

IMNN Earnings Call Transcript

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Quarter: 3

Operator: Good morning. My name is Martin Fernandez, and I will be your operator today. At this time, I would like to welcome you all to the Imunon Third Quarter Financial Results Conference call. All lines have been placed on mute to prevent any background noise. Following the speaker's prepared remarks, there'll be a question-and-answer session. You may press star and one on your phone to ask a question at that time. Please keep in mind, if you're using a speakerphone, you must release your mute function to allow the signal to reach our equipment. Again, that's star and one to ask a question during the Q&A session. I would now like to turn the call over to Peter Vozzo from ICR Healthcare, Investor Relations Representative for Imunon. Please go ahead.

Peter Vozzo: Thank you, Myron. Good morning, everyone, and welcome to Imunon's Third Quarter 2025 Financial Results and Business Update Conference call. During today's call, management will be making forward-looking statements regarding Imunon's expectations and projections about future events. In general, forward-looking statements can be identified by the words such as expects, anticipates, believes, or other similar expressions. These statements are based on current expectations and are subject to a number of risks and uncertainties, including those set forth in the company's periodic filings with the Securities and Exchange Commission. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. I also caution that the content of this conference call is accurate only as of the date of this live broadcast, November 13th, 2025. Imunon undertakes no obligation to revise or update comments made during this call except as required by law.

Peter Vozzo: With that said, I would like to turn the call over to Dr. Stacy Lindborg, Imunon's President and Chief Executive Officer. Stacy.

Stacy Lindborg: Thank an you, Peter, and good morning, everyone. Joining me on the call this morning is Dr. Douglas Faller, our Chief Medical Officer, and Ms. Kim Graper, our Interim Chief Financial Officer, who will be reviewing our financial results for the third quarter of 2025. Mr. Michael Tardugno, the Executive Chairman of our board, and Dr. Khursheed Anwer, our Chief Scientific Officer, are also on the line and will be available for Q&A.; We continue to make meaningful progress with our proprietary IL-12 immunotherapy, IMNN-001, through the OVATION 3 pivotal phase III trial for newly diagnosed advanced ovarian cancer. The urgency of this program remains front and center to our efforts to create value for shareholders and to address the unmet need of ovarian cancer, which continues to claim far too many lives as the standard of care in the frontline setting has not advanced in over 30 years.

Stacy Lindborg: Our OVATION II study demonstrated the first-ever overall survival benefit in a critical FDA endpoint in our randomized frontline trial. We are now laser-focused on confirming those unprecedented results in a well-regarded, rigorous phase III trial. Three days ago, we hosted a highly successful R&D; day in New York City at the Harvard Club, featuring renowned ovarian cancer opinion leaders, clinicians, statistical experts, alongside members of our leadership team. The event underscored the transformative potential of IMNN-001 for women with newly diagnosed advanced ovarian cancer. The investment community and those interested in advances in ovarian cancer

treatment and women's health more broadly heard directly from investigators about the unmet need in this disease affecting globally 300,000 new cases each year and claiming the lives of 13,000 women each year in the U.S. alone.

Stacy Lindborg: This is why IMNN-001's potential to deliver a 13-month median overall survival benefit in phase II, with a hazard ratio as low as 0.42 in PARP-maintained patients, represents a potential paradigm shift. We have just come off a powerful series of presentations at the world's leading oncology and scientific forums, including ASCO, SITC, ESMO, the AACR Ovarian Cancer Special Conference focused on advancements in ovarian cancer, and finally, IGCS. The momentum is undeniable. OVATION 3 enrollment is surging ahead of plan, and this one-to-one randomized trial is evaluating IMNN-001 plus the standard of care, neoadjuvant and adjuvant chemotherapy with interval debulking surgery versus standard of care alone in women who have treatment-naïve advanced ovarian cancer. In July, we initiated a 500-patient all-comers trial of women with advanced ovarian cancer, which has the flexibility to prioritize a 250-patient HRD-positive subgroup.

Stacy Lindborg: This would enable us to realize a 40% cost savings with this prioritized group. The study design employs interim analyses for early efficacy stopping rules demonstrating trial success with power above 95% on the clinically meaningful primary endpoint of overall survival. As was discussed at R&D; day, this analysis is accelerated over a traditional trial, which would only read out the overall survival at the end of the study. Success with these interim analyses is expected to deliver full approval, not accelerated approval. Key updates since our last call that I'll just quickly tick through. First, the site activation status of Ovation III. We have been deliberate and consistent with our cash management responsibilities, which applies to our decisions around site activation. Four sites were initially activated in the U.S., and we expect this to double before year's end with four additional sites well-progressed in startup activities.

Stacy Lindborg: Returning investigators from OVATION 2 are being joined by additional top-tier centers, many of which are proactively reaching out to Imunon following the recent publication of the OVATION 2 study results in the Journal of Gynecologic Oncology, which was published on the same day as the 2025 ASCO platform presentation. We also have inquiries about the trial from interested sites at other recent conferences. Furthermore, while we have moderated the activation of sites in 2025 to reflect our current cash position, we are preparing for a site activation surge. To this end, we have accelerated the engagement of a global CRO to identify new study centers for startup in the new year, and we estimate we will have all sites in the new trial activated before the end of 2026. Next, I'll comment on enrollment velocity.

Stacy Lindborg: You know, the first patient in OVATION 3 was randomized and treated in July of this year, and we have seen strong investigator enthusiasm for the trial, which has surpassed our internal enrollment target set for the end of 2025, with nine patients randomized by the end of October. I think you can all appreciate how important it is to have strong momentum at the start of the trial, and we have started this trial with an impressive pace. Moving to regulatory and design validation, the FDA has endorsed overall survival as a single study registration endpoint, and based on precedent and European regulations, we expect OVATION 3 to meet regulatory expectations for approval in Europe. During our R&D; day, Dr.

Stacy Lindborg: Giorgio Poloni, PhD in statistics with the company Berry Consultants, a highly regarded statistical consulting firm, highlighted this adaptive event-driven study design, a technique that is well-aligned with precedented FDA approvals in oncology via interim analysis of overall survival. He also highlighted the robust statistical foundation of our phase III trial with conservative power estimates, yielding high estimates of probability of success of this trial. Let me just pause, and if you did not have the opportunity to join our symposia live, I would encourage you to look on our website, the imunon.com website, in the Investor tab and under Scientific Presentations to watch it. We provide details of the power assumptions, and it is remarkable to hear directly from these experts that were on the faculty that day. Lastly, new translational data and our MRD study. We had Dr.

Stacy Lindborg: Amir Jazari from MD Anderson Cancer Center presenting at our R&D; day. He's the lead PI for the ongoing phase II minimal residual disease, or MRD study, being conducted in collaboration with the Breakthrough Cancer Foundation. Dr. Jazari spoke to data collected so far in the trial, demonstrating IMNN-001's preferential uptake by peritoneal macrophages, including profound tumor microenvironment remodeling. Patients achieved complete pathological responses with durable intratumoral IL-12 and interferon gamma expression, all with negligible systemic exposure and excellent tolerability, even as IMNN-001 in this trial is being administered with bevacizumab, and treatment has continued in maintenance settings. Additional biomarker data, which was presented at CITSI last week by Dr. Faller, further confirmed T-cell and macrophage infiltration and immune activation that's predictive of superior prognosis. Dr.

Stacy Lindborg: Primal Thacker from Washington University emphasized during the R&D; day that IMNN-001 is able to turn what are immunologically cold ovarian tumors hot by engaging both innate and adaptive immunity, renewing the promise of immunotherapy in this devastating disease. These mechanistic insights, paired with unprecedented survival signal, have fueled investigator commitments to accelerate enrollment. We estimate full enrollment in OVATION 3 will occur by late 2028, and I'll note that this can be accelerated with financing. I'll now turn over the call to Dr. Douglas Faller for some clinical commentary and comments. Douglas?

Douglas Faller: Thank you, Stacy. As Stacy noted, our R&D; day on Monday in New York really crystallized the excitement we are seeing within the gynecologic oncology community regarding IMNN-001 and OVATION 3. Dr. Thacker's and Dr. Jazari's presentations, followed by the rich discussion during the Q&A; portion of events, underscores the clinical importance of the data collected and reported in both OVATION 2 and in the MRD study in women treated with IMNN-001. Excuse me. As Stacy mentioned, over the last three months, we've been invited to present our OVATION 3 trial and the emerging translational data from OVATION 2 at four prestigious international scientific and clinical congresses. These include the ESMO 2025 in Berlin, the International Gynecologic Cancer Society meeting in Cape Town, the AACR Special Conference on Ovarian Cancer in Denver, and the Society for Immunological Therapy of Cancer CITSI International meeting in 2025 in Washington, D.C.

Douglas Faller: These global forums gave us the opportunity to interact with both scientists and clinicians. After our presentations, a number of clinical investigators, impressed by our novel therapy and the patient benefit realized in OVATION 2, approached me asking if their hospital could participate in the OVATION 3 trial. Similarly, scientists intrigued by the demonstration in patients that IMNN-001 turns immunologically cold tumors into hot tumors with anti-tumor activity asked about the possibility of collaborating with us. Interestingly, at the CITSI meeting several days ago, several participants noted the renewed interest in harnessing the powerful anti-tumor effects of interleukin-12, as evidenced by at least 15 interleukin-12 related presentations. However, they also noted that with the exception of ours, these presentations were focused on their early attempts to formulate or deliver interleukin-12 so as to avoid the well-known systemic toxicities. These attempts include intratumoral injection, which is not a long-term strategy.

Douglas Faller: All of these efforts were preclinical or early phase I. In contrast, Imunon, as you know, has a pivotal phase III registrational trial, OVATION 3, actively recruiting. This OVATION 3 trial has been fully leveraging the excitement of IL-12 as a cancer therapeutic and the remarkable OVATION 2 clinical outcomes. As Stacy mentioned, study startup, as defined by protocol approval, to patient enrollment was achieved in 15 weeks, nearly half of what is typically seen as the industry standard for phase III trials. As we engage with our first set of study centers, we continue to see great interest and enthusiasm from our investigators, with the early sites so far activated far exceeding monthly estimates of the number of patients enrolled per site per month. OVATION 3 is still in its early stages, but we're observing clean safety run-in data from the first patients.

Douglas Faller: Meanwhile, the ongoing phase II MRD study, as Stacy mentioned, continues to reinforce IMNN-001's favorable profile, giving us real-time confidence as we scale the pivotal trial.

Following a recent MRD study DSMB meeting, we're pleased to share that the benefit-risk profile of IMNN-001 has been further strengthened in this MRD study and mirrors what we have seen in OVATION 2: no dose-limiting toxicities, no discontinuations due to IMNN-001, and no elevations in immune-related adverse events. Furthermore, preliminary clinical data presented by Dr. Jazari at R&D; day highlights a high probability of progression-free survival on the IMNN-001 arm, a lower MRD positivity rate, and a lower percentage of biopsies positive during second look in the MRD patients.

Douglas Faller: Lastly, the MRD study's demonstration of the feasibility and safety of combining Imunon with bevacizumab and the preliminary view into the idea of IMNN-001 as maintenance positions IMNN-001 uniquely for future trials and possible label extensions that could contribute even further to the fight against this terrible cancer. Back to you, Stacy.

Stacy Lindborg: Thanks, Douglas. Before turning to our financial update, I'd like to offer and really further highlight progress in advancing our MRD trial and share an update. First, notably, the Breakthrough Cancer Foundation selected this trial for funding from hundreds of competing proposals, which is a very strong endorsement that echoes Dr. Jazari's remarks at our R&D; day of the importance of frontline therapy as the best opportunity to achieve a cure for ovarian cancer. Based on the preliminary clinical data from the trial that Douglas just reviewed, we are thrilled with the consistency of IMNN-001's effect compared to our OVATION 2 clinical results. We've made great progress in the enrollment of the MRD trial, with three patients being randomized and treated in the month of October, resulting in a total of 25 patients randomized to date.

Stacy Lindborg: Based on this progress, in September, we reviewed the MRD study and confirmed that its core objectives, which include those that we have internally for the IMNN-001 development plan and Breakthrough Cancer Foundation's goals as well, these core objectives can be fully met with a smaller cohort of patients. Accordingly, we decided to cap enrollment at 30 patients in the intent-to-treat population, a milestone that we expect to reach in the first half of 2026. We will be thrilled to close out this trial and capture its full learnings, enabling us to channel our resources into the pivotal OVATION 3 phase III trial. In fact, I'll mention that we've already begun conversations with this success in mind. We've started conversations with MRD investigators about transitioning their sites to OVATION 3 at that time, a move that would further accelerate enrollment in our registration trial.

Stacy Lindborg: I'll note that we've received positive reactions to these inquiries. Turning to our financial strategy, we continue to navigate a challenging biotech capital markets environment with discipline and foresight. Our multi-pronged approach, combining the potential for non-dilutive partnerships with prudent equity raises, opportunistic use of our ATM facility, remains on plan, and we've made significant progress. Shareholder dilution is a valid concern, and we share it. That's why every financing decision is a stress test against our commitment to preserve value while actively working to fully fund this pivotal program. We have ongoing reviews for potential partnerships with Therplast and interest expressed by pharmaceutical companies on PlaCCine from a recent scientific meeting, but nothing that is imminent. These kinds of partnerships take time to build, and I look forward to providing more detail if we advance these discussions to terms.

Stacy Lindborg: On the equity side, we've raised \$4.5 million during the third quarter through warrant exercises and targeted ATM usage. Monthly cash burn is now approximately \$1.25-\$1.5 million, reflecting streamlined G&A; expenses, renegotiated facility leases, and a laser focus on advancing IMNN-001 milestones. Furthermore, operating expenses for nine months ended September 30 between 2025 compared to 2024 is 31% lower, which includes a 44% decrease in R&D; expenses and a 52% decrease in CMC expenses. Mind you, this is all while manufacturing product for phase III, conducting CMC development work in preparation for reduced cost of products sold in the commercial landscape, and accelerating site patient activation. With cash through mid-Q1 2026 and multiple near-term catalysts such as enrollment momentum, regular presentations at medical and scientific congresses, and the potential for partnership progress, we are well poised to extend our runway further, ideally through value-enhancing non-dilutive transactions.

Stacy Lindborg: A few other updates of note: the NASDAQ compliance matter is closed. We achieved the dollar minimum bid price requirement on August 9th. We sustained shareholder equity above the \$2.5 million confirmed on August 22nd. In fact, we're far above this. This matter was also formally closed by NASDAQ on September 3rd, 2025, and I'm delighted to report that, as reported in the current NQ, we are at \$4.1 million in the shareholder equity threshold. Now I'll turn over to Kim Graper for our review of the third quarter 2025 results.

Kim Graper: Thank you, Stacy. Detail of Imunon's third quarter 2025 financial results are included in the press release we issued this morning and in our Form 10-Q, which we filed before the market opened this morning. As of September 30, 2025, cash and cash equivalents were \$5.3 million. During the third quarter, the company received approximately \$4.5 million of net proceeds from the exercise of warrants and sales under our ATM equity facility. The ATM facility carries a nominal 3% fee with no warrants. We project that this cash balance extends our operating runway into mid-quarter, first quarter of 2026. R&D; expenses were \$1.9 million for Q3 2025, down from \$3.3 million in the same period last year, primarily due to completion of the OVATION 2 study and lower costs associated with the phase I PlaCCine DNA vaccine trial and development costs for the PlaCCine DNA vaccine technology platform.

Kim Graper: G&A; expenses were \$1.6 million in Q3 2025, down from \$1.7 million in the same period last year due to lower employee-related legal and travel expenses. Net loss for Q3 2025 was \$3.4 million, or \$1.16 per share, compared to \$4.8 million, or \$3.76 per share in the third quarter of 2024. Please note that all shares and per-share amounts have been adjusted to reflect a 15-for-1 reverse stock split of our common stock, which we effected on July 25th, 2025, and the 15% stock dividend we have declared in the quarter. With that, the financial review, I'll turn the call back to Stacy.

Stacy Lindborg: Thank you, Kim. Before we open the line for questions, I want to reflect on the questions we received through the webcast, the live webcast at Monday's symposia. I was able to work the majority of these questions into my prepared remarks, with the exception of one question that I'd like to address as we kick off our Q&A.; This question came from David Bouth through our tool, and I'll read the question. It looks like macrophages are the primary cell type that takes up IMNN-001, but how long do these cells continue to produce IL-12 based on the presence of IMNN-001? Is there some type of feedback mechanism that IMNN-001 produces to prolong the production of IL-12 in these cells after IMNN-001 is metabolized, or is there an IMNN-001 plasmid that encodes IL-12 long-lasting? It's a very great question.

Stacy Lindborg: I apologize, David, we did not see it and were not able to address it day of the meeting, but I would like Khursheed to offer comments to this question.

Khursheed Anwer: Sure, Stacy. Yeah, it's a good question, of course. The unformulated plasmid, which is administered into the peritoneal cavity, typically clears, I would say, within 24 hours and may last a little longer if it is formulated with a delivery system such as that in IMNN-001, where the nanocomplexes have a protective effect on the DNA. However, once the plasmid is taken up by the cells of the peritoneal cavity, such as macrophages or other immune cells or epithelial cells, it is internalized into the cell nucleus and can stay much longer, giving rise to long-lasting, up to several days, the levels of gene product, which is IL-12 in the case of IMNN-001. Yes, it is indeed the plasmid inside the cell that lasts longer, giving rise to the pharmacokinetic that we have seen with IMNN-001 of IL-12 and interferon gamma production.

Stacy Lindborg: Thanks, Khursheed. I appreciate that. Operator, with that, please open the call for questions.

Operator: Thank you. We will now begin the question-and-answer session. To join the question queue, you may press star and then one on your telephone keypad. You will hear a tone acknowledging your request. If you're using a speakerphone, please pick up your handset before pressing any keys. To withdraw your question, please press star and then two. We'll pause for a moment as the callers join the queue. We have the first question from the line of David Bouth from Zacks. Please go ahead.

David Bouth: Hey, good morning, everyone. Stacy, I appreciate you answering that question that I had the other day. Sorry, I wasn't able to ask it in person there. Thank you for that response there. I wanted to start, actually clear something up to make sure I understood. You had mentioned that positive results in one of the interim efficacy in looking at the interim analysis would lead to a full approval, you think. Is that a full approval for all ovarian cancer patients, or would it be just for the HRD population?

Stacy Lindborg: Yeah, you're clarifying that. I think that when we were talking about the ability to accelerate the analyses through the use of an internal interim analysis, I wanted to make sure that people understood that that was the acceleration of getting to results. If we are successful and we meet the statistical thresholds that are outlined and agreed to by the FDA, we would expect full approval in the group that we're testing. The trial is continuing in an all-comers population, then at the end of the trial, that would allow a broader label indication. I think it is really important to understand we're really reflecting the devastation of this disease and the need, as we saw. We know that we're also making rather conservative assumptions, power assumptions.

Stacy Lindborg: It is very possible, like Giorgio spoke to, the likelihood of being successful at one of the two interim analyses. We want that urgency to be very clear. We want to be able to move forward rapidly with a BLA filing based on that data, and then to be able to allow for the product to be approved in that indication and accessible to patients. It would allow the trial to continue to the end and to have to then potentially expand to the all-comers population.

Operator: Okay, thanks. That makes sense. Kind of keeping along the same theme, what P-value, or can you say what P-value needs to be hit at either the first or second interim analysis in order to be able to stop the trial if it's efficacious?

Stacy Lindborg: Yeah, unfortunately, it's a little more complicated than just a raw P-value, and this is where Giorgio did a really great job of really highlighting the simulation results. They set complex operating characteristics that ultimately are needing to take into account kind of an information fraction of where you are in the trial and therefore appropriately control type 1 error rate. The logistics of it are very well documented, and there was a very large report that was submitted to the FDA that these simulations really documented proper control of type 1 error rate, and then all of the operating characteristics that the FDA would be keen to understand. It's not just a fixed P-value, and if you are interested in more, we can have perhaps another conversation on it. It's very well laid out based on where this would occur.

Stacy Lindborg: Because when in the point of the trial, when the 50th HRD event, which is the trigger for the first interim, would occur, that's not a fixed point in time. It's an unknown that will evolve, and then that will affect these thresholds.

Operator: Okay. Yeah, understood. Lastly, I believe it was Dr. Hazard had talked about pain management for when IMNN-001 is administered and kind of how that pain management has evolved, basically, with her experience with the drug. I'm just curious, is there a set protocol for that pain management at all the different clinical sites, or is it kind of up to the clinician's discretion?

Stacy Lindborg: That is a really great question. Douglas, do you want to take that?

Douglas Faller: Be happy to. Thank you for asking the question because, obviously, patient comfort is critical for us and for the ability of patients to get the drug. In patients who have ovarian cancer in the peritoneal space, they are often quite tender because of the inflammation that is there before the drugs start to work. Infusing anything into the space can cause discomfort for patients. This happened in some patients in OVATION II, and the physicians, in combination with Imunon, decided that rather than waiting for this to occur, we could prophylactically treat patients, give them some analgesia prior to the infusions, prior to even the first infusion. If there were going to be any discomfort, this would alleviate it. If it turns out it is not necessary later on, that could be stopped for individual patients. It has been quite useful, quite successful.

Douglas Faller: We're not seeing this was this, and it's, to answer your question more fully, this is part of the protocol. This is mandated for all patients. This was also incorporated into the MRD study, and we have data from Dr. Jaziri's sites that he's managing that this has been very successful. They've not had problems with any sort of abdominal discomfort in patients. In Ovation III, we've not seen that either. The prophylaxis for potential discomfort with the infusion seems to be working very well.

Operator: Okay, great. I appreciate that, and thanks for taking the question.

Douglas Faller: Thank you. We have the next question on the line of James Malloy from Alliance Global Partners. Please go ahead.

James Malloy: Good morning. Thank you very much for taking my questions. I had a question for Dr. Faller. One of the things you talked about on the R&D; day was about the durability response in sort of speaking to the mechanism of action of triggering the immune system and some of the IL-12 expression in the fluid and tissues. Can you walk us through that a little bit, please?

Douglas Faller: Very happy to. Please stop me if I'm telling you something you already know and it's not appropriate to your question. The problem with IL-12 delivered systemically, as you know, has been it's simply not tolerable. It's too potent. Like IL-2, you can't give it at high enough doses systemically, let's say intravenously, because of its, it's hard to call it toxicity. Let's call it adverse events. I don't call it toxicity because it is actually the intended activity of the cytokine. Patients have, just like IL-2, patients with third space, a lot of fluid outside of the vascular system, low blood pressures, fevers, etc. That's prevented IL-12, excuse me, and IL-2 from being used effectively. Here, we're delivering the drug where the tumor is, into the intraperitoneal space. That's where the ovarian cancer has spread in all the patients that we're treating.

Douglas Faller: As Khursheed mentioned earlier, this is a gene therapy. The plasmid gets taken up by the tumor cells and also by the tumor microenvironment cells, the stromal cells, and express IL-12. IL-12 then induces interferon gamma and TNF alpha, two incredibly potent immune effectors that stimulate both the adaptive and the innate immune systems. The IL-12 levels in the peritoneal fluid we've reported in Ovation I and Ovation II go up by several logs. There's a tremendous amount of IL-12 and its downstream effector cytokines expressed in the intraperitoneal fluid and in the tissues, as you would expect, in the peritoneum. However, in Ovation I and in Ovation II, we've monitored IL-12 levels systemically, and we don't see increases in IL-12 systemically, no more than twofold. This is the basis for the remarkable safety we have.

Douglas Faller: We're not seeing the kind of immune adverse events that everyone else who tries to deliver the drug systemically has seen. We're not seeing any cytokine release syndrome kind of events, which completely goes along with the fact that we're not elevating cytokines, IL-12 or its effectors, systemically. It's just where the tumor is in the intraperitoneal space. The durability, Khursheed already addressed the amount of time that the plasmid is expressed. We can see IL-12 levels in the peritoneal fluid for at least a week after a single injection, and we give the drug weekly, at least during the time that the patient's getting chemotherapy. The durability of responses, when I was pointing to the slides, was just showing that we give the drug during the chemotherapy, which is six cycles essentially, plus interval debulking surgery at the beginning of treatment for the patients.

Douglas Faller: Yet we're seeing effects years later. We're seeing the curve separate. We're seeing a benefit for survival in patients. This is long after we've stopped giving the drug. This is consistent with what you would like to see, what you'd expect to see from an effective immune therapy. Once you've educated the immune system to kill the tumor, it should persist. You should not necessarily have to keep stimulating, although in the MRD study, we are exploring maintenance therapy to see if that would add additional benefit.

James Malloy: Great. Thank you for that. One of the things that Stacy had mentioned, I think, as well as talking about the OVATION 3 meeting, the regulatory approval for the EU, any details on that process? Maybe also, I know you mentioned, Stacy, that obviously you are constrained by the amount of cash

you have to run the trial. If you had more cash, you could run it quicker. If you had unlimited funds, how quickly could you run this trial?

Douglas Faller: Stacy, maybe I could address, if you do not mind, the regulatory issues, and then you could talk about the financial ones.

Stacy Lindborg: Please, go ahead.

Douglas Faller: Okay. The issues in Europe are twofold, as I'm sure you know. One is getting the trial, excuse me, is getting the drug approved by the EMA. Equally important is getting payers to actually agree to support use of the drug in Europe. What payers want to see in cancer is survival. PFS is not something that traditionally, in my experience, payers are willing to pay for. Our endpoint is overall survival. We've already ticked the box that the payers would want to see. The study is designed in a way that should be completely acceptable to the EMA. I've had a lot of experience in dealing with the EMA and many other regulatory agencies outside of the U.S. We could open studies in Europe.

Douglas Faller: It's not necessary for European approval, but let me turn it over to Stacy now with respect to what we'd like to do with adequate funding.

Stacy Lindborg: Yeah, it's an interesting question. I can tell you that when you think about some of the remarks that Douglas provided that really characterize how quickly we're moving, I can promise you we're going to be very focused on advancing this trial and taking advantage of every opportunity that we can. We've done a number of different kind of internal forecasts. As I shared before, right now, our estimate is that we'll be able to fully enroll this trial in about three years. We have done a forecast that is as quick as two years. I think that is something that we put plans behind to consider how we would achieve it, and we believe that it is possible. Beyond that, I really wouldn't want to go too much further. There are ways that you could actually pull it in even further.

Stacy Lindborg: I think it gives you an idea of the way that we're looking at this and ensuring that we will be ready and able to accelerate very quickly some of these proactive approaches with the CRO that we're working with that, interestingly enough and importantly, do not change the overall price that we expect to pay, including even pay the CRO. We're just advancing activities so that we'll be poised and we can actually see the site activations when we want them, rather than waiting to engage them at that time. Those are some of the operational strategies.

James Malloy: Thank you very much for taking the questions.

Stacy Lindborg: Awesome. Thank you.

Douglas Faller: Thank you. We have the next question from the line of Emily Bodnar from H.C. Wainwright. Please go ahead.

Stacy Lindborg: Hi. Thanks for taking the questions. First one, I'm curious if you're planning to share an update from the OVATION 2 trial, particularly the PARP inhibitor-treated patients in terms of median OS since in the last update. It was not reached yet. If so, when you might expect to do that? Second question, how many sites for the OVATION 3 trial are you expecting to be sites that were part of OVATION 2? Are those the sites that you're kind of targeting initially? Thank you.

Stacy Lindborg: Yeah. Emily, thanks for both of those questions. Let me take a stab at both, and then if there are other points, Douglas, you could maybe add on. In terms of OVATION 2, in our protocol, we stated that we would monitor overall survival. We designated the period of time that we would continue to monitor it. It really puts us in a place where we're starting to wind down sites. We expect by the end of the year that we'll have the data fully refreshed and the sites that will be closing. I think at the end of the day, when you look at this trial, we know that the data that we've collected, even going to the very first interim across the all-comers, the median was observed in both treatment arms. We know the data was mature for very robust conclusions.

Stacy Lindborg: I think I would say we shouldn't expect, nor would the medical community expect to see significant changes to these results. We will likely have this process really finalizing towards the end of the year and early next year. Douglas, I don't know if you have any kind of—you already commented on the reflection of how long we're seeing this effect past the treatment period. When we ultimately look at the size of separation, and at R&D; day, we looked at some of the graphs that have come out of these recent immune checkpoint inhibitors where you see really no separation. Tell me your reflection as a clinician on the time periods when we were observing and did these two readouts. Really, were these appropriate in terms of when you would be expecting the separation, the phase of the curve to really be well-estimated?

Douglas Faller: Certainly. You have actually already spoken to it, Stacy, that in Ovation II, the primary endpoint is median, well, a secondary endpoint was median survival in the entire population. That is when our initial readout, we achieved that information. In trials in cancer, once you have gotten median survival in your primary population, longer observations yield less and less information, I think. Curves with fewer patients on them start to become less informative. We are very pleased to be seeing the effects over time that we have seen. I think that the concept of using this drug in the neoadjuvant setting really was a remarkably smart choice early on in its development. This became of great interest at ASCO. Using immunologically active drugs in the neoadjuvant setting where there is still tumor there allows the immune system to be educated in the setting of the tumor.

Douglas Faller: Using it later in an adjuvant setting when there's little or no tumor there, drugs even like checkpoint inhibitors, as was being realized at ASCO, are much less effective. I don't have anything beyond that to say, Stacy.

Stacy Lindborg: Thank you. Emily, your second question was about the sites from Ovation II and maybe even I do not know if you were getting at the overlap or the total number in Ovation III, but we will have great overlap in Ovation II and Ovation III. Not surprisingly, we started with sites that were very strong enrollers, very enthusiastic about the trial. We see that certainly extending to many other sites from Ovation II. We will have new sites simply because we are planning to have up to 50 sites. We will ultimately look at the number of sites that we need to really stay with our forecast and keep enrollment going. We will plan accordingly. We have flexibility in the way the protocol is written that we can go higher if we decide we want to do so.

Stacy Lindborg: It's a careful, you have to carefully manage not bringing in too many sites, really keeping your sites that are performing extremely well. The enthusiasm of these early sites, and I would say really the sites from Ovation II, not only from their knowledge of the product. You heard Dr. Thacker at R&D; day actually comment on the fact that she's been working on IMNN-001 for almost a decade. She was involved in Ovation I. Ovation II now is, again, the study PI for Ovation III. Their confidence and conviction in what's happening in these women, which of course they see when they're doing surgery, they observe as they're meeting with them for years after enrollment in the trial. It's palpable, right? It's incredibly clear. They believe very much that the potential for this product to be transformative to care is great.

Stacy Lindborg: It's really wonderful to see these clinicians that are also offering up to meet with new sites. They're very willing to share operational updates as well as really talk about data and what they've observed in patients over time. It really is kind of the best of both worlds.

Stacy Lindborg: Thanks for taking the questions.

Stacy Lindborg: Thank you, Emily.

Douglas Faller: Thank you. Ladies and gentlemen, that concludes the question-and-answer session for today. I will now turn the call back over to Dr. Lindborg for closing remarks.

Stacy Lindborg: Thank you. And thanks to everybody for joining the call. With OVATION 3 enrolling ahead of plan, we've talked about the compelling clinical and translational data from R&D; day and also

recent conferences, including SITC just last week. And active partnership discussions, Imunon is poised for multiple value-inflecting milestones. We remain diligent in stewarding the resources you provided, as I hope you're able to see very clearly in the queue, and are steadfast in our mission to redefine ovarian cancer treatment and deliver lasting shareholder value. So thank you all for your support and look forward to meeting again at the next quarterly earnings.

Douglas Faller: Thank you. Ladies and gentlemen, that concludes today's conference. Thank you for participating, and you may now disconnect your lines.