Event Name:  INO - Inovio Fourth Quarter 2018 Financial Results Conference Call
Event Date:  Tuesday, March 12, 2019, 4:30 PM Eastern Time

Officers
Ben Matone; Inovio Pharmaceuticals, Inc.; Director of Investor Relations
J. Joseph Kim; Inovio Pharmaceuticals, Inc.; President, Chief Executive Officer, Director
Peter Kies; Inovio Pharmaceuticals, Inc.; Chief Financial Officer

Analysts
Gregory Renza, RBC Capital Markets
Christopher Raymond, Piper Jaffray
Joel Beatty, Citigroup
Stephen Willey, Stifel Nicolaus
Naureen Quibria, Maxim Group
Yi Chen, H.C. Wainwright & Company
Jonathan Aschoff, National Securities Corporation

Presentation

Operator:  Good afternoon, everyone, and welcome to the Inovio Fourth Quarter 2018 Financial Results Conference Call.

(Operator Instructions)

Please also note today's event is being recorded.

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

Ben Matone:  Thank you, operator. Good afternoon, everyone, and thank you for joining the Inovio Pharmaceuticals Fourth Quarter and Full Year 2018 Corporate Earnings Conference Call. This call is being webcast live on our website, ir.inovio.com, and a replay will be available as indicated in our press release. During this call, we will conduct a question-and-answer segment, which will be reserved for equity research analysts.

Before we begin, I would like to remind everyone that on this call we will make certain forward-looking statements that relate to our business, which include our plans to develop our DNA immunotherapy platform in combination with our proprietary delivery devices, developments and timing on certain clinical data and readouts, as well as our capital resources, which include our cash burn guidance for 2019. These statements involve certain assumptions, risks and uncertainties and could cause actual results to differ materially from these statements.

All of these statements are based on the beliefs and expectations of management as of today. 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, which is posted on our website, as well as the
risk factors included in our filings with the SEC.

Joining us from Inovio are Dr. J. Joseph Kim, President and CEO; and Peter Kies, Chief Financial Officer. Now I would like to turn the call over to Inovio's President and CEO, Dr. J. Joseph Kim.

J. Joseph Kim: Thanks, Ben. Good afternoon, everyone. Thank you for joining us.

Today, I'll reflect on our progress from the last quarter and the past year and tell you what you can expect from Inovio in 2019 from our HPV program, from our cancer combination trials, and from our global health vaccine portfolio. Finally, I'll close with a progress report on our new and exciting dMAb program. Later in the call, you'll hear from our CFO, Peter Kies, with a financial update and more detail from our recent financing; a financing, by the way, that nearly doubled our year-end cash position of $81.5 million, and thus supports us in achieving results that will move our products over the goal line to commercialization.

For me, the highlight of 2018 was when four head and neck cancer patients, who initially were treated with MEDI0457, subsequently received a checkpoint inhibitor when their cancers progressed. The result: two of the four patients achieved a sustained complete response, or full cancer remission, for over two years. This is every oncologist's dream, achieving a sustained complete response using an immunotherapy in their metastatic cancer patients.

The fact that the treatment with our synthetic DNA vaccine, followed with two different PD-1 inhibitors, showed a complete response in two out of four progressors, is very encouraging. I'll do the math for you: That's a 50% complete response rate using our combo strategy, compared to a 4% complete response rate by PD-1 inhibitors as monotherapies in metastatic head and neck cancer. That's only 8 out of 192 patients for KEYTRUDA and only 6 out of 240 patients for OPDIVO. In this context, our MEDI0457 data is even more impressive.

And to expand on these developments, we reported that 20 out of the 22 patients showed elevated CD8+ T cell response, T cell activity that lasted at least several months after the final vaccine dose. This strongly suggests that the sustained CD8+ T cell responses from the dosing of MEDI0457 in these patients drove the complete responses in combination with PD-1 inhibitors.

While additional data from the ongoing MEDI0457 Phase 2 clinical study will provide more insights and statistical power to these current data, the two complete responses demonstrate the potential of our overall cancer combination strategy using our T cell-activating product combined with various checkpoint inhibitors against an array of cancers.

We expect continued updates and future publications from this program, which is now owned by AstraZeneca, as we continue to monitor these two full-remission patients, as well as the other 18 non-progressors from our Phase 1 study.

Let me add more on our ongoing partnership with AstraZeneca. Here's what you can expect in the coming months. First, a Phase 2 study of MEDI0457 in combination with their checkpoint inhibitor, durvalumab, in metastatic recurrent head and neck cancer is going well. Last December
we announced that AZ started a second Phase 2 study in collaboration with MD Anderson to evaluate MEDI0457 plus durva, targeting a broad array of HPV-related cancers. Important to Inovio was that the treatment of the first patient with cervical cancer resulted in a milestone payment from AZ to Inovio with cervical cancer as the second major cancer indication for this product.

Looking forward, we expect one additional Phase 2 milestone payment from AZ for a third major cancer indication when they dose a patient in another HPV-related cancer indication in the same study being conducted at MD Anderson in 2019.

Moving now to our INO-5401 cancer combination trial.

I'll begin with our collaboration with Regeneron Pharmaceuticals. In this Phase 2 trial, we're evaluating INO-5401 plus INO-9012 in combination with Regeneron's PD-1 inhibitor in patients with newly diagnosed glioblastoma. This trial currently has 20 sites open within the United States. The study continues to recruit extremely well, with a total enrollment of 52 patients almost completed. We anticipate interim efficacy data in the second half of this year that will show progression-free survival at six months, accompanied with immune responses and safety data.

Inovio's other Phase 2 study of INO-5401 plus INO-9012, in combination with Genentech's PD-L1 inhibitor, is under evaluation for the treatment of advanced or metastatic bladder cancer. Here, we recently opened sites in Europe to further accelerate enrollment, along with 13 active sites in the U.S. Just like our GBM program, we anticipate interim efficacy results in the second half of this year.

To remind you, INO-5401 is composed of three of our most active SynCon cancer antigens combined into a single product. Our goal is to see if we can replicate the level of T cell responses and antitumor responses we observed in our head and neck cancer study.

Taking a look at our prostate cancer product, INO-5150, late last year we presented data from our Phase 1/2a study at ESMO. INO-5150 demonstrated a slowing of prostate-specific antigen doubling time in men with prostate cancer. Additionally, the data also revealed that 86% of the patients remained progression-free at Week 72 of the study, and it's really exciting to see almost nine out of 10 patients show no growth in their tumors a year and a half after treatment. We hope to advance INO-5150 into a novel checkpoint combination Phase 2 trial for prostate cancer with a partner.

Shifting now to our lead product, VGX-3100, which continues to move forward in a global Phase 3 trial. At the beginning of the month, we announced another company milestone with the start of the second and final portion of our Phase 3 trial, REVEAL 2, to begin recruiting patients. To be clear, with REVEAL 1 enrollment nearly completed, we will be utilizing European and other ex-U.S. sites, including new sites in Latin America, to complete REVEAL 1 study. We are jumpstarting REVEAL 2 initially with only U.S. sites, both new sites as well as those which have been our top U.S. recruiters for REVEAL 1. Once REVEAL 1 is completely enrolled, we will shift all of these sites to focus on REVEAL 2.
The decision to open REVEAL 2 ahead of schedule and utilize our relationships with both U.S. and ex-U.S. sites does two things. First, it ensures we won't interfere with and overburden the sites on active recruitment, and second, as previously guided, it keeps the company on target to have a BLA submission for VGX-3100 in year 2021.

Turning our attention now to developments within our infectious disease portfolio.

We reported that Inovio's vaccines for HIV, Zika, Ebola, delivered intradermally or through the skin, generated robust long-term antibody and T cell immune responses, demonstrating nearly 100% vaccine response rate with very favorable safety profile. In this regard, we expect to see -- we expect to have clinical data from several Phase 1 vaccine programs published in the next few months, which include Ebola vaccine study, MERS U.S. vaccine trial, HIV vaccine study and the Puerto Rico Zika vaccine trial.

So why is this important? This data is important because they are among the highest responses we've seen in any DNA vaccine; actually, with any vaccine. These results are important because they will help us bring in more partnerships, as well as funding from extensive sources like CEPI, DARPA, Gates and the NIH. We plan to further develop transformative vaccines with future partnerships and funding.

In 2019, Inovio and its partner GeneOne Life Science, with the full funding from the International Vaccine Institute, are conducting a Phase 1/2a MERS vaccine study in South Korea with data report expected this year. Inovio also plans to initiate a Phase 2 MERS vaccine field trial in the Middle East with full CEPI funding in the second half of 2019.

Regarding our other infectious disease targets with full funding from CEPI, we will move our Lassa vaccine into the first human trial in the second quarter, and a Phase 2 study is planned for year 2020 in Africa. These CEPI programs are important because our vaccines represent the first-in-class products, and the successful completion of Phase 2 studies could lead to a stockpile of these vaccines by CEPI in preparation for emergency use.

Finally, I am really pleased to say that all patient samples have been collected for Inovio's Zika vaccine trial in Puerto Rico. Inovio's partner GeneOne is analyzing all samples blindly and we will report safety, immune responses and infection rate data from this study later this year.

Before I turn over the call over to Peter, I'd like to touch on this morning's release where we announced the appointment of Dr. Jacqueline Shea as Inovio's Chief Operating Officer. Dr. Shea is an experienced life sciences senior executive with an extensive track record of leadership. She has most recently served as CEO and COO of Aeras, the leading organization dedicated to developing new and more effective TB vaccines. At Inovio, she will be responsible for Inovio's manufacturing, commercial, BD and alliance management operations. Jacqui will join us as a key member of the executive team along with our CFO and CSO in formulating and implementing overall corporate strategy.

Under Dr. Shea's leadership, Aeras and its partner GSK recently reported groundbreaking
primary efficacy data in the New England Journal of Medicine that GSK's M72 TB vaccine, in a Phase 2b efficacy study, significantly reduced the incidence of pulmonary tuberculosis disease in adults with latent TB, giving much needed hope for a new, more effective TB vaccine. M72 vaccine, tested successfully under Jacqui's leadership, is a potential game-changer and represents one of the greatest advancements in TB vaccine in the last 50 years.

Across the board, Inovio has taken steps to streamline our management responsibilities to better align comprehensive development strategy from discovery to commercialization. To make this happen, we announced today that Inovio's global clinical, regulatory and R&D functions will report to Dr. Laurent Humeau, Inovio's Chief Scientific Officer. As a part of this realignment, Dr. Mark Bagrazzi, formerly our Chief Medical Officer, has left the company. I've known Mark for 25 years, and wish him the best in his next endeavor. In place of the Chief Medical Officer position, Inovio's newly formed Medical Council will oversee all clinical studies and medical-related reporting and monitoring activities and report to Dr. Humeau. Inovio's Medical Council is comprised of three of Inovio's current vice presidents of clinical development MDs.

Our strategic reorganization will improve execution of current clinical programs and provide management alignment to seamlessly connect new product research to commercial product candidates. Jacqui, Laurent and the MDs who will serve on our Medical Council are all accomplished industry executives who have demonstrated their leadership qualities and deliver commercial results.

With that, I'll turn the call over to our CFO, Peter Kies, who will discuss Inovio's fourth quarter and year-end financials. Peter?

Peter Kies: Thanks, Joseph. Inovio's total revenue for the fourth quarter and year ended 2018 was $2.5 million and $30.5 million respectively. This compares to $8.8 million and $42.2 million for the same periods in 2017.

Beginning on January 1, 2018, due to an accounting rule change, all contributions received from current grant agreements have been recorded as a contra-research and development expense, as opposed to revenue, on the consolidated statement of operations. For the quarter and year ended December 31, 2018, $2.8 million and $9.5 million respectively was recorded as a contra-research and development expense, which would have been classified as grant revenue in the prior year. Had this change in presentation not occurred, total revenue would have been $3.5 million and $40 million for the quarter and year ended December 31, 2018, respectively, compared to $8.8 million and $42.2 million for the same periods in 2017.

Total operating expenses would have been $34.8 million and $134.1 million for the quarter and year ended December 31, 2018, respectively, compared to $31.7 million and $125.9 million for the same periods in 2017.

Research and development expenses for the quarter and year ended December 31, 2018, were $26.4 million and $95.3 million respectively, compared to $24.6 million and $98.6 million for the same periods in 2017. The year-over-year decrease in research and development expenses was primarily due to the $9.5 million contra-research and development expense recorded from
grant agreements as previously discussed. This was offset by an increase in clinical trial costs and partnering expenses.

Inovio's net loss for the quarter and year ended December 31, 2018, was $33 million or $0.34 per share, basic and dilutive, and $97 million or $1.05 per share, basic and dilutive, respectively, as compared to $21.5 million or $0.24 per share, basic and dilutive, and $88.2 million or $1.08 per share, basic, and $1.09 per share, dilutive, for the same periods in 2017.

Total cash and cash equivalents as of December 31 were $81.2 million, compared to $85.5 million as of September 30, 2018. During the year ended December 31, the company sold approximately about 5.7 million shares of its common stock under a current and prior ATM sales agreement for an aggregate net proceeds of $29.2 million. As Joseph mentioned earlier, following our latest offering in the first quarter of 2019 that resulted in net proceeds of approximately $75.8 million, raised through a convertible senior note offering, the company has nearly doubled its year-end cash balance. We expect the company's net burn to remain consistent with prior years, where we anticipate the net burn to be approximately $70 million annually.

As a reminder, our fourth quarter 2018 balance sheet and income -- and statement of operations can be found in today's press release or in the Form 10-K filed with the SEC, as well as on our website under Investor and Financial Reports.

With that, I'll turn the call back over to Joseph. Thanks.

J. Joseph Kim: Thanks, Peter. The last thing I want to draw your attention to today is actually a first. Just a few weeks ago, Inovio announced that a subject was dosed as part of the first ever human study of Inovio’s DNA-encoded monoclonal antibody, or dMAb, technology, funded fully by the Gates Foundation. This trial's focus is on evaluating this dMAb's ability to prevent or treat Zika virus infection. However, results from this trial will also help to broadly advance Inovio’s dMAb platform in infectious disease and cancer.

Remember the innovation packed in our dMAb, when delivered directly into the body, the genetic codes provided by the synthetic nucleus instruct the body’s cells to become the factory which manufactures the therapeutic antibody product, enabling a major leap forward in antibody technology. While Inovio prepares a disruptive alternative to traditional monoclonal antibodies, remember that they represent the largest segment of pharmaceutical markets today, accounting for more than $100 billion in pharmaceutical sales each year, with treatments spanning cancer, infectious diseases, inflammation and cardiovascular diseases. With its synthetic design and inpatient production, dMAb products may represent a transformative entrant to this important class of pharmaceuticals.

We're in a great position to execute on our innovation and expansion into other areas that utilize our immunotherapy technology, a technology that has exhibited a very favorable safety profile and one that's generated continued funding and interest from groups like the Parker Institute, the Gates Foundation, DARPA and many others, along with major pharma and biotech companies like AstraZeneca, Roche, Genentech and Regeneron.
In closing, we listen to our investors, and we've taken strategic actions to ensure Inovio's continued advancement and to improve our ability to deliver results. Let's face it: We had a good 2018, but I know we can do better. I can confidently say that we are entering the rest of 2019 as a very well-financed organization with the right resources and leaders in place to advance our later-stage programs into commercialization.

Now I look forward to taking questions and adding additional color on our programs and developments with you. Operator, please open the line for the analysts.

Questions & Answers

Operator: (Operator Instructions)

Our first question today comes from Gregory Renza from RBC Capital Markets.

Gregory Renza: My question is, I just wanted to drill down a little bit on the REVEAL trials and the respective timelines. Helpful to hear about the alignment of REVEAL 1 and 2 as far as REVEAL 2's initiation, as well as your reiteration of the BLA filing around 2021. However, I just wanted to get a sense of what the implications are around seeing that data. I think previously you had spoken about a 2020 timeline, and just wanted to see how that squares with the trial alignments, and also just some observations on clintrials.gov, which suggests that there may have been an extension of the completion date for the trial around 2021, for both trials. Thank you very much.

J. Joseph Kim: Yes, thanks, Greg. REVEAL 1 and REVEAL 2, as you know, are -- we're enrolling 198 patients in each of these primary and confirmatory Phase 3 studies. Under our current assessment, we feel that we should be able to achieve clinical efficacy and safety data by the second half of 2020. Obviously these are predicated upon our execution and closeout of the enrollments for both studies and execution of these studies.

In terms of the clintrials.gov, we're going to adjust those based on some regulatory requirements from the government and it's going to reflect on full impact and estimates from all of the moving parts of the trial, but we're very optimistic and confident that we should be able to see the efficacy and safety data from both studies towards the end of 2020, as we had estimated previously, and we're on target for BLA filing during year 2021.

Gregory Renza: Great, thank you. And just a quick follow-up with respect to the addition of some Latin America sites. I'm just curious on your expectations for that, to what extent that would potentially accelerate or bolster the enrollment trajectory to date?

J. Joseph Kim: We're very bullish on those new sites and new countries. Certainly there's a lot of -- there are a lot of women with the cervical pre-cancer in those areas, and we are very optimistic that those new sites will bring additional acceleration for our enrollment going forward for both REVEAL 1 and REVEAL 2.

Operator: Our next question comes from Chris Raymond from Piper Jaffray.
Christopher Raymond: And sorry, this might be a little repetitive, because I'm not sure I heard your answer on the first question, but another one on REVEAL: So can you just confirm -- I thought initiation of REVEAL 2 is gated by the completion of REVEAL 1. So can you just confirm, are you -- you announced that you're initiating it, but is first patient in still a ways off, or when will that happen?

J. Joseph Kim: Yes. So thank you, Chris. So it -- we were very simplistic in our description of the switchover previously. Obviously you don't -- it's not a spigot that you turn off right away in opening up a second trial. So there's going to be an overlap between REVEAL and REVEAL 2. So we launched the REVEAL 2 a couple of weeks ago, and we expect the first dosing from REVEAL 2 to occur in April. And we're continually finishing up the REVEAL 1 enrollment. So there's going to be a little bit of overlap. And it's like the two curves overlapping in the front and the back end. So we felt this would provide the best crossover and best positioning of both studies because finishing one study before the other really doesn't buy us the -- any time in our BLA submission. So as we have been executing our REVEAL studies for the last year or so, we felt that this is the best way to maximize overall the timeline or shorten the timeline to BLA filing the best.

Christopher Raymond: Great. And then maybe just a follow-up on -- I think you mentioned your GBM combo trial for 5401 is almost done with enrollment. Can you -- and I'm sorry if you said this already, but can you maybe talk about when that will be completed, what's your sort of sequence for providing the data, or what can we expect to hear on that trial, I guess, this year? Thanks.

J. Joseph Kim: Yes. We're so excited about finishing the enrollment for 5401 GBM study. As -- just to remind you of our primary efficacy endpoint, it's improvement in overall survival at both 18 months and also at 12 months, 18 months, OS 18, being more definitive. But obviously that's going to take some time, so this year we have been projecting the data for PFS, or progression-free survival, at six months into the study as an early indicator for how well these patients are doing. But I have full confidence that we'll do that with total 52 patients before the year-end. I have also strong confidence that we'll have PFS 12, or at 12 months, for a vast majority of our patients before the year-end.

So what do these results mean? Well, we can track the progression-free status of these patients leading into our overall endpoints probably early next year. Obviously, OS numbers are more definitive, and it's tracking, certainly, to our primary endpoints, but I think PFS will give us a pretty early good readout to how well these patients and how well our trial is executing.

But overall, I'm very happy. We're ahead of the schedule in terms of enrolling these GBM patients. And then we're challenging ourselves to catch up or bring our bladder study to the similar rate that we're enjoying in GBM. So I -- this goes back to all of our Phase 2 and Phase 3 studies. We've been doing well up to now; we want to make sure we can do even better, and that's part of our strategic reorg and our renewed focus and reenergizing of our programs to make sure we have full alignment, full devotion of our resources and efficiency and, ultimately, patients are waiting, and we want to make sure that we can get to our final data as rapidly as
possible.

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

Joel Beatty: The first one is on MEDI0457. Obviously the early data has shown a strong response rate in a small number of patients, much higher than what you'd see with monoclonal antibodies. Could you discuss what data could be coming next and what remains to be seen before advancing that program into a pivotal study?

J. Joseph Kim: Yes. So I mean -- thanks, Joel. We're very, very excited about MEDI0457. It's second of our efficacy readouts, the first being 3100, that's showing. And we're beginning to have larger body of evidence showing the clinical efficacy of our programs, really impacting the disease. And we're very excited about that.

Now, that being said, this product was licensed out to AstraZeneca in 2015, so they have a full say and full development rights and so on. Inovio is a passenger in their vehicle. Certainly very profitable in that as they advance those programs we'll be collecting our milestone and ultimately the royalties and so on, which are very significant and -- but as we observe these data to come out, we expect MEDI's Phase 2 trial targeted with about 50 head and neck metastatic cancer patients, in combination of 457 plus their durva PD-L1 inhibitor, to be the next study report to come out. AZ has complete control over that study result, but I can tell you that they're probably very excited to report those data in the coming months and quarters, but they have the full say.

Now, they have expanded into other indications in a second study, so I touched on that in my prepared remarks. So the MD Anderson study is a pan-HPV cancer study, MEDI0457 plus durva study, so dosing of the cervical cancer patients as part of that study triggers a second Phase 2 milestone payment from AZ to us. We expect the third indication to be dosed -- patient to be dosed later this quarter, potentially, or the second quarter, and that will trigger, any day now, a third Phase 2 milestone payment from them.

So these trials are moving. Obviously AZ has the full control and cadence of executing these trials, but the data that will come out, we feel, will comprehensively support our thesis, which is taking Inovio's CD8+ T cell-generating immunotherapy, combine it with a checkpoint inhibitor, will bring about higher clinical efficacy than just the monotherapy with a checkpoint inhibitor, and it should work against all of these different cancers caused by or associated with HPV. With MedImmune product, we want to expand that with our own study in INO-5401 into GBM and bladder and other cancers that we can hit with INO-5401. If we can expand what we saw in MEDI0457 to INO-5401, there's no ceiling for what Inovio's platform or immunotherapy platform will do in cancer, and we're very excited about what's to come.

Joel Beatty: Great. And then another question on the dMAb program. Just a few weeks ago or so, it sounds like, you dosed the first patient. Could you discuss the process of monitoring that patient and where that's at, and what the steps would be towards dosing additional patients with dMAb?

J. Joseph Kim: Yes, thank you. These are dose-escalation studies, so the first three are standard
three-plus-three design. So first three patients have been dosed. There's been zero safety concerns. At the lowest dose and then after 28 days, we move onto the second dose, and so on. And once all those escalations have been done, we can complete and backfill all 24 patients.

So our bar for the first study, our objectives are pretty low. We want to see measureable expression of these dMAbs in the patient blood -- patients’ blood. Once we can detect that, we can utilize our optimization algorithm to improve the overall expression.

So while this is a Zika dMAb study, it also has huge value for our dMAb platform development at the same time. And I can add here that being able to democratize the uses of powerful monoclonal antibody therapy for additional people around the world has been a dream of Bill Gates, and that's a dream that I share. And we may have the true technology to be able to do that. So that's why Gates Foundation is interested, because you can apply the dMAbs in a much practical fashion.

Inovio has additional motives. We think this is a better product. All of our products are kept in the long term at 2 degrees to 8 degrees refrigeration instead of being frozen. We can express better. We just had a new paper that compares our optimized design of KEYTRUDA to have three or four higher expression gene for gene with additional potential patents covering those sequences.

So the potential of our dMAb products platform is immense, and we're at the -- we went from conceptual wish to animal tests with high levels of expression in a matter of two, three years. Now we have progressed this program into clinical evaluation. So I don't know where we're going to be. We're certainly going to advance the ball quite a bit in the next 12 months with additional trials starting. We expect additional corporate partnerships in this regard, certainly a lot more funding from Gates and other sources. So far we've received funding from DARPA and the NIH and Gates Foundation. We expect additional supportive funding from multiple organizations in addition to corporate partnerships that we would like to strike, and we have discussions ongoing at this point. So I think the dMAbs are not fully baked into any of your models, all of the analysts on the call. So I think this is where we can bring more value to our shareholders moving forward.

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

Stephen Willey: Just to follow up on REVEAL, Joseph, the guidance for year-end '20 data dissemination, is that the 40-week read from both REVEAL 1 and REVEAL 2?

J. Joseph Kim: No, REVEAL 1 is . . .

Stephen Willey: Or is that just the REVEAL 1?

J. Joseph Kim: Yes, REVEAL 1 is a 36 primary endpoint with additional one-year safety period. So that is an 88-week -- full 88-week study. REVEAL 2, in contrast, has one month follow-up or four weeks' follow-up, so that's a 40-week study. So that's the only difference between REVEAL 1 and REVEAL 2.
Stephen Willey: So in terms of the guidance for having data from these trials in the second half of 2020, is that going to be the 36- and 40-week data from both of these trials?

J. Joseph Kim: No, it's -- we expect 88 and 40 weeks' data from REVEAL 1 and REVEAL 2 respectively.

Stephen Willey: Got it. And then just with respect to enrollment into the bladder cancer trial, it sounds like it's maybe occurring a little bit slower than expected. What's the attribution there? Is that -- I know it's a pretty competitive development landscape right now. Is it just difficulty in finding patients? Is it just site logistics?

J. Joseph Kim: Yes, well, I think compared to its sister study in GBM, our bladder study is behind. But that speaks to the desperation and the demand that GBM patients and sites have for that disease. So I wouldn't characterize that we're behind, but I will say that the bladder is a lot more competitive.

But I think our U.S.-based -- the 13 sites we have in the U.S. are competitively enrolling patients. We wanted to bring in more sites ex-U.S. to accelerate this trial because we designed the 5401 study to be a bookend study by looking at the spectrum of immune responsiveness tumors, bladder being one end, more immune-responsive type of tumor, versus GBM being the other. So we would like to execute on both studies, when we started, to be in a similar cadence and timing.

Now, we got overblown by the demand and the enrollment velocity that we had for our GBM study, so we just want to push, give a nudge to our bladder study as well. So we have a little bit of sibling rivalry within our programs. I think that's healthy, and we want to -- the resources that we're saving in GBM in terms of the accrual, we can push into our bladder. So that's why we're doing that.

Stephen Willey: Okay. And then just on the dMAb program, is that presumably targeting a viral protein that's part of the . . .

J. Joseph Kim: No. Well, so . . .

Stephen Willey: Or is it targeting a host protein?

J. Joseph Kim: So this is a full-length sequence, optimized sequence that binds to a Zika GP protein, this particular dMAb product that's in Phase 1 study. But in theory, and we have developed a couple of dozen different dMAbs targeting anywhere from PCSK9 all the way to our own version of KEYTRUDA and OPDIVO all the way to Humira equivalent.

So really, I don't think it really matters what we target. We can bind and maintain functionality just by adjusting our DNA sequence. That's really the beauty of this platform, is we can transcend some of the folding and stability issues of protein-based monoclonals during their construct and during their manufacturing and during their formulation and delivery. So our dMAb platform has significant advantages over conventional MAb technology.
So our goal is to make sure that we have the proper delivery and knowhow and the algorithm to design and execute on these dMAbs, and we're learning really tremendous amounts every week and every month. So there will be even more exciting scientific advancements in dMAbs in the coming weeks. And this clinical study that we initiated last month just really points to the advancement of this in human subjects, and so far, so good.

Stephen Willey: Okay. So the program is specifically targeting, then, a viral protein that doesn't have any host homology?

J. Joseph Kim: Yes.

Stephen Willey: Okay. And is the threshold -- I know you talked about some of the other targets that you've developed preclinically or at the bench, but does -- is the threshold for moving into patients and targeting, obviously, a functional host protein, does the safety threshold there become higher?

J. Joseph Kim: Well, higher than a viral protein, but a lot of our targets have already been tried, like a PD-1 target. We don't believe we will add any more safety concerns than protein PD-1 inhibitor like pembro or nivo, for instance. But these are -- I mean, we're going to take necessary care and due diligence when we dose-escalate each of these programs.

Operator: Our next question comes from Jason McCarthy from Maxim Group.

Naureen Quibria: This is actually Naureen on for Jason. So I'd like to just drill down on the GBM study that you have with Regeneron's PD-1. If you're looking at checkpoints, they've been -- it's been challenging in GBM indication, and a lot of others haven't found much success. If you look at CheckMate 143 with OPDIVO, the rationale was that it didn't succeed because 40% of the patients were taking steroids to control brain swelling, but they clearly interfered with the immune response. Are you taking that into consideration with your combination as part of your trial, or how do you address or circumvent this issue?

J. Joseph Kim: Yes, those are all considerations. Obviously the doctors have to treat the patients as any complications develop during their cancer. The difference, I think, between the study that you refer to versus this one is, we have targeted the newly diagnosed patients. I agree with you, GBM has been a challenge for checkpoint monotherapy. Let's face it, Naureen. GBM's been a challenge for all therapies. So that speaks to a lower bar -- or high bar in ensuring efficacy, but low bar in showing marginal improvements in efficacy.

So I spoke earlier while talking to Steve about the tumor responsiveness spectrum. We think that's one of the reasons why GBM has been so hard to treat, especially within immunotherapy. We think we can improve that by generating CD8+ T cells against our three targets, WT1, PSMA and hTERT, and combining with Regeneron's PD-1 inhibitor that has been tested in GBM as a monotherapy, we think we can improve the overall impact of the immunotherapy. That's our goal. As I said, the bladder has a higher probability of success but a higher threshold or higher
bar in showing the marginal improvement. But GBM as a sister study, it's got a higher threshold of efficacy but lower bar to show marginal improvements in efficacy. So that's why we are concurrently conducting these two studies. We also feel that our immunotherapies, 5401 or MEDI0457, they should all work with any checkpoint inhibitors. And that's the reason why we've chosen to use two different checkpoint inhibitors with Regeneron's PD-1 for GBM and Genentech's PD-L1 for bladder. And we look forward to seeing the data and reporting the data in the coming months.

Naureen Quibria: Sure. And in the same study, these are postsurgical patients, correct?

J. Joseph Kim: Yes, yes.

Naureen Quibria: So just as a follow-up, recently at UCLA, there was a small study that showed that if you treat with checkpoints prior to surgery, it's more effective. So would you consider putting an arm combining INO-5401 plus Regeneron's PD-1 prior to surgery and radiation treatment?

J. Joseph Kim: We haven't looked -- well, we haven't considered all the different possibilities and study designs. As we develop this program through the current trial, Jeffrey Skolnik, who heads up our oncology clinical development, and his team are extremely well in tune with other goings-ons and other advancements. So if it rises to our interest to actively test that hypothesis, or rather passively see how those results are going to evolve, I can't really comment on that in this call. But rest assured, we are looking at all of our competitive approaches and other data.

And GBM is challenging, and that's why we chose this as one of our targets. And I think it speaks to the desperation of this disease, and certainly the opportunity to bring better medical intervention utilizing, hopefully, with INO-5401 and Regeneron's PD-1 inhibitor, cemiplimab. So we're very optimistic with this program.

Operator: Our next question comes from Yi Chen from H.C. Wainwright.

Yi Chen: Is there any update regarding GLS-5700 in Puerto Rico and whether that trial is going to read out before the dMAb study? And if both trials have positive results, does one product takes priority -- the dMAb product takes priority over GLS-5700? And which of them has potentially the fastest regulatory pathway available to reach the market?

J. Joseph Kim: Great question, Yi. Very thoughtful. GLS-5700, our Zika vaccine, in Puerto Rico, as I updated in the prepared comments, all of the visit samples have been collected. The data analysis assays are being done now. It was -- just to recollect ourselves, it's a double-blinded trial, 80 patients receiving our vaccine, 80 placebo, and we're opportunistically looking at the infection rates of Zika. So it's a very ambitious and very exciting study, and we'll report this as soon as we have the full set of data. But we're very much looking forward to this. We will present this and publish in just the way we do with all of our programs.

Now, I wouldn't say our Zika dMAb or the Zika vaccine, they're not necessarily competing, per se. In fact, our DARPA contract that we received first for Ebola and for other programs, actually
the beauty of our technology is you can co-dose, both the dMAb for short-term immediate protection and a vaccine to provide a longer-term protection. And these were deemed to be very important for U.S. military as well as, perhaps, the travelers and other healthcare professionals and highly risked groups, and folks who are more exposed endemicly. So I think one does not preclude the other, but that would be a great problem for us to have. But independently, I expect to have data from both studies providing great information. The development path for each of those really will depend on partners and funders and a real clinical end for these vaccines and dMAbs. But they both have their own strength in what we're trying to get out from these clinical studies.

Operator: Our next question comes from Jonathan Aschoff from National Securities.

Jonathan Aschoff: I was kind of wondering, regarding both of the head and neck cancer patients that responded to PD-1s after progressing on 457, is there really any evidence that 457 contributed to either of those complete responses, given that the patients progressed between vaccination and PD-1 therapy?

J. Joseph Kim: Yes. Great question. So we're able to tease out the antigen-specific T cell responses in these patients, and some of that was included in the Clinical Cancer Research publications from last fall. Obviously we're doing a lot more follow-ups from these patients, as well as, as more patients eventually progress, we'll be able to track that.

Perhaps the best answer would be, MEDI's concurrent study that they're dosing, already metastasizing recurrent head and neck patients with both durva and MEDI0457, and testing the immune responses in these patients and looking at clinical response compared to the patient experience with durva alone, I think that's a more direct comparison. A lot more data should be forthcoming from all of these studies.

Jonathan Aschoff: Okay. And -- thanks for that. Outside of any ATM use or warrant exercise or receipt of milestones, how long does your $157 million last? Would that be about mid-2020?

J. Joseph Kim: No, it's -- our guidance is about $70 million in net burn for '19 and '20 each, so we think we'll have -- that's more than two years of cash runway.

Jonathan Aschoff: But that burn includes things like ATM and warrant and milestones, or it excludes them?

Peter Kies: Hi, Jon, this is Peter Kies. It excludes ATM activity, but milestone activity would be included in that.

Jonathan Aschoff: Okay. And the last thing, may I ask why Mark left?

J. Joseph Kim: Can you say that again?

Jonathan Aschoff: Why did Mark leave?
J. Joseph Kim: It was part of the strategic reorg. I felt that combining and aligning -- I asked him to leave, and aligning clinical, regulatory and R&D functions under same supervision would benefit from better alignment and better execution. So -- and we explained that in the prepared remarks, but I think we should be able to -- we've been doing this well, but I feel that we can do better. We've got to move faster. We have to execute better. We owe it to our shareholders. We owe it to the patients that we're looking to help. And this strategic reorg and really, frankly, all of our efforts are trying to enhance our capabilities and our execution capabilities to improve on our delivery.

Operator: And ladies and gentlemen, at this time, and showing no additional questions, I would like to turn the conference call back over to management for any closing remarks.

J. Joseph Kim: Well, thank you, everyone, for your questions and joining us on the call today. We look forward to sharing more on our trials and program advancements on our next earnings call in May. Have a great evening. Thank you.

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