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Transcript of
Inovio Pharmaceuticals, Inc.
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Participants

Jeff Richardson - VP, Strategic Relations
Dr. J. Joseph Kim - President and CEO
Peter Kies - CFO

Analysts

Charles Duncan - Piper Jaffray
Matthew Eckler - RBC Capital Markets
Yi Chen - H.C. Wainwright
Joanne Wuensch - Maxim Group

Presentation

Operator
Greetings, and welcome to the Inovio Pharmaceuticals Incorporated Third 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.

I would now like to turn the conference over to your host, Mr. Jeff Richardson. Thank you, Mr. Richardson. You may now begin.

Jeff Richardson - VP, Strategic Relations
Good afternoon. 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 for you today are Dr. J. Joseph Kim, Inovio's President and CEO; and Peter Kies, our Chief Financial Officer. Now, Dr. Kim.

Dr. J. Joseph Kim - President and CEO
Thank you, Jeff. Good afternoon, everyone. Before talking about our operations and financial results, I want to remind you of the path we're traveling and the mileposts we have passed, because I think that underscores the reason why we're so confident about achieving our goals.

What are these goals? My vision for Inovio is to become the leader in the following three critical areas: First, we will be the company that transforms the treatment of HPV-associated disease with the first immunotherapy to treat both pre-cancer and cancer caused by this common infection. Second, in the field of immuno-oncology, our T cell activating immunotherapies will be considered the go-to combination therapy with checkpoint inhibitors. Third,

through public-private alliances, Inovio will become the leader in rapid vaccine development to combat emerging infectious diseases and biodefense threats.

I'll take each one of these goals briefly and show you how far along the path we are in achieving our objectives.

First, Inovio will be recognized as a leader in HPV-caused disease. Overall, Inovio is well-positioned to comprehensively treat HPV-associated diseases across the continuum of HPV infections from pre-cancerous conditions through to cancer in both women and men with VGX-3100 – already the most advanced product for treating these diseases.

In June of this year, Inovio commenced a Phase 3 clinical program to evaluate the efficacy of VGX-3100 to treat cervical dysplasia caused by HPV. The pivotal data from this program will support the licensure application of VGX-3100, and I'm proud to point out this product will be the first immunotherapy and the first non-surgical therapy for this disease.

In a little over three months since Phase 3 initiation, Inovio has already opened nearly 35 U.S. sites and now initiated several sites internationally, all recruiting and ready to dose patients. By the end of the year, we expect to open at least 50 sites in at least six countries. Our team is focused on executional excellence.

In April, Inovio also commenced a randomized open-label Phase 2 trial to evaluate the efficacy of VGX-3100 in women with high-grade HPV-caused vulvar neoplasia, a disease with high unmet medical need. The primary endpoint of the study is histologic clearance of high-grade lesions and virologic clearance of the HPV virus in vulvar tissue samples. In the past 90 days, we've opened 10 sites in the U.S., recruiting and ready to dose patients.

You may not be aware of the significant morbidity associated with current surgical treatments for VIN in young and middle-aged women. This includes long-term pain, disfigurement, and sexual dysfunction. And the recurrence rate for VIN is very high, resulting in a repetitive need for invasive surgeries.

In 2018, we also plan to initiate a Phase 2 proof-of-concept study to extend our HPV franchise into anal neoplasia, another HPV-caused disease with high unmet medical need. Our collective efforts here are simple. We plan to bring VGX-3100 to the market as the first immunotherapy to treat all HPV-associated pre-cancers, offering an alternative to surgery and a means of treating both the disease and the underlying HPV infection. We expect the Phase 3 data from the two cervical dysplasia studies to be available in 2020 with VIN and AIN open label Phase 2 data in 2018-2019 timeframe.

Moving to HPV-caused cancers, Inovio's T cell activating product MEDI0457, formally called INO-3112 which MedImmune in-licensed from Inovio in 2015, targets all HPV-caused cancers. Just last May, Inovio announced that MedImmune initiated a new clinical trial investigating the combination of MEDI0457, with MedImmune's PD-L1 checkpoint inhibitor.

MEDI0457 is a novel immunotherapy designed to generate antigen-specific killer T cell responses targeting HPV-associated tumors. I'm pleased to report the combination trial is enrolling and dosing patients at a strong pace. These are patients with metastatic HPV-associated head and neck cancers with persistent or recurrent disease after chemotherapy treatment.

Also, as a part of the $700 million 2015 MedImmune-Inovio deal, the two companies are also collaborating on a new funded research program in which MedImmune has selected a novel cancer immunotherapy candidate to advance into the clinic in 2018. This new product was designed and developed by Inovio to treat an undisclosed cancer. The clinical development of this product will trigger milestone payments from MEDI to Inovio as well as

royalties based on sales. A Phase 1 milestone payment from this study is expected to be received in the second half of 2018.

Transforming the treatment of HPV disease is our first goal. Establishing our T cell activating immunotherapies as a foundational component of combination strategies to improve patient responses to checkpoint inhibitors is our second objective. In this regard, Inovio already has one of the most extensive and dynamic T cell immunotherapy combo portfolios in our field with three, let me say again, three different PD-1 or PD-L1 immuno-oncology combo efficacy studies with three different collaborators: MedImmune, Regeneron and Genentech. I've already summarized our advancements with MedImmune's checkpoint inhibitor.

Within the last past 30 days, Inovio initiated two Phase 2 immuno-oncology trials combining Inovio's INO-5401 along with two other PD-1, PD-L1 checkpoint inhibitors from Genentech and Regeneron. The first is combining Genentech's PD-L1 inhibitor with Inovio's INO-5401 to evaluate the safety, immune response and clinical efficacy of the combination therapy in approximately 80 patients with advanced unresectable or metastatic bladder cancer.

The majority of the patients enrolling in the bladder trial have previously received and failed to demonstrate meaningful response to an anti-PD-1 or PD-L1 checkpoint inhibitor alone. Thus, the study will evaluate potential benefits of this combination therapy within a bladder cancer patient population with very limited treatment options and poor outcomes.

And just last week, we initiated a Phase 2 trial in patients with a newly diagnosed glioblastoma or GBM, designed to evaluate Regeneron's PD-1 inhibitor in combination with Inovio's INO-5401. This is an open-label trial of 50 patients evaluating safety, tolerability, immune responses, as well as the progression-free survival and overall survival.

I'm proud of the road we've taken here. It's certainly not the easiest path going up against a deadly, very aggressive brain cancer, but we joined the fight with our proven T cell activating immunotherapy combined with Regeneron's PD-1 inhibitor. I really like our chances.

Remember, GBM is the most aggressive brain cancer and its prognosis is extremely poor. The median overall survival for patients receiving standard of care therapy is approximately 15 months, and the average five-year survival rate is less than 3%. So, if this combination treatment shows at least a moderate level of efficacy against this aggressive cancer, we would expect to have a clear and expedited path to bring this product to market.

All of these PD-1 and PD-L1 open-label combo studies could have efficacy data by 2019. And of course, we're not limited to combination trials with just PD-1, PD-L1 checkpoint inhibitors. Inovio's T cell activating immunotherapies may enhance the effectiveness of a range of other immune modulators and we are actively speaking with additional collaborators.

Our third objective is to utilize public-private partnerships to become the leader in rapid development of vaccines to combat emerging infectious diseases and biodefense targets. Importantly, we see Inovio achieving this goal through full external funding as we have been doing before. And ultimately, we plan to leverage our platform's safety and immunogenicity data set to build out a novel, commercial vaccine franchise. More to come here.

We were proud to have opened our mailbox to find the October issue of the prestigious *New England Journal of Medicine*, which highlighted results from our Phase 1 trial of Inovio Zika vaccine generating high levels of binding antibodies to Zika in 100% of the study participants.

Let me remind you that Inovio was and remains the first organization in the world to report positive Zika vaccine data from a clinical study. We've also posted similar encouraging HIV, Ebola and MERS vaccine data,

consistently posting greater than 90% immune response rate across the vaccine trials, all rising from our product development engine, our DNA vaccine platform. A second Phase 1 Zika vaccine study now fully enrolled with 160 participants in Puerto Rico is designed with the placebo control to explore a potential trend towards clinical efficacy. We expect to have this data in 2018.

Because our DNA vaccines can be rapidly designed and manufactured, our products are well-positioned to meet major public health challenges. Fully funded via a previous $3.5 million grant from NIH and working with our collaborators at U.S. Army, Inovio last month announced the publication of a study in which our vaccine provided 100% protection for non-human primates challenged with a lethal dose of the Lassa fever virus, a virulent hemorrhagic virus similar to Ebola which infects approximately 300,000 people annually. Because of the rapid and wide global travel and commerce, Lassa is not only a major health threat in native Africa but throughout the world. Lassa virus has been classified as a Category A biological threat agent by the U.S. CDC, and along with MERS and Zika viruses, Lassa virus has been singled out as the top potential global epidemic target for new vaccine development by newly formed multi-billion dollar Coalition for Epidemic Preparedness Initiative or CEPI in 2017.

That's a review of our three main objectives and our accomplishments towards our goal to date.

Now, I'd like to introduce our CFO, Peter Kies, who will discuss our solid financial outlook. Peter?

Peter Kies - CFO
Thanks, Joseph. Total revenue was $2.6 million for the three months ended September 30, 2017 compared to $12.5 million for the same period in 2016. Operating expenses were $31.8 million for the current year quarter compared to $32.7 million for the prior year quarter.

The net loss attributed to common stockholders for the quarter ended September 30, 2017 was $34.1 million or $0.39 per share compared to $20.8 million or $0.28 per share for the quarter ended September 30, 2016. The increase in net loss for the quarter resulted primarily from lower revenue recognized from our DARPA Ebola grant and a higher non-cash accounting expense related to the change in the fair value of the investment in our affiliated entity. The decrease in revenue was primarily due to nearing of successful completion of our DARPA Ebola grant.

Research and development expenses for the third quarter of 2017 were $25.5 million compared to $27 million for the third quarter of 2016. The decrease in R&D expenses was primarily related to less expenses incurred related to our DARPA Ebola program. General and administrative expenses were $6.3 million for the third quarter of 2017 versus $5.8 million for the third quarter of 2016, a slight increase from our increase in headcount.

On July 25th of this year, we closed an underwritten public offering of 12.5 million shares of our common stock, raising $75 million. Looking at the big picture, this raise nearly doubles Inovio's cash position. It will strongly support advancement of our Phase 3 trial and four Phase 2 immuno-oncology trials and other pipeline advancements. And the financing brought in new institutional investors into the stock.

We also amended our partnership with the ApolloBio such that Inovio would receive $15 million in upfront payment and $35 million in equity investment with a share price of $7.22 in return for ApolloBio attaining a license and commercial rights to VGX-3100 in the Greater China region. The agreement will become effective upon approval by ApolloBio shareholders and the Chinese government, which could occur by year-end.

Finally, our financial position remains very solid with total cash and cash equivalents and short-term investments of $141.9 million as of September 30, 2017. At quarter end, the company had 90.3 million shares outstanding and 99.7 million shares outstanding on a fully diluted basis.

Joseph, back to you.

Dr. J. Joseph Kim - President and CEO
Thank you, Peter.

Let me close with this message. There are two attributes I want you to remember when you think of Inovio: first, relentless innovation; and second, executional excellence.

Inovio is innovation, advancing a broad pipeline of activation immunotherapies and vaccines for people in need. And we continue to innovate with new immunotherapies and DNA-based monoclonal antibodies, targeting new disease areas in new ways. Inovio is also executional excellence; that is we do what we say we're going to do and we do it with efficiency, speed and quality, and we hold a recent track record to prove it.

We started a pivotal Phase 3 and four Phase 2 trials for important pre-cancers and cancers. We forged cancer immunotherapy partnerships and collaboration with top-tier pharma companies like MedImmune, Genentech and Regeneron, and we supported global public health advancing clinical vaccine initiatives in HIV, Ebola and Zika, all advanced with third-party funding which demonstrated consistent 90% to 100% response rates across all studies.

For a company that really began with a 2009 merger, I'm proud of our accomplishments, which gives me great confidence in our meeting our three major goals. We always remember that patients are waiting.

Thank you for your attention. I'm pleased to address your questions and comments.

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

Q: Hi, guys. Congrats on the progress in the quarter and thanks for taking my questions.

Dr. J. Joseph Kim - President and CEO
Thank you, Charles.

Q: Joseph, let me ask you about the cervical dysplasia trial or the REVEAL program. I guess, there are two trials. Do you have any operational goals in terms of that which you'd like to share for with us, and then, in terms of the visibility we may have on that trial over the course of say the next 18 months for 2018, let's call it—?

Dr. J. Joseph Kim - President and CEO
Yes, absolutely. So, as you know, each of our REVEAL trials will enroll 198 patients across the globe. About approximately half or slightly less than that will come from the United States, the rest will come from Europe, Asia and even a site in South Africa. So, we're very excited to get this launched. And as you know, we got held up a bit with the device related hold. But we were able to overcome that. So, our teams, our highly dedicated and efficient team members are dedicated to keep our heads down, get the sites open. As I mentioned, almost 50 sites in six different countries, those sites will be opened and operating to recruit patients as rapidly as possible. And that will continue on, we will add additional sites in 2018 as well. So, really, it's all about executing the site openings and utilizing those sites to recruit the patients.

So, REVEAL 1, just to talk about, the timeline is the last patient in plus nine months on drug plus 12 months follow-up. So, it's a total of 88-week study. REVEAL 2 in contrast is nine months on drug and with the one month follow-up; so, it's a total of 40-week study. So, we're still targeting enrolling all almost 400 patients across the two

trials, landing the un-blinded data in 2020 from both REVEAL 1 and REVEAL 2. And there is nothing that I see that we cannot achieve those objectives. So, we're very excited about the progress we're making. And you know and I know, we were just dying to go from our clinical hold. So, we have a team that's truly dedicated and executing with excellence, as I mentioned, in the enrolling of these patients.

Q: And I know that IRB, Institutional Review Boards are proving to be more challenging than in the past for a whole host of companies. But, your excitement over the progress is related to perhaps a few sites being open and maybe even available for enrolling patients. Would you anticipate being able to give some incremental updates over the course of the next 12 months on site initiations and patient enrollment?

Dr. J. Joseph Kim - President and CEO
Yes, thank you. First part of what you said, IRBs in our experience have not been the limiting step for Inovio. Our products fortunately have an extremely strong record of safety across our platform programs. We've dosed to-date 1,500 patients across all of our pipeline products over 5,000 different administrations with stellar safety records. So, we haven't had any, knock on wood, IRB issues, just both in the United States and overseas. So, we will continue to execute. And really, I don't want us to give like a play-by-play of the enrollments rates. Rather, I like us to provide the guidance on how we're tracking compared to what I said. And our goal is to have the un-blinded including safety data of the results from REVEAL 1 and 2 by 2020.

Q: Okay. That's fair. I appreciate the added color. And then, as you look at 2018 and 2019, what's the thing that you're looking forward to in terms of turning over a card or whatever that could further enhance your conviction in the technology and growth prospects for Inovio?

Dr. J. Joseph Kim - President and CEO
Yes. We're going to continue to add new trial data. We have couple of very exciting posters and at SITC this weekend, both our hTERT vaccine, INO-1400 as well as our MEDI0457 updates from our Phase 1 with some signal of efficacy. So, we're very excited about additional data that will be coming out from all of our oncology and infectious disease program.

And staying on infectious disease, we expect to have additional data from our hepatitis B immunotherapy, INO-1800 in the first half of 2018, along with additional Zika vaccine data from our Puerto Rico trial that's got the signal of clinical efficacy built in to a typical immune response and safety vaccine study with 160 persons participating in Puerto Rico that we'll report in 2018, among other things. And we always like to have some positive surprises. So, we expect data and other business development progress in the coming year.

Now, since I mentioned the Puerto Rico trial, you may be wondering because of the hurricane and so on. So, we were able to dose all 160 participants prior to the hurricane devastation. And there is a one year followup. So we're in that one year follow-up stage from this summer on. So, I'm pleased to say we expect minimal impact to our Puerto Rican Zika vaccine trial. I mean that's not to say that we may find additional impact as we go. But so far the sites and others are up and running. So, we are very encouraged by that.

Q: Very good. Well, I appreciate you taking my questions. And I'll hop back in the queue.

Dr. J. Joseph Kim - President and CEO
Thank you, Charles.

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

Q: Hi, guys. This is Sean calling in for Joel. I'd like to thank you so much for taking our questions today. My first question—

Dr. J. Joseph Kim - President and CEO
Yes. Hi, Sean.

Q: How are you? My first question is with the goal of your primary corporate goal of becoming the go-to HPV pre-cancer therapy, is the goal to kind of receive a broad HPV label then? And if so, what signals do you think are most important to get you there from your REVEAL and vulvar and anal neoplasia studies?

Dr. J. Joseph Kim - President and CEO
So, thank you for the question. We're going to block and tackle each indication one at a time because of the differential in timing. Obviously, we're going to get to send cervical data first from REVEAL 1 and 2. Our primary endpoints for our REVEAL 1 and 2 are similar to our VIN Phase 2 endpoint, and will be similar to our AIN study that we'll launch in early 2018. These are both the histologic trends of the lesions. So, the actual clearance of the lesion or the regression, and the clearance of the virus HPV in the tissue which caused the problem in the first place. So, that's the primary endpoint for our cervical dysplasia study as well as our VIN study. So, really, I think based on our CIN Phase 2b data, we believe we will be able to demonstrate tremendous impact on both the lesion regression and the clearance of the virus. Because ultimately, if you can clear the virus, you can remain -- you can provide long-lasting therapeutic impact to these patients. And that's what we're going for.

Q: Great, that's very helpful. And I just have two quick questions on your hTERT program coming off the heels of SITC abstract. First one was, hTERT kind of being a very prominent and ubiquitous tumor antigen, can you comment on what the path forward could look like in that neoadjuvant setting there?

Dr. J. Joseph Kim - President and CEO
Yes. So, the current Phase 1 study was actually an enabling study looking at nine different solid tumors with our hTERT antigen therapy alone. But now, based on our early promising data, we've placed hTERT antigen as the anchor antigen for INO-5401 along with PSMA and WT1. So, we're not planning to develop hTERT as a monotherapy. Rather, we have added two other brother antigens that can provide in a similar way a pan, a very broad universal cancer treatment using these three pan cancer antigens hTERT, PSMA and WT1. So, in our poster, we're showing safety, because these are cancer antigens, we want to see that we can deliver this in a safe way, answer is yes. And we are showing some immune responses to hTERT in the early look at these patients, so quite excited about the progress.

To stay on the topic, we've already shown anti-PSMA immune responses in our prostate cancer study. So, we know the PSMA and hTERT are generating specific T cell responses in cancer patients. And we have pretty good indication from preclinical data that WT1 is also an excellent generator of T cells.

So, why am I so excited about INO-5401 is that we have a potentially "pan cancer" immunotherapy that can generate specific CD8 positive T cells and we are combining with Genentech's TECENTRIQ, PD-L1 for bladder cancer and Regeneron's REGN2810, recently declare breakthrough therapy as a PD-1 inhibitor for our glioblastoma trial. So, we have two shots on goal there, with 5401, very excited about that. Our third shot on goal for PD-1 combination is with MEDI0457. And we're going to show some exciting data at SITC in the poster session. So, please stay tuned.

Operator
Our next question comes from the line of Matthew Eckler of RBC Capital Markets. Please proceed with your question.

Q: So, Joseph, just to kind of follow up a little bit on the upcoming SITC data, I know, we'll see a poster presentation on MEDI plus nivolumab in the single head and neck cancer patient who has given the two drugs sequentially. So, I guess thinking a little bit about, one, what data we might see, as well as any read through to the logic and potential outcomes from the ongoing combo study being run by MedImmune, maybe if we could just start there.

Dr. J. Joseph Kim - President and CEO
Yes. So, it looks you've read the abstract. So, thank you for pointing that out. This is a very exciting data. We know we had 22-patient Phase 1 study with MEDI0457. It's a monotherapy trial. We were able to generate very—in significant percentage of these patients very strong T cell immune responses measured both in the blood and T cell infiltrating in the tumor issues in the head and neck in some of these patients. So, we've shown that data. What's exciting about this is one of the patients who had modest level of T cell immune responses started to progress at month 11. And so, this patient was subsequently taken out of our trial. And then, the oncologist provided PD-1, nivolumab in this case, inhibitor. And just within four doses, the patient had a complete response, and the patient remains through 16 months disease-free of the cancer.

So, now, you have to temper this with this being just in one. But it's only one person that subsequently had checkpoint therapy post dosing with MEDI0457. So, what does this mean for MEDI0457 plus IMFINZI study, the PD-L1 inhibitor from MedImmune? Very excited, I think it's a metastatic head and neck cancer patient setting, 50 total patients. So, it's not a small study. ORR typically in this level is significantly less than 20% with checkpoint alone. So, our goal is to see ORR of higher percentage than that. And we're very optimistic, we're very bullish on this because we know we can generate anti-HPV anti-tumor T cells from our Phase 1 study. And what is doubly exciting here is we're dosing PD-L1 inhibitor at the same time as the dosing of MEDI0457. So, it's a true one-two punch, and we couldn't be any more excited about any study because of the potential of what we found in the earlier Phase 1 study results that are being presented at SITC.

Q: Okay, great. Thanks, very helpful there. And then, maybe shifting gears a little bit thinking about the VGX-3100 studies in vulvar and anal. So, based on the timelines you've discussed, we'll very likely see that data ahead of the Phase 3 CIN readout. So, maybe just talk a little bit about what you see as the threshold for go, no-go decision in terms of moving either of those indications forward.

Dr. J. Joseph Kim - President and CEO
It's an open label study and unlike cervix, vulvar and anal areas are more determinable throughout the study period. And there are very little spontaneous regressions. So, the placebo was not needed. We don't want to give what the threshold is, because it's a highly unmet medical need indications where surgery is the only option and those surgeries have tremendously negative impact to these patients, and they recur. Even after a successful surgery, over 50% of these patients recur. So, they have to undergo another painful surgery and sometimes in the same year, and those recurrences are devastating. And what we want to do is to not only treat the lesions, which is a great goal, but also clear the virus that caused it.

We were heartened by the fact that we saw that in our cervical dysplasia Phase 2 studies. And we'll look forward to showing that in our REVEAL 1 and 2 study. So, what do we expect? We expect to see similar results with some tempering because it's first time we're going to vulvar tissues and it's first time we're going to anal tissues. And all tissues are not the same, not all organs are the same. But we think we have an immunotherapy that leverages the CD8 killer T cells targeted against HPV antigens that are present in all of these lesions. I like our chances.

Q: And is REVEAL 2 still on track to initiate by year-end?

Dr. J. Joseph Kim - President and CEO

Actually, because of the timing and so on, and I just alluded to the FDA agreed in having the follow-up period, the safety follow-up period for REVEAL 2 to be limited to one month after the efficacy readout, unlike the REVEAL 1. That gives us a little lower leverage. So, we probably will start later than that. But, our goal is to end and land the two planes at the same time. Two planes are taking off at a different time, and we know we need to enroll a total of 400 patients. So, it really doesn't matter what sequence we do. Although, because REVEAL 1 has an 11-month longer follow-up time, it behooves us to start that first. So that's what we're focusing on first. But, we are still on track with our timeline that I gave previously.

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

Q: Regarding the three collaboration therapies in the immunotherapy space, could you give us some idea when we can likely see some updates or data readout for those three trials?

Dr. J. Joseph Kim - President and CEO
So, do you mean the immuno-oncology study, the combo study?

Q: Yes.

Dr. J. Joseph Kim - President and CEO
Yes. So, I mean, I could speak less on MEDI-run studies, because they control it. We're just a passenger in that trial; they're the drivers. But, INO-5401 studies, we're the driver. And these are open-label and we'll be tracking the progress. So, I think I estimated by 2019 will be a significant amount of data. We might see early indications in 2018. We have our fingers crossed, but that's only by 2019, we hope to have significant elucidated efficacy results. These are very exciting data, studies, and we definitely want to get to efficacy readouts as rapidly as possible.

They're powered and they're sized to be significant. So, bladder is 80 patients. Sixty of them are going to be enrolled from the PD-1 refractory patient population with very little other treatment options ahead of them. So, we hope to recruit these patients very quickly. And glioblastoma, the newly diagnosed glioblastoma, again very dire prognosis going forward; it's the same indication that Senator John McCain has been diagnosed with this year, and we also want to enroll those patients and provide some avenues potentially with 5401.

Q: Assuming the results from these two trials, with 5401 are positive, is Inovio considering a further development for those two indications by yourself or you have other strategies planned for these two indications?

Dr. J. Joseph Kim - President and CEO
If either or both have moderate level of efficacy above what's been seen, I think you'll have to beat the potential partners away with sticks. In other words, PD-1 alone, or PD-L1 are in less than mid-single digit in ORR, maybe even less than that. Most companies don't even quote what their efficacy levels are for GBM. That's a high bar or low bar in terms of showing efficacy to move forward into pivotal and licensure. So, we should be that lucky and we hope to be there in the near term.

And then, bladder, one of the most immune responsive tumors, but still over 80% of the checkpoint therapies, these patients are refractory. So, we're drawing from a large population. And if we can turn their PD-1, PD-L1 non-responsive status to responsive status even in a moderate level of percentages, we think that's a homerun. So, in those cases, I think we would have a plenty of potential partners including the ones that we're collaborating with currently along with others who are just watching enviously I think with this progress from these studies, and not to mention what we expect exciting data from MEDI0457. Obviously that's already spoken for to MedImmune. But I think there will be a great indicator of what's to come.

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

Q: Hi. My name is Joanne. I'm calling for Jason McCarthy. The first question he had was if you could walk us through the glioblastoma trial design, in particular, the enrollment criteria for the patients. Will patients be stratified based on MGMT status? And in addition, since the checkpoint will be used in the study, will you have a biomarker data from the patients' receptive tumors profiling the level of PD-L1 expression?

Dr. J. Joseph Kim - President and CEO
Last question first. We're going to look at those biomarkers and PD-L1 and so on. And the first question, yes, we will enroll both MGMT positive as well as negative or unknown, and they'll be stratified, so a total of 50 patients and post-surgery and radiation along with temozolomide. So, really these GBM patients are going to be treated with standard therapy, and we'll be dosing them with 5401 and Regeneron's PD-1 inhibitor, post that. Typically, they have pretty low, 15 months median survival, with five-year survival rate of less than 3%. So, we're hoping to see the change in overall survival, as well as other biomarkers including immune responses to these antigens, as well as the markers that we'll be tracking. So, this is going to be highly informative and hopefully with efficacy endpoints. So, it's a very ambitious, but should be highly informative study for the power and the impact of 5401 with checkpoint in addition.

Q: Could you also give us an update on the DNA-based monoclonal antibodies and plans to move candidates and other infectious disease and oncology into the clinic?

Dr. J. Joseph Kim - President and CEO
Yes. So, we've published dMAb as an earlier technology program. We actually only started this two years ago, fresh as an application or a platform to generate monoclonal antibodies directly from our DNA, injected DNA sequences. We're challenged by $54 million contract from DARPA across two grants, as well as additional funding from the NIH and the Gates Foundation. So, we've just in the last three months published three impactful research publications in cancer immuno-oncology and as well as Nature Communications and so on. So, we published actually six papers into the last two years. Our plan is to take one or more of these candidates fund with grant funding into clinical studies in 2018, which we see as not just a product development, but also as a platform validating clinical study.

So, behind all of our published dMAb work, we have some exciting other candidates. We have our own version of Humira, which is a largest selling rheumatoid arthritis drug. Or I think it is a highest grossing pharmaceutical product today, over $10 billion in sales. We have our own dMAb version of that. We have our own dMAb version of PD-1, PDL-1 and other undisclosed checkpoint inhibitors. So, these are all preclinical, but we're developing them in our very prolific research engine. So, we're going to show some proof-of-concept or proof-of-principle with the early infectious disease targets to show that we can generate the levels that are relevant clinically in people, and we look forward to starting that in 2018.

Along the way, obviously, we're going to show our expression in higher animal models like the non-human primates and so on, leading up to that. So, you should expect lot more publications on dMAb coming from our group as well as our collaborators, executing on our funded research from various places, and certainly we are moving in lightning speed and transforming this one, say, just an exciting thought into a clinical product to be evaluated starting next year.

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

Q: So, quick followup, thanks for taking it. Question that I've been asked by investors is relevant to the REVEAL program. When a person is being—or actually the other two programs as well for VIN and AIN. When a person is being treated in those programs, how do you deal with the prospects of the potential re-infection or do you believe that the technology prevents that from getting traction as well?

Dr. J. Joseph Kim - President and CEO
So, first of all, I think that's a great question. I'm not sure we have, other than our followups. For instance, if it's let's say HPV type 16 and the new infection, let's say we cleared it and then the person gets re-infected from a partner or whatever with the same type of virus, how the immune system works is the T cells existing in the patient's body should clear the new invading virus of the same type. But, in clinical trials, it's going to be very difficult to track whether that is an unfinished clear virus from originally or if the person has been re-infected.

In reality, in my knowledge of 25 years in T cell immunology is it shouldn't matter. So, T cells don't care whether it's a virus from last year or ten years ago or from today, as long as the T cell can recognize those specific viral antigens from the same virus type that will clear. So, that's a long-winded answer but that's a very interesting question which will be really difficult to prove one way or the other. But, all we care is during the study period, are we clearing the virus and clearing the lesion and during the followup. And we're also planning to have post licensure Phase 4 followups, get the information and so on. And we have other efforts to investigate how long are the true timing, the long-term impact of this. And we could only evaluate that in the clinic.

But, what I can tell you is in monkeys—monkeys aren't people—and using HIV virus, vaccines, our collaborators have tracked up to eight years at the NIH, I mean, the cost and the efforts in generating killer T cells that last for eight-plus year in preclinical study. So, we think potentially—and this is how the immune system works. Once you have memory T-cells against an antigen, they should last for very, very long time. And potentially that's what we would see, but that's going to be very hard to show in a short study. We plan to continue to track them, even through licensing and having this product on the market.

Q: That makes sense to me, certainly based on my rudimentary knowledge of immune system function. But, I'm wondering if you have any evidence from tracking patients from previous studies. It certainly would make sense to me that if you bolster T-cell responses, you ought to do that to any further infection. But any data that you can rely on there?

Dr. J. Joseph Kim - President and CEO
Yes. And we should have a lot more preclinical and clinical studies, which could add insights to those through publications and more study reports. So, we'll look forward to bringing those and adding to that data set that we are starting to amass in this area.

Operator
There are no further questions over the audio portion of the conference. I would now like to turn the conference back over to management for closing remarks.

Dr. J. Joseph Kim - President and CEO
Thank you very much for following up on our progress. Please stay tuned for the rest of the year and beyond. Thank you.