 data from our Ebola, HIV, and MERS studies in 2018. In all of these studies we have consistently demonstrated over 90% immune response rates across these trials, while maintaining a favorable safety profile. Moreover, a clinical presentation on our PENNVAX HIV vaccine Phase 1 study has been selected as a primary presentation at the annual HIV Vaccine Trials Network Conference next week, so more to come.

Continuing the theme of our infectious disease focused business, we are thrilled with our recently announced partnership with the Coalition for Epidemic Preparedness Innovations, or CEPI, as we focus on developing vaccine candidates against Lassa fever and Middle East Respiratory Syndrome, or MERS, in which CEPI will fund up to \$56 million over five years to support the advancements of these infectious disease targets through the end of Phase 2 studies.

As stated in our release back in April, the shared goal of Inovio and CEPI is for Lassa and MERS vaccines to be available as soon as possible for emergency use.

As CEO, Richard Hatchett of CEPI elegantly stated, "Epidemics don't respect borders, they destroy lives and devastate economies." The Inovio-CEPI partnership demonstrates the confidence of both organizations in our ASPIRE DNA vaccine platform to rapidly produce countermeasures against emerging viral threats and in protecting large populations from potential pandemic.

As we have conveyed previously, a key demonstration of such capabilities was that we were the first organization in the world to develop, manufacture, and report positive human data from a Zika vaccine in less than seven months, when a traditional vaccine could normally take several years to reach this point. You should expect to hear more on new data, new funding, presentations, and publications from Inovio's advancement of infectious disease vaccines this year.

More specifically on Zika, we await the completion of study and immunologic visits by early third quarter, and we are targeting a study completion and data report on our 160-person Puerto Rico Zika vaccine study in the fourth quarter.

With that, I'd like to turn the call over to our CFO, Peter Kies, who will discuss our first quarter financials. Peter?

Peter Kies – Chief Financial Officer

Thanks, Joseph. Good afternoon, everyone. Total revenue for the first quarter was \$1.5 million for the three months ended March 31, 2018 compared to \$10.4 million for the same period in 2017. The decrease in comparable revenue for the first quarter compared to a year ago was primarily due to the revenue recognized from the termination payment received from Roche during the first quarter 2017 of \$4 million.

The decrease was also due to a decrease in grant funding recognized from our DARPA Ebola grant of \$4.7 million. This was partially offset by an increase in grant funding recognized from our Zika virus sub-grant of \$1.2 million.

As a result of the adoption of the Accounting Standard Update Number 2014-09, revenue from contracts with customers, beginning in January 2018 all contributions received from the current grant agreements have been recorded as a contra-expense as opposed to revenue on the consolidated statement of operations.

For the three months ended March 31, 2018, \$2.2 million was recorded as a contra-research and development expense, which would have been classified as revenue in the prior year. Had this change in presentation not occurred, total revenue would have been \$3.7 million for the three months ended March 31, 2018, compared to \$10.4 million for the same period in 2017. Additionally, operating expenses would have been \$36.5 million compared to \$32.3 million for the prior year period.

Net loss attributed to common stock holders for the quarter ended March 31, 2018 was \$32.4 million, or \$0.36 per share on a basic share basis compared to \$23.1 million, or \$0.31 per share for the quarter ended March 31, 2017.

Research and development expenses for the three months ended March 31, 2018 were \$24.6 million, compared to \$24.5 million for the same period in 2017. The increase in R&D expense was primarily related to our VGX-3100 clinical trials, activities under our collaboration with MedImmune, and an increase in employee headcount to support our R&D and clinical trial activities.

These increases were offset by the \$2.2 million contra research and development expense recorded from the grant agreements, as previously discussed, as well as a decrease in expenses related to the DARPA Ebola grant as it nears completion.

General and administrative expenses were \$9.7 million for the three months ended March 31, 2018, versus \$7.8 million for the same period in 2017. The increase in G&A expenses was primarily related to the Chinese VAT taxes and advisory fees incurred in connection with the ApolloBio upfront payment we received. This was offset by a decrease in non-cash stock-based compensation.

Providing more light on the Apollo upfront payment, although we received the cash during the last week of March, we did not recognize the revenue during the first quarter. We expect revenue recognition to occur in subsequent quarters.

Finally, cash and cash equivalents and short-term investments were \$112.8 million, compared to \$127.4 million as of December 31, 2017.

With that, I'll turn it back to you, Joseph. Thanks.

Dr. Joseph Kim - President and Chief Executive Officer

All right. Thanks, Peter. As you can see, our financial position is on solid ground. Before we open the line for Q&A, it's important to recognize both what we have accomplished during the first quarter and where we are on positioning ourselves to deliver and execute over the next 12 to 18 months.

First, we're extremely pleased with our latest partnerships that have enabled us to form both a global presence and market awareness towards the adaptability of our ASPIRE platform, while providing non-dilutive funding that continues to fuel our very prolific R&D programs to bring novel therapies to clinic.

Second, our latest accomplishments further validate our robust ASPIRE immunotherapy technology, while combining the DNA immunotherapy with our wholly-owned CELLECTRA delivery devices on targeting both pre-cancers and cancers in Phase 3 and multiple Phase 2 studies, along with emerging infectious disease vaccines.

Demonstration of the value of such platform and pipelines, we believe, will continue in the forms of more clinical data, partnerships, and non-dilutive funding in the coming quarters.

As I mentioned before, we have broad sets of catalysts over the next 12 to 18 months that we're very excited about at Inovio, and I feel we have positioned ourselves appropriately to be the global leader for treating all major HPV-related diseases.

I now look forward to taking your questions and discussing our progress in greater depth. Operator, please open the line for questions.

Operator

Thank you. We will now be conducting a question and answer session. [Operator instructions]. Our first question comes from the line of Greg Renza from RBC. Please proceed with your question.

Q: Hi, guys. Thanks for taking the question and congrats on the progress.

Dr. Joseph Kim - President and Chief Executive Officer

Thank you, Greg.

Q: I just want to start more near term. With respect to ASCO, you mentioned 5150 and others, and I just wanted to get a sense of what we could be looking for with regards to some of the titles that have been posted that are certainly relevant to you and Inovio.

Dr. Joseph Kim - President and Chief Executive Officer

Yes. So, we have two posters, along with MedImmune and MEDI0457, and one is a Phase 1 study monotherapy that we did in cervical cancer. So, there will be a new data set that we're presenting, which shows safety and immune responses in this cancer population. Second is MedImmune's Phase 2 trial early design. So, they're both relevant to MEDI0457. Our third poster at ASCO is a more complete set of strong immune data from our prostate cancer, 5150, along with some of the early signals of efficacy from this study.

So, we're very excited about those three poster presentations. And because of the embargo, I don't want to say any more, but I look forward to following up post-ASCO.

Q: Of course, that helps. Thank you. And then just turning to REVEAL 1, and I certainly recognize that you've indicated not to give sort of a play-by-play as far as how that is progressing, but I just wanted to get your thoughts on the pacing. If I recall back in March, I think some of the sites were maybe 50 U.S. and 10 ex-U.S. I'm seeing an even split of perhaps 60, I think is what you've just recently indicated, globally. So, I just want to get a sense of how that pacing has progressed in the more recent past, and how you see that perhaps replicating, or certainly amplifying out thereafter to get to your ultimate goal of full capacity.

Dr. Joseph Kim - President and Chief Executive Officer

Thank you. Early in the year, or last year—in the beginning of the study we started obviously with the U.S. sites first, and then we started to add on the ex-U.S. sites. And it's a dynamic situation where if the sites are not producing or performing as we have in our internal metrics, we close them down, so we don't maintain the non-performing sites. So, there's two dynamic force of adding additional ex-U.S. sites in Europe and Asia, as well as optimizing the sites in the U.S.

Q: Got it. Thanks. And then just more holistically, what do you see as the biggest risk or risks to delivering a successful study here, both on time and with the successful outcome of delivery?

Dr. Joseph Kim - President and Chief Executive Officer

So, you're referring to REVEAL 1 and 2?

Q: Yes.

Dr. Joseph Kim - President and Chief Executive Officer

So, the biggest risk is not recruiting fast enough or on time. I think the design is very much similar to the Phase 2b study, which we've successfully met all of the efficacy and safety endpoints. So, I feel very confident in terms of how the product is going to perform and the studies are designed.

Our team is really focused on executing, opening up the sites, right regions, right sites and just cranking out the enrollment. And obviously when you add the ex-U.S. sites and the potential upside of adding China through our partnership with Apollo, those are exciting works. So, I think we see those as positive opportunities that can perhaps accelerate and add to our efforts that we didn't have before in the last year or even earlier.

So, we're obviously managing all the potential risks, while adding a lot more upside. The ApolloBio relationship is beyond just cash in, it's our ability to access a billion people, or a huge market in terms of trials recruiting patients as well as a potential commercialization market going forward.

Q: Got it. That's helpful. And just one more from me, and I'll hop back into the queue. I just noticed the mention in the press release about the Geneos Therapeutics, a wholly-owned subsidiary, just curious have you drilled down a little bit on that about your overall plans, how to think about that as an entity and what can be expected in terms of not just timing but also some of the potential products and technical candidates under that roof? Thank you.

Dr. Joseph Kim - President and Chief Executive Officer

Thanks, Greg. So, we disclosed that we have set up this subsidiary in previous calls and previous filings, where what we are doing is really setting aside the neo-antigen, which are new cancer antigens that each patient generates as his or her cancer proliferates and mutates, in a personalized medicine approach, so each product is actually for a specific patient. We recognized a while back that Inovio's DNA-based immunotherapy platform may be one of a few appropriate platforms to address that in a commercially and clinically positive way.

And because this business model is disparate from our current model of, for instance, INO-5401, off the shelf, antigens, three antigens combined that can treat all patients, we decided to carve out this exciting opportunity as a separate entity, while keeping the upside economic and ownership upside of this new entity. So, we're in the process of raising separate investor capital dedicated to promoting and advancing Geneos' personalized neo-antigen cancer vaccine, and we will disclose to the public as more information is available, but we expect to close the Series A funding round in 2018.

And separately, we'll be building out the company to appropriately execute on those strategies. So, please stay tuned for more information. I don't have any other publicly available information to that. But I think this is another exciting way of monetizing for our Inovio shareholders in a maximum way and going after these exciting opportunities without expanding Inovio's internal resources as much as possible.

I see this as keeping the upside without expanding the resources. So, I see this as an extremely positive advancement, but we'll keep the public more apprised as we advance these programs further.

Q: Thanks, Joseph.

Dr. Joseph Kim - President and Chief Executive Officer

Thank you.

Operator

Our next call comes from the line of Alex Schwartz from Stifel. Please proceed with your question.

Q: Hi, Joseph and team, congrats on the progress. I had a few questions.

Dr. Joseph Kim - President and Chief Executive Officer

Thank you, Alex.

Q: I see the Phase 2 anal dysplasia trial is posted in clinicaltrials.gov, and some of the KOLs kind of believe that the highest unmet need may be here. Maybe from your perspective, what are the key elements of the trial design? And then in addition, I see the primary endpoint, is that 36 weeks, do you have a sense of, will you be able to look at interim data, and when might we see initial data from this trial?

Dr. Joseph Kim - President and Chief Executive Officer

So, last question first. Yes, there is an open label trial, so we'll be able to track the progress near real-time. We have an early look analysis, so we expect to have some early efficacy data in 2019.

As I said, though, it's an open label study. And we do agree—we certainly agree wholeheartedly about the anal neoplasia being a huge unmet medical need. These patients have to go through very painful and devastating surgery, and they're reminded daily of their problems. And surgery is not the answer because 50% to 60% of these cases, they have to have repeat surgeries, and sometimes more than once a year, which I could imagine, short of death, any more discomfort disease than this.

So, we agree with you. Our KOLs, our advisers agree with you, and we couldn't be more excited in starting this trial. There will be more information. We expect to start the enrollment in the second quarter, this quarter, but we received all the approvals from the FDA and IRBs to start the study. So, you should hear more about this going forward.

Q: Okay, great. And then can you provide additional color on the recent \$56 million Lassa fever and MERS award, how did this come about? And then secondly, what antigens are you targeting, and just what's your overall approach to tackling these two diseases?

Dr. Joseph Kim - President and Chief Executive Officer

Yes. Again, the last part first. We published extensively on the MERS and Lassa fever vaccines from the preclinical studies, where we actually—so MERS spike protein and Lassa fever glycoprotein-focused vaccines. We have 100% protection in lethal challenge models in monkeys as well as other species, so it's a highly effective vaccine in preclinical settings, and we published those results in the past.

And how did it come about? When CEPI was created in early 2017 as a result of a convergence of thoughts from some of the world's global health leaders, including one of our Board members, Professor Adel Mahmoud, who used to be the President of MERS Vaccines; Stanley Plotkin, who's on our SAB; and Jeremy Farrar, who's Head of the Wellcome Trust. Those three gentlemen wrote a piece in *The New England Journal of Medicine* in 2016, really as a call to arms for doing better in global health threats, new epidemics, after the experience with Ebola and Zika, and other events.

As a society, we should have enough resources to develop premade vaccines against known unknowns that usually keeps these global health experts up at night. So, they put their money where their mouth is, meaning

some of the top organizations, Gates Foundation, Wellcome Trust as well as several world governments of Norway, Japan, Germany, India, and counting, have put together a fund and created an organization called CEPI to disburse these funds. So, they had an open call and their RFP or their proposal, they decided that the first three targets of known unknown threats that can kill millions of people in the future were MERS, Lassa fever and Nipah.

So, Inovio coincidentally had preclinical programs already existing with great data, as I said, against MERS and Lassa. In fact, we have human clinical data from MERS vaccine in the U.S. study that I mentioned earlier, so it became a perfect fit between CEPI and Inovio. And I think this is a great organization that will fund our programs, as well as others—and you'll hear much more about efforts by CEPI and these other global funding organizations that can really promote putting the 21st century vaccine technology against these global threats. So, we're really happy and honored to be part of this.

Q: Okay. Well, thank you for additional color, and congrats on the progress.

Dr. Joseph Kim - President and Chief Executive Officer

Thank you.

Operator

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

Q: Thank you for taking my call.

Dr. Joseph Kim - President and Chief Executive Officer

Hi.

Q: Hi. My first question is, now that Apollo has closed the licensing deal, have they provided you with any color regarding the development time frame of VGX-3100 in China? And also, specifically for the potential of including China in the global Phase 3 trial, when can we expect some updates on that front?

Dr. Joseph Kim - President and Chief Executive Officer

The update's later. And what I can tell you is we already had the kickoff meeting last month, and we have a very extensive collaboration, joint development meeting. So, it's a very coordinated effort between the two groups, and obviously they're all in, and we're very happy to have them support and really carry the ball in China.

As far as China's impact on our REVEAL trials, I think I mentioned this before in previous calls, the REVEAL 1 and 2 trains are going to go. We're not going to wait for China to hop on, but we're hopeful that as the train progresses they will be able to hop on and really accelerate the pace of the train. Our goal is to have China become one of our countries and sites for our current Phase III study, but we are not going to wait for that.

We're working very hard to coordinate, so that they can hop on without us slowing down. Otherwise, obviously, the China development plan can be independent of the REVEAL studies that we have ongoing. So, we're still at the early stage and we're working very closely with the ApolloBio team in concert to make this happen.

Q: Okay. Thank you. And my second question is, for INO-5401, the two Phase 1/2a trials in bladder cancer and brain cancer, if you reported positive results from these three trials in 2019, will Inovio proceed with the following Phase 2b trial, or is there any possibility that Genentech and Regeneron could take over for future development?

Dr. Joseph Kim - President and Chief Executive Officer

So, the quick answer is we could have partners work with us. But it really depends on the data, and obviously assuming the positive efficacy readout scenario, then I think the possibility is unlimited. Just to remind everyone, INO-5401 would only be potentially effective against GBM and bladder if we can demonstrate that in those two ends of the spectrum of immune-responsive cancers, these antigens, hTERT, WT1 and PSMA are expressed in multiple other cancer types.

We would look to develop this against colorectal cancer, breast cancer, lung cancer, to name a few, along with bladder and GBM. So, we could have potential partnerships with Regeneron, Genentech, or Merck, or BMS, for that matter. So, really, we have positioned these studies to be able to give us those upsides and flexibilities, while working with some of the top partners, like Regeneron and Genentech, to help us to get there.

So, I think we can have our cake and eat it too. And obviously, if both of these studies show positive signals in efficacy we'll be very happy, and so would our shareholders.

Q: Thank you. And my last question is for PENNVAX-GP. Can we expect to see additional data from PENNVAX-GP during the rest of 2018, and would that be in the scenario of preventive or therapeutic use?

Dr. Joseph Kim - President and Chief Executive Officer

Again, the quick answer is yes, and next week. So, I guess you weren't listening to my prepared remarks, Yi— just kidding—I said these study results, a complete set of long-term data was selected as a plenary presentation at the Annual HVTN Conference in D.C. So, there will be more data.

This is all in a preventive setting, and as I mentioned in previous calls, we also have a second therapeutic study that's going to get going this quarter, fully funded by the NIH funding, that will take PENNVAX-GP and treat HIV-infected individuals who are well-controlled with drugs. Our goal is to combine PENNVAX with PD-1 checkpoint inhibitor along with drugs to perhaps a possibility of looking at the clearance of the virus from their viral reservoirs, or hideaway locations, to bring about function of cure.

I just have to add that this is a very lofty and high upside goal, but we're in the position to use NIH funding with Dr. Steven Deeks of UCSF as a PI, to go after this high-risk, high-benefit approach. But PENNVAX-GP will have its own development path as a preventive vaccine with stellar data that we've gotten thus far from our HVTN study, and we also expect, or are hopeful to see a positive outcome from our therapeutic study that will start in the second quarter of this year.

Q: Thank you.

Dr. Joseph Kim - President and Chief Executive Officer

Thanks, Yi.

Operator

Our next question comes from the line of Joel Beatty from Citi. Please proceed with your question.

Q: Good evening. This is Shawn calling in for Joel. Thanks for taking my questions, and congratulations on all of your progress.

Dr. Joseph Kim - President and Chief Executive Officer

Thanks.

Q: Can you talk briefly on VGX-3100 and how it could be used in a real-world setting? Do you kind of envision it being exclusively as a monotherapy, or are there opportunities to be used in a combination setting?

Dr. Joseph Kim - President and Chief Executive Officer

So, primarily, we see this as a monotherapy, as a first in line treatment for cervical dysplasia. Women who have high-grade dysplasia ascend to three stages, so we can bring about the regression of the lesions as well as potentially the clearance of the virus. And that's a very exciting outcome and helps these patients avoid surgery that can negatively affect their cervical competence for having future babies. So, that's how we envision to be using.

For VIN and AIN indications, obviously we'll also look to be the go-to-treatment option prior to surgery. And for all these indications, it will be the first non-surgical therapy to be approved if we're successful in doing so.

Q: Thank you. That's very helpful. And then just as a brief follow-up to the previous question in the PENNVAX-GP therapeutic setting, can you talk briefly on that trial design and what the potential endpoints could be?

Dr. Joseph Kim - President and Chief Executive Officer

Yes. The primary endpoints are safety and immunogenicity of the vaccine, along with the usage of the PD-1 inhibitor, and then their secondary endpoints look at the clearance of the viral transcripts in the reservoirs. The greatest challenge for treating HIV-infected patients has been from day one is, no one is ever cured, and the people and doctors have thrown tons of higher dose drugs, more combination of drugs and those have not resulted in the clearance of the virus. So, other than the Berlin patient who became cured, "through a bone marrow transplant," there has been zero patients who has been cured from active therapy.

Now, our hypothesis, or our thoughts are, when you combine a vaccine that can generate, just like our PENNVAX-GP, very strong killer CD8 positive T-cell immune response against the virus, combine it with the checkpoint inhibitor to free up those T cells and attack the virus where they hide out, along with the powerful drugs that can knock them out once they get out of their hiding area, it may be a great triple combination that could provide a function of cure.

Now, again, I want to caution folks, we're not declaring that this is what we expect to see, but we are hopeful to see, and this is such a high-risk, high-benefit-type of approach that we're happy to be using NIH funding to do so. But I'm very excited about this study overall.

Q: Thank you for all that, Joseph. I appreciate it.

Dr. Joseph Kim - President and Chief Executive Officer

Thanks, Shawn.

Operator

We have no more questions at this time. I'd like to turn back to management for any closing comments.

Dr. Joseph Kim - President and Chief Executive Officer

Yes, thank you very much. As we discussed, we have a very exciting 12 to 18 months coming up, with lots of data flow from our vaccine and IO and other studies, so we expect more funding, more publications, more presentations, more partnerships, and just proper execution across all of our pipeline and platform programs.

So, as I said, please stay tuned. We're very excited about what's to come the rest of 2018 and beyond. Thank you very much.

Operator

This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation.