Inovio Pharmaceuticals, Inc.
Q3 2019 Earnings Call
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J. Joseph Kim, Chief Executive Officer, President and Director
Peter Kies, Chief Financial Officer
Jeffrey Skolnik, Vice President, Clinical Development, Oncology

Analysts
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Shawn Egan; Citigroup Inc.
Ellen Sands; Stifel, Nicolaus & Company
Gregory Renza; RBC Capital Markets
Nicole Gabreski; Piper Jaffray
Naureen Quibria; Maxim Group

Presentation

Operator: Good afternoon, everyone, and welcome to Inovio's Third Quarter 2019 Financial Results Conference Call.

(Operator Instructions)

Please note today's event is also being recorded.

At this time I would like to turn the conference call over to Mr. Ben Matone, Senior Director, Investor Relations. Sir, please go ahead.

Ben Matone: Thank you, operator. Good afternoon, and thank you for joining the Inovio Pharmaceuticals Third Quarter 2019 Earnings Conference Call. On the call today are Inovio's President and CEO, Dr. J. Joseph Kim; our Chief Financial Officer, Peter Kies; and Dr. Jeffrey Skolnik, Vice President of Clinical Oncology Development.

Today's call is being webcast live on our website, ir.inovio.com, and a replay of today's call will be made available shortly after the call is concluded. Following a general business update, we will conduct a question-and-answer segment, which will be reserved for equity research analysts.

On this call, we will be making forward-looking statements that relate to our business, which include our plans to develop Inovio's integrated platform of synthetic DNA immunotherapies in combination with our proprietary delivery devices, as well as clinical and regulatory developments and timing of clinical data readouts, along with our capital

resources.

All of these statements are based on the beliefs and expectations of management as of today. These statements involve certain assumptions, risks and uncertainties and could cause actual results to differ materially. We assume no obligation to revise or update forward-looking statements whether as a result of new information, future events or otherwise. Investors should read carefully the risks and uncertainties described in today's press release, as well as the risk factors included in today's 10-Q filing with the SEC.

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

J. Joseph Kim: Thank you, Ben, and thank you, everyone, for joining on the call and webcast. As we near the close of the year, I do want to spend some time reflecting on our 2019 accomplishments, but also focus more on 2020 as a transformative period for Inovio.

Let me take us on a time machine to November 2020. By this time next year, we will have shown you GBM overall survival data at 12 and 18 months for INO-5401; REVEAL 1 top line efficacy data for our Phase 3 cervical dysplasia product, VGX-3100; VGX-3100 Phase 2 results for both vulvar and anal dysplasia; an RRP study up and running via orphan designation; our Lassa vaccine will be in a Phase 1b trial in Africa and our MERS vaccine in Phase 2 studies in the Middle East, all with full funding from CEPI; our China partner, ApolloBio, will be in Phase 3 in China with VGX-3100; and we expect AstraZeneca to report on Phase 2 head and neck cancer efficacy results with MEDI0457 combined with their checkpoint inhibitor. What an incredible set of value drivers in one year!

But let me turn off my time machine and focus on the present. Last week we reported positive interim data from our ongoing Phase 2 trial of our newly diagnosed glioblastoma multiforme, or GBM, which combines Inovio's INO-5401, a T-cell-activating immunotherapy encoding for three tumor-specific antigens -- hTERT, WT1 and PSMA -- as well as INO-9012, an immune activator encoding for interleukin-12, in combination with Libtayo, Regeneron's PD-1 inhibitor.

In summary, the key interim data from the 52-patient clinical trial showed that 80% of MGMT gene promoter methylated patients and 75% of unmethylated patients were disease-progression-free at six months, measured from the time of their first dose. These results substantially exceed historical standard-of-care data. That data was presented at the Society for Immunotherapy of Cancer Annual Meeting last week. Coming next year, Inovio will report 12- and 18-month overall survival data.

Before we go into the other cancer combination program updates, we'll have Dr. Jeffrey Skolnik, who heads up Inovio's immuno-oncology development, who last week presented this data at SITC, to provide some more granularity on this data and how it compares to historical standard of care. Jeffrey?

Jeffrey Skolnik: Thank you, Joseph. As Joseph mentioned in his opening remarks, last week was very positive for our GBM program, and we're very excited to share this new clinical data with both the clinical and investment community. The excitement over these data was obvious to me as our late-breaking SITC poster presentation garnered significant attention from meeting attendees.

We want to underscore that glioblastoma is a disease that is extremely challenging to treat and that most patients die of their brain cancer within one to two years of their diagnosis. In our latest interim data reveal, we demonstrated that 75% of our MGMT promoter unmethylated patients and 80% of our MGMT promoter methylated patients were progression-free at six months. This is very favorable when we compare them to historical controls. We would expect only about 40% of unmethylated patients and about 60% of methylated patients to be progression-free at six months.

We were also very excited that almost all patients tested so far generated antigen-specific T-cells to the tumor-associated antigens created by our therapy, and we look forward to our data next year, as you've indicated, Joseph, to potentially confirm an overall survival benefit.

J. Joseph Kim: Thank you, Jeffrey. While we certainly can appreciate that this is a very difficult-to-treat cancer, we should all feel encouraged by this new data and what it really means for the future of Inovio's capabilities in immuno-oncology and for patients suffering with GBM who have not witnessed any new effective treatments for years.

Furthermore, I want to stress here the GBM data provides two additional far-reaching implications. First, because the tumor-associated antigens comprising INO-5401 -- namely hTERT, WT1 and PSMA -- are also overly expressed in dozens of other cancers, we can potentially use it to treat many of these cancers. These are pancreatic, renal, HCC, lung, gastric and other cancers. We plan to comprehensively and methodically address these opportunities, perhaps with a global partner.

Second, our GBM data also validates our overall SynCon platform for utilizing other important tumor-associated antigens we have developed as additional cancer products. Thus, while our INO-5401 GBM program is certainly very important for the patients suffering from GBM and represents a great commercial opportunity for Inovio, we are just beginning to witness only the very tip of this peak with even a greater mountain of opportunities below it.

I began our call today referencing 2020 as a transformative year for Inovio and we have been working for a while to make this possible. We have been preparing it with strategic portfolio management, workforce adjustments and funding support. When we look at where Inovio is today, I see a more sharpened resolve than where we were just two years ago. Our core focus continues to be on advancing our versatile HPV treatment capabilities that target HPV-related diseases which lack therapeutic alternatives to surgery, and we add to that our strategies to develop fast-to-market products like RRP

and GBM.

First let me address our most advanced asset, VGX-3100, beginning with our Phase 3 for treating women with high-grade cervical dysplasia. We completed enrollment of 198 patients in the second quarter for REVEAL 1 and we remain on target to provide top line efficacy data from REVEAL 1 trial by the fourth quarter of 2020. We are looking forward to seeing if we can achieve the efficacy and safety data in REVEAL 1, which we had already demonstrated in the 167-patient Phase 2b studies.

Remember, cervical cancer is still one of the leading cancer causes of death in women globally, and HPV 16 and 18 subtypes, addressable by VGX-3100, are still responsible for about 70% of cervical cancer. Thus, all the more reason on why we believe our immunotherapy to pre-cancers as an effective and proactive alternative to surgery will be graciously accepted among the patient community.

Meanwhile, we continue to be both vigilant, diligent and cost-effective on opening clinical sites for REVEAL 2 within the U.S. and globally. As of the end of October, we have 31 sites actively recruiting and enrolling patients globally, having recently opened new sites in Argentina, Lithuania and Spain. Overall, enrollment for REVEAL 2 remains on course.

As a reminder, while both REVEAL trials will be required to file a BLA, keep in mind that these two trials are identical, with the one exception being safety follow-up timing, REVEAL 1 being an 88-week-long trial which includes a one-year safety follow-up versus a 40-week-long trial for REVEAL 2 which includes a one-month safety follow-up. Coupled with our upcoming clinical data and improving the commercial profile for VGX-3100 will be the pretreatment biomarker and diagnostics kit we are co-developing with our collaborator QIAGEN. Again, the purpose of this kit is to identify patients most likely to respond to VGX-3100.

So while the most significant update for VGX-3100 will occur later next year, that being Phase 3 REVEAL 1 top line data, we do anticipate data readouts from our ongoing Phase 2 VIN and AIN programs over the next few months. Following the completion of enrollment of 33 patients in our Phase 2 trial of VGX-3100 for HPV-related high-grade vulvar dysplasia, as well as the completed enrollment in our 24-patient Phase 2 trial in patients with HPV-related high-grade anal dysplasia, we plan to report interim data from both the VIN and AIN studies at a medical conference in the first quarter of next year. While we can't provide specifics on the conference at this time, we feel that this will be the most appropriate venue to share VIN and AIN interim efficacy and safety data, garnering the most attention and appreciation for these disease targets.

Lastly, as it relates to new significant HPV target opportunities, we continue to have discussions with the FDA and are confident that we will be in a position to initiate a pivotal clinical trial of INO-3107 for HPV-related RRP, which we expect to move forward as a rare orphan product within the first half of 2020. RRP, or recurrent respiratory papillomatosis, is a disease where the patients literally have to schedule their

lives around planning, undergoing and recovering from surgery, having surgery sometimes as many -- as much as three to 10 times a year and spending annually as much as $500,000, as many of them have multiple overnight stays in the hospital and require multiple postsurgery medications.

So I know all of you share our eagerness to get this study off the ground and share our excitement about the tremendous market opportunity that this program has, and most importantly, the clinical benefit it offers to patients that are constantly reminded of this terrible disease.

I should also mention that in addition to INO-5401, presented as a late-breaker poster at SITC, INO-5151 was also featured in a trial-in-progress poster at the same conference. INO-5151, which is a combined formulation of INO-5150 and INO-9012, is being incorporated in one arm of this exploratory cohort platform study, three-cohort platform study, being conducted by the Parker Institute for Cancer Immunotherapy and Cancer Research Institute as part of the company's previously established clinical collaboration agreement. In this particular cohort, INO-5151 is being combined with Bristol-Myers' PD-1 inhibitor, nivolumab, and Celldex Therapeutics's FLT3 ligand CDX-301.

Let me again emphasize here that our cancer combination portfolio, you can expect overall survival data from our INO-5401 cancer combination trial with Regeneron for GBM, building upon the promising PFS-6 data that was recently presented. Moreover, the fully enrolled head and neck cancer Phase 2 trial sponsored by our partner AstraZeneca, combining MEDI0457 with AZ's checkpoint inhibitor, will be completed by the third quarter next year. Collectively, these anticipated efficacy data readouts in 2020 all point to great promise for Inovio's product pipeline and further solidify Inovio as the leader in synthetic DNA immunotherapy.

Before I turn it over to Peter for a financial update, while we're certainly excited about the continued developments being done within cancer and HPV, I'd be remiss not to mention the latest progress within our infectious disease business, recognizing that this is an area which I believe is often underappreciated by investors. As we stated back in July, while we narrowed our resources and focused within infectious diseases, our previously established global partnerships were not affected with this realignment. We continue to utilize and embrace our ongoing partnerships for the development of both vaccines, dMAbs and delivery devices, which support the development and investigation of multiple pandemic and infectious disease targets.

In fact, I have an update for you from our Lassa and MERS vaccines, funded by infectious disease partner CEPI, or the Coalition for Epidemic Preparedness Innovations. For Lassa, we completed enrollment of the first ever human vaccine study where we began enrollment in May of this year. Looking ahead and based upon the performance of the Phase 1 trial with INO-4500, our partner CEPI will continue to fund the next Phase 1b trial for Lassa in West Africa, where Lassa infection is endemic. This trial is expected to begin enrollment early next year.

Additionally, and moving to our vaccine for MERS, Inovio again will lead all other organizations and begin the first ever Phase 2 study in the Middle East and Africa where outbreaks have been observed.

We're also waiting for our partners to finish analyses for a Zika vaccine in Puerto Rico, as well as our HIV vaccine studies.

Moreover, we're making advancements in our dMAb and dBiTE technologies, and you will certainly hear more about them in the future. Using direct local delivery into the body by CELLECTRA platform, the synthetic genetic codes provided by the dMAbs instruct the body's cells to become a customized, patient-specific factory which manufactures their own therapeutic monoclonal antibody products, enabling a major leap in antibody technology. Traditional monoclonal antibodies represent the largest segment of pharmaceutical markets today, accounting for more than $100 billion in pharmaceutical sales last year, with treatments spanning cancer, infection, inflammation and cardiovascular disease.

With its synthetic design and in-patient production, dMAb products represent a disruptive and innovative entrant to this important class of pharmaceuticals. Collectively, dMAb and dBiTE offer the opportunity to provide superior and cost-effective therapeutic options across cancer and infectious diseases.

Inovio has already received over $60 million in external funding to support the advancement of this technology. Most recently, Inovio and its collaborator The Wistar Institute received a $4.6-million grant from the National Institute of Health in support of continued development of Inovio's dMAbs and innovative application of this to develop antimicrobial-resistance products.

Inovio's overall goal is to create a paradigm-shift approach to monoclonal antibody technology that results in a pipeline of high-impact dMAb products for cancer and infection, which can be developed with corporate partnerships, external funding and collaboration. As an example, earlier this year, Inovio advanced its first ever dMAb candidate, INO-A002, to Phase 1 dose-escalation trial to assess safety and tolerability and expression of dMAb-produced antibodies with full funding from the Bill & Melinda Gates Foundation. Stay tuned for the data to be reported in 2020.

With that, I will ask our CFO, Peter Kies, to provide a financial update. Peter?

Peter Kies: Thanks, Joseph, and good afternoon, everyone. I'll begin with a general overview of the third quarter financial results and then also touch on the recent realignment that we announced in July.

Total revenue for the third quarter was $867,000, compared to $2 million for the same period in 2018. Total operating expenses were $24.8 million for the three months ended September 30, 2019, compared to $28.6 million for the same period last year. The year-over-year decrease in revenue under collaborative research and development

arrangements was primarily due to a decrease in reimbursed drug manufacturing activities related to our partnership with AstraZeneca.

Inovio's net loss for the quarter was $23.1 million, or $0.23 per share basic and $0.25 per share fully diluted, which compares to $25 million, or $0.27 per share basic and diluted, for the same period last year.

As of September 30, 2019, cash and cash equivalents and short-term investments were $93.8 million, compared to $81.2 million as of December 31, 2018.

In August, Inovio closed a private placement of 1% convertible debt due 2024 with an aggregate principal amount of KRW 18 billion, or approximately USD 15 million, issued to a group of institutional investors led by Korea Investment Partners. These bonds are convertible into Korean Depository Receipts, or KDRs, assuming Inovio has completed a secondary listing of its security on the KOSDAQ market of the Korean stock market exchange, in the form of KDRs, or otherwise shares of common stock if KDRs are not listed at the time of conversion. Net proceeds from the offering were approximately $14.5 million after deducting offering expenses payable by Inovio.

In July, the company implemented a strategic cost-reduction plan, including a 28% staff reduction and cessation of several R&D and clinical programs, which resulted in an approximate 25% reduced annual burn. The reallocation of resources focuses the company's commercialization efforts for its lead asset, 3100, while also developing high-value, fast-to-market HPV product candidates such as INO-3107 to treat RRP and INO-5401 to treat GBM.

As a reminder, you can read the details of our 10-Q at the EDGAR on the SEC website. Also, our financial statements for the third quarter of 2019 can be found in today's press release and in our Form 10-Q, filed with the SEC. This can also be accessed on our webpage under Investor Relations, Financial Reports.

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

J. Joseph Kim: Thanks, Peter. Before we take your questions, I think it's really important to reiterate that next year stands as a transformative period for Inovio. This time next year, we could have multiple clinical and business development milestones across many therapeutic areas. Within the next 12 months, we're about to unveil significant game-changing data on VGX-3100, INO-5401 and MEDI0457, while working vigorously to see if we can potentially have INO-3107 leapfrog them all to the market.

We have been working very diligently to get to this moment. I would especially want to thank our dedicated employees and our collaborators and our long-term shareholders for their faith and conviction.

Now I look forward to taking your questions. Operator, please open the line for the analysts.

Questions and Answers

Operator: (Operator Instructions)

Our first question comes from Charles Duncan from Cantor Fitzgerald.

Pete Stavropoulos: Hi, this is Pete Stavropoulos on for Charles. Congratulations on the quarter and congratulations on the GBM data that you presented last week. I know that you mentioned ApolloBio in your prepared remarks, but I'm not sure if I missed something. So last quarter you mentioned that they filed an IND with the Chinese FDA, so has there been a response from the Chinese FDA? And have they started to explore opening clinical sites in China of -- with the recruitment in REVEAL 2?

J. Joseph Kim: Yes. So China FDA, or NPMA, has accepted the IND from ApolloBio. We're taking many steps with ApolloBio to open the trial for VGX-3100 in China. The details we can't really discuss at this moment, but you can be assured that the China plan will be executing fully in 2020 by ApolloBio for VGX-3100.

Pete Stavropoulos: All right, thank you. And one question about the biopsy-based companion diagnostics for VGX-3100, just so that I sort of get a better understanding. Is this completely in QIAGEN's hands, beyond you providing REVEAL samples? And will Inovio or QIAGEN hold patent rights? And will there be a share in the revenues?

J. Joseph Kim: Yes. So it's a co-development collaboration, still. A lot of the early development work has been done. And then QIAGEN brings their commercialization and execution excellence. They -- this is what they do. They develop and sell diagnostic kits. So our goal is to have this complementary kit available as a pre-treatment biomarker-based kit that can help us guide, and the doctors and the patients guide, the usage of VGX-3100 where the patients who can benefit the most will use VGX-3100. And that has huge implications for us. We can charge more, we can have patients have better overall efficacy. So it has multiple positive effects. It would improve overall to the healthcare dollars as well because we can have this targeted usage of 3100 in patients who value the most. So I think the key is to really utilize Inovio's expertise and QIAGEN's expertise in really making this combination possible.

We'll provide more information as we advance this further in 2020, and we're making great progress right now.

Operator: Our next question comes from Joel Beatty from Citi.

Shawn Egan: This is Shawn Egan on for Joel. A few from me today, the first one on 5401, your glioblastoma program. Maybe if you could just talk at a high level, what the next steps are? Do you plan on waiting till the full OS data matures to kind of -- prior to making any decisions on a path forward, or maybe any high-level thoughts on what a pivotal design could look like? And then I have a follow-up as well.

J. Joseph Kim: Yes. So I'm going to turn it over to Jeffrey for a detailed answer, but top, really, big picture is, we're very excited about the early data, and we're beginning to imagine and draw out what a pivotal trial could be. Obviously, as we see the later survival data, we will be even more ecstatic. So I'm going to turn it over to Jeffrey for any additional insights.

Jeffrey Skolnik: Thanks, Joseph, and thanks, Shawn, for the question. Exactly. So we'll be looking, as Joseph has said, to the middle of next year, and then into the third and fourth quarters of next year for our overall survival data, and that, together with what we continue to learn from the current study, will help us inform the design of our next trial. But obviously, as you'd imagine, we've certainly already put time and effort into thinking where we'd like to move this opportunity and potentially what that design would look like. So we look forward to the overall survival data into next year, which we're extremely excited to see.

Shawn Egan: Thanks, Jeff. And then a follow-up, also in regards to the diagnostic from QIAGEN. Are there any learnings that you could leverage to -- that could be broadly applicable across your platform, or are those really tailored to the VGX-3100?

J. Joseph Kim: Yes. So -- but details have to be studied further, but we think there are learnings. There could be, certainly, across HPV space, and certainly impact into our I-O programs as well. So the biomarkers and focused, targeted therapies for I-O, really, is the next-generation improvements in this field. So we're going to apply everything we learn from all aspects, but especially in the biomarker work, to make our programs better.

Shawn Egan: Thanks, Joseph. And I just have one last question: I noticed on clinicaltrials.gov that the daratumumab/MEDI0457 study decreased enrollment down to 35 from 50. Can you comment on any rationale for that, or is that in Astra's hands?

J. Joseph Kim: Yes. Well, it's really in AstraZeneca's hands, but we see that as a positive, that they have enough patients to look at what they want. And based on what's publically stated in clinicaltrials.gov, they're looking to fully close out the study by third quarter next year, and we're expecting -- we're sort of estimating because they have the full say in when and where to present head and neck cancer data, but we're thinking sometime mid-year next year, give or take a couple months, is where they would likely present. So I think that sets up the additional arsenal in our 2020 expectations in terms of meaningful Phase 2 and Phase 3 data in 2020.

Operator: Our next question comes from Stephen Willey from Stifel.

Ellen Sands: This is actually Ellen on for Steve. So I think the first one, just about VGX-3100, I believe the guidance may have changed from your '19 to first quarter '20, and correct me if I'm wrong there. So I was just wondering if that is the result of just wanting to present at a specific medical conference in first quarter '20 or if it had to do with enrollment dynamics at all. And then also, related to that, just wondering what kind of

data points that we'd be able to expect from this interim update in first quarter '20. Thanks.

J. Joseph Kim: Yes. I think you're referring to our Phase 2 VIN and AIN studies for VGX-3100. Yes, the enrollment dynamics were on point and on track. We completed the 33 patients in VIN study and 24 patients in AIN study. We feel, as you stated, to have a meaningful place to present our data, so there's really not a lot of data-presenting opportunities in the late fourth quarter, so we're going to be doing it at a medical conference in the first quarter next year.

Ellen Sands: Okay, great. And then can you talk about any commercial plans or any specifics you have outside of the diagnostic tool for VGX-3100 for REVEAL 1 and 2 as that kind of gets closer to reading out?

J. Joseph Kim: Yes. I mean, we're very excited about the REVEAL 1 data, and really, that's the next near-term data, major milestone. We've all been waiting for this for the last couple of years. And then REVEAL 2 comes after that, and certainly we have internal preparations for commercialization, launch readiness and so on. We're talking to multiple interested potential partners who may work with us, and all these things, we're looking into the future, but we're very excited about what VGX-3100 can do for patients who are suffering with cervical precancer today, where currently the only treatment option is blasting off the tops of -- full top layers of their cervix, negatively impacting their ability to have future babies.

So we can -- we think we have an immunotherapy solution that can treat the disease, clear the cause of the disease in HPV 16 and 18 viruses, and spare the cervix from surgery. So we're quite excited, and we think the market will embrace VGX-3100 as an immunotherapy option for cervical dysplasia, and certainly to other indications, vulvar and anal dysplasia as well.

Ellen Sands: Okay, great. And then one last one from me that's related to the GBM study. Can you just remind us what the bar will be, OS-wise, to move forward once we see those readouts? Then additionally, do you think we'll get additional patient baseline data along with those 12- and 18-month OS readouts next year? Thank you.

J. Joseph Kim: Jeffrey?

Jeffrey Skolnik: Thanks for the question, Ellen. So yes, in general, we would expect to be using standard-of-care numbers, obviously, around OS12 and OS18, and similarly, to use median overall survival data based upon the current standards of care. And there, again, are several published numbers. We would anticipate that about 60% or so, 50% to 60% of patients will be alive at 12 months with glioblastoma if you look at all comers. And then obviously, fewer to be alive at 18 months; that could drop to about 40%, 50%. So we'll continue to follow our data through 12 and 18 months, taking a look at what the standards are.

Ellen Sands: Great. And then the patient baseline? Do you think there will be any information on that, or will it be limited to what we saw at SITC?

Jeffrey Skolnik: So when you say patient baseline, tell me a little bit more about what you mean.

Ellen Sands: Yes, so just specifically, if patients had a full surgical resection or partial.

Jeffrey Skolnik: Sure. So yes, we would anticipate that as we continue to publish our data and we have our full data set, you'll get even more information about the baseline for these patients. Again, as you know, all patients, obviously, in the study are newly diagnosed, and all of our data, very importantly, are being calculated from Day 0, the first day of our therapeutic intervention.

Operator: Our next question comes from Gregory Renza from RBC Capital Markets.

Gregory Renza: Just to follow up on 5401 and the GBM study, Joseph, in your prepared remarks and subsequent, you've mentioned just the concept of working with or finding a global partner, given the expansion potential. I'm just wondering if you could perhaps just remind us of the agreement and the arrangement you've got with Regeneron on this, and any detail there about future engagement would be helpful. And then I think similarly, just maybe broadly as well, what you see as sort of the optimal point of engagement from a partner as this program matures and moves forward. Thanks.

J. Joseph Kim: Yes. Regeneron has been a great collaborator in this regard. I say collaborator because it's not a full-blown licensed partnership like the one relationship we have with AstraZeneca for MEDI-0457.

So INO-5401 has not been licensed to anyone. Now, Regeneron is providing their important PD-1 Libtayo -- inhibitor, Libtayo, to the study. They also get the benefit of looking at the data, perhaps before everyone else. For that advantage, I think they have some timing and knowledge and information advantage over other potential partners. So -- but we have not spoken for INO-5401 to Regeneron for GBM or for other fields.

But obviously a perfect partner would look a lot like Regeneron and perhaps other big pharmas with their own PD-1 or PD-L1 inhibitors, as we have shown that our immunotherapies are almost equally effective in combining with these PD-1 or PD-L1 inhibitors. Just a reminder, we have PD-L1 inhibitor combination with AstraZeneca with their development for 0457, PD-1 with Regeneron, and our prostate cancer 5151 is just entering a combination study with nivolumab from Bristol-Myers. So I believe our therapies can be effective combined with any of these checkpoint molecules, inhibitor molecules, but someone like Regeneron, with the global reach, the goal of applying 5401 to make the checkpoint inhibitors perform even better compared to the competitors in their space, without adding any additional toxicity, increasing efficacy, is something that we think someone like Regeneron or other big pharmas in this competitive space would be very much interested in.

And just to take a short moment further, I mean, I stated at this prepared remark part, but 5401's success in GBM has -- is great for GBM and for the patients and for Inovio, and that's a great opportunity on its own. But the way we designed this product is, it's a multi-cancer-targeting product, much like the similarity to Nektar's program where they can combine and address multiple different cancers. We can do that, utilizing very prolific tumor-specific antigens or associated antigens in WT1, hTERT and PSMA. And then we have dozens more of these novel antigens in our toolbox which could be utilized to create even more potent cancer immunotherapies to combine with checkpoint inhibitors.

So I think we are very excited about the GBM trial on its own, but we have other, broader plans, and because our resources are certainly limited as a small biotech, bringing in a global partner that can fully utilize this versatility and potential broad range of efficacy, we think, would be a great partnering opportunity going forward.

Gregory Renza: Great, thank you. And just one more from me on 3100, and as far as the timing, and I appreciate you putting a finer point on what we potentially can expect next year; I'm just curious if you can comment a bit on some of the thinking about having the top line efficacy data. Certainly you've spoken in the past about landing REVEAL 1 and 2 planes, if you will, around the same time. But just curious about that cadence by fourth quarter. Would we expect to see some cut of safety there as well, or would we wait for the full -- wait for that following the full 88 week for REVEAL 1 at a later point? Thank you.

J. Joseph Kim: Yes, Greg, thanks for that question. So the top line is focused on group level efficacy results. Full safety will be after the full 88 weeks for REVEAL 1 and full 40 weeks for REVEAL 2. Now, these are 198-patient studies. We did already demonstrate strong safety at Week 36 and Week 88 using our 167-patient Phase 2b study, which really is pretty much identical to our REVEAL 1 and REVEAL 2 studies. So -- and we haven't seen any signals of safety throughout any of our DSMB meetings. So we're quite confident, as we always are with our platform programs, across our pipeline. So safety is not a real concern, overly a concern for us.

Gregory Renza: Great. And then could you just -- perhaps just comment on your level of confidence that you adhere to your previously stated prospect of having a BLA filing for 2021? Thank you very much.

J. Joseph Kim: Well, it really depends on the execution of REVEAL 2, because REVEAL 1 timeline will support, potentially, 2021. So we should have more guidance in the future.

Operator: Our next question comes from Chris Raymond from Piper Jaffray.

Nicole Gabreski: This is Nicole Gabreski on for Chris. So just had a few questions. So the first was on the RRP program. So with the initiation of a pivotal clinical trial for INO-3107 in first half of '20, so I guess it sounds like you guys have had discussions with

FDA, so just wondering what still needs to be worked out with regulators, and if you have any color at this point on endpoints for the trial.

J. Joseph Kim: So we're still discussing that. As an orphan indication, we want to be as aggressive in timing and sizing of the studies as well. So we're not yet ready to unveil the overall design and the endpoints yet, but our overall objective is to use, similar to what we've shown in our pilot study in RRP -- by the way, we expect to have the clinical publication in the next few months to come out of this RRP study -- but just using as an immunotherapy to avoid or delay surgery would be a -- we think is a meaningful clinical endpoint.

And while this discussion is still going on with the FDA, I don't want to overstep that, but our -- I can confidently say that we will be starting our RRP trial in the first half of 2020. We've been working to manufacture the clinical product, getting all of our clinical potential PIs motivated and marshalled, and so everything is getting prepared behind the scenes. We look forward to sharing more information, more detail in the future.

Nicole Gabreski: Thanks, that's helpful. And then maybe a second question, just after the Phase 2 GBM update, we went back through the literature and noticed that there just seems to be some debate around whether PFS6 in GBM translates to overall survival. So just kind of wanted to get your thoughts on this, and just what your confidence level is moving forward to the first OS readout next year.

J. Joseph Kim: Well, I can just say the field is split on the predictability of PFS6 to future overall survival, but actually, that's not the point. I think the point is -- and Jeffrey can add to this, but we're excited about the data we have at six months for progression-free survival. We're not projecting we're going to be successful in OS, but we are waiting with bated breath, and in less than six months from now, we will have OS12, and less than a year from now we will have OS18. So while the previous studies were not able to correlate the success of PFS6 to OS12 and 18, that's not the question we're trying to address.

We think we have an immune-activating approach that, combined with a checkpoint inhibitor, brings a better level of efficacy, and if our hypothesis is right, and so far the PFS6 is supporting that, we think -- we're very confident and highly optimistic for the OS numbers. But by no means are we saying we can correlate and predict success. Jeffrey, would you add any more granularity to that, or?

Jeffrey Skolnik: Thanks, Nicole, for the question. Yes, I completely agree with you, Joseph. I think what we've demonstrated is that we have immune responses to our T-cell-enabling therapy and that we have an efficacy signal. And those two things give us the confidence to move onto an overall survival endpoint. And exactly as you said, Joseph, I would not prognosticate, but we are very excited to see what our overall survival data look like.

J. Joseph Kim: I would say I like our chances.

Operator: And our final question today comes from Jason McCarthy from Maxim Group.

Naureen Quibria: This is actually Naureen on for Jason. So congrats on the GBM data, and actually I'd like to follow up on a number of those questions. I was just wondering, with regards to the trial design for the GBM study, if we could drill down a little bit there. In the clinicaltrials.gov, it says some of the patients received TMZ and radiation if it was clinically indicated. But then when I look back at the poster at SITC, it suggests that the entire cohort -- the methylated cohort may have received additional TMZ, up to six additional cycles. So I was wondering if you could provide a bit of clarity on this, if it was a subgroup within the Cohort B that received additional chemo, or if it was the entire cohort, and if it's not the entire cohort, will there be a breakdown on the data as well in the future?

J. Joseph Kim: Thanks, sure.

Jeffrey Skolnik: Thanks, Naureen, for the question. So exactly as you've indicated, all patients on the study, whether they were MGMT methylated or MGMT promoter unmethylated, received three weeks of radiation and three weeks of temozolomide concurrently, and then exactly as you've suggested, all patients on Cohort B, the methylated -- MGMT promoter methylated patients, went on to receive adjuvant temozolomide up to six cycles. So again, all patients received radiation and temozolomide for three weeks, and then those that were methylated received additional temozolomide, up to six cycles.

J. Joseph Kim: So this is the standard of care for these populations, so yes, we followed the directions from the FDA and our KOLs, who helped us design the trial and helped us to execute the conduct of the trial.

Naureen Quibria: Yes, that makes sense. Thank you. And I was just wondering -- I actually brought this up in the past -- normally with checkpoints, or at least in the past, all of them have failed in the past, and people have said or suggested that it's because there's a need for steroids, and steroids actually decrease the efficacy of a checkpoint. But in your study, you have these compelling results, so I was wondering, were steroids actually used in all the population? What percentage of the patient population? And what are your thoughts on that, if Inovio's platform is actually able to counteract the inhibitory effects of steroid on a checkpoint to promote its activity? I was just wondering as to whether there was steroid use and if you have any thoughts on that.

J. Joseph Kim: Great question. Jeffrey?

Jeffrey Skolnik: Yes, Naureen, that's a great question. So as Joseph mentioned, when we designed the protocol, we worked very closely with our key opinion leaders in the field, many of whom were and are part of the single-agent checkpoint studies, as you've mentioned, and they themselves have been very disappointed at the data that have come from those single-agent checkpoint studies. We of course feel that combining with a T-

cell-enabling therapy like INO-5401 plus INO-9012, we really give, as Joseph has said before, a one-two punch to the tumor, increasing the opportunity for efficacy. But to your point, steroids certainly can be suppressive in generating an immune response, and so we did pay attention to the amount of steroid that was used and our study does control for and collect that information. And those data should be forthcoming in an upcoming scientific presentation when we bring all those data together.

Naureen Quibria: That's great to hear. And just one more follow-up, again on the GBM study. There's been some suggestion that checkpoints may actually work better in the neoadjuvant setting, so I know it's thinking far ahead, but have you also considered a potential similar study with INO-5401 in such a setting?

Jeffrey Skolnik: Yes, that's an outstanding question. The short answer is, of course we are paying attention very closely to the literature, and as you are aware, there have been recently several publications looking at neoadjuvant checkpoint in GBM, and thankfully, the authors of one or more of those papers are KOLs that we have the opportunity to interface with. So we're excited to see the data from this trial, and we keep all opportunities open based upon the emerging literature and the science.

Operator: And ladies and gentlemen, with that we'll conclude today's question-and-answer session, and at this time I'd like to turn the conference call back over to Joseph Kim for any closing remarks.

J. Joseph Kim: Thank you very much. 2020 is going to be awesome; stay tuned. Thank you.

Operator: Ladies and gentlemen, that will conclude today's conference call. We do thank you for attending today's presentation. You may now disconnect your lines.