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Corporate Speakers:

- Jan Medina; Agenus Inc.; Director of IR
- Garo Armen; Agenus Inc.; Chairman & CEO
- Jennifer Buell; Agenus Inc.; President & COO
- Andrew Hurley; Agenus Inc.; Chief Commercial Officer
- Christine Klaskin; Agenus Inc.; VP of Finance
- Steven O'Day; Agenus Inc.; Chief Medical Officer

Participants:

- Kelly Shi; Jefferies Group LLC; Analyst
- Mayank Mamtani; B. Riley Securities, Inc.; Analyst
- Matt Phipps; William Blair & Company; Analyst

PRESENTATION

Operator
Good morning, ladies and gentlemen. Thank you for standing by, and welcome to the Agenus Second Quarter 2021 Conference Call and Webcast.

(Operator Instructions)

Please note that this event is being recorded and may be used in future Agenus' promotional material. I would now like to turn the conference over to Jan Medina, Director of Investor Relations. Jan, please go ahead.

Jan Medina
Thank you, Myra, and thank you all for joining us today. Today's call is being webcast and will be available on our website for replay. I'd like to remind you that this call will include forward-looking statements, including statements regarding our clinical development, regulatory and commercial plans and timelines as well as timelines for data release and partnership opportunities. These statements are subject to risks and uncertainties, and we refer you to our SEC filings for more details on these risks. As a reminder, this call is being recorded for audio broadcast.

Joining me today are Dr. Garo Armen, Chairman and Chief Executive Officer; Dr. Jennifer Buell, President and Chief Operating Officer; Andy Hurley, our Chief Commercial Officer; and Christine Klaskin, Vice President of Finance.

Now I'll turn the call over to Garo to highlight our progress during 2021 so far. Garo?

Garo Armen
Thank you very much, Jan, and thank you, everyone, for joining us today. In addition to the named officers of the company, we also have Dr. Steven O'Day, our Chief Medical Officer, to answer any questions that you may have at the end.

I will start by displaying what I did at our shareholders' meeting approximately 8 weeks ago. And there, we try to explain our business in simple terms so that there's clarity about what we focus on, our key operational drivers and some of the supportive programs we have. Starting with our significant value creators, 1181, that's AGEN1181, which is our next-generation CTLA-4 compound.

And you'll hear about that on many future occasions, as you have heard before. And with our 1181 program, we have already enrolled well over 100 patients in our clinical trials. And the results of updated clinical data will be made available in the second half of this year at major -- at least one major clinical conference. Our second significant value driver, which we talked about at the shareholders meeting is our AGENT-797 program, which is our iNKT cells.

Now we cannot say very much about that because we have filed an S-1 for a proposed public offering. Third major driver is our AGEN2373. Now this is a 4-1BB agonist. We also call it CD137. This compound, which has been tested for the last -- almost a year, has shown excellent safety profile, and we're seeing now, hence all very early clinical activity. And in the second half of this year, you'll hear more about this compound. And of course, we have our QS-21 program, which has gotten a lot of attention because of COVID and because of what this compound can do for other vaccines beyond what's been in the headlines with COVID prophylaxis.

Now as you know, we get questions often about which programs to prioritize and how do we fund these programs. And of course, early on in the beginning of this quarter, we closed on a very important transaction. It was the Bristol-Myers in-licensing of our TIGIT bispecific, and the bispecific arm has not been disclosed yet. This is a very exciting compound. We have thought that Bristol is one of the best candidates to advance this program, if not the best candidate. And we also disclosed that at the time of our consummation of this transaction, that it was a competitive process. So this transaction allows us to get to $200 million, which we've already received.

In addition to that, they are well over $1 billion worth of contingent milestone payments and royalties upon commercialization. But also very importantly, we have a number of other potential transactions in the queue. And some may happen during the course of the second half of this year and some beyond. Now we also talked about potential spinout strategies. We talked about the S-1 filing for a proposed IPO for MINK. MINK, by the way, for those of you who may remember, is the original AgenTus company. This is our cell therapy company. And we also anticipate other potential spinouts from businesses that have been cultivated with Agenus and are ready to be on their own. Now we've also talked about potential project financings as strategy to bring in additional cash,

particularly for programs that we plan on pursuing ourselves without necessarily having to outlicense them. And there are a number of such programs in our portfolio.

Now the third category that we mentioned were what we call supportive programs and supportive programs certainly include balstilimab, our PD-1 antibody. And we've said that while our PD-1 antibody, on its own, may not be a blockbuster potential. It can be a blockbuster potential product in connection with some of the other elements in our portfolio. We've also talked about our balstilimab plus zalifrelimab, and you will hear more about that very soon at a major medical conference, ESMO, which we announced with our earnings disclosure today.

Now we've also been in discussions for potential clinical collaborations for some of our earlier assets, meaning balstilimab as well as zalifrelimab. These compounds can be very valuable in connection with other people's assets that will benefit from the synergy provided by PD-1 and CTLA-4 combinations. And those will benefit us further by expanding the market with these combinations for our PD-1 and first-generation CTLA-4 antibodies.

The fourth pillar we spoke about are our key operational capabilities, which, on one hand, allow us to advance our programs in the clinic very rapidly; on the other hand, they also allow us to manufacture our candidates reliably and rapidly; and thirdly, they allow us to be able to launch our own product as Dr. Andy Hurley, today, will be speaking about briefly.

So with that, I will turn this call to Dr. Jennifer Buell.

Thank you, Jennifer.

Jennifer Buell
Thank you very much, Garo. I'll just build a little bit upon what Garo mentioned. Our research and development productivity, which is really unique to Agenus, has now become business as usual for us. In the past 6 years, we've delivered 17 new discoveries to the clinic, which is a really remarkable progress. But in addition to those filings and the clinical advancement of these programs, we've also filed our application for our first program, our BLA application. We now have balstilimab, as Garo mentioned, has been accepted for priority review by the FDA with an action date of December 16. So we're quite excited now, as Garo mentioned, Andy will tell you about the commercial infrastructure that we're setting up to build for balstilimab and then beyond balstilimab.

Of course, as you hear from Dr. O'Day in the upcoming months, data and progress from AGEN1181 is -- has been quite remarkable. So the infrastructure that Andy's going to be building will support bal and set us up for the launch of AGEN1181. In addition to these discoveries and advancements, one of those 17 announced discoveries entering the clinic advancing to the clinic is AGEN1777. Now that's a TIGIT bispecific molecule which is now in a strategic collaboration with Bristol. And a few important components, Garo mentioned, Bristol is really the most remarkable company to bring this forward. They're

committed to advancing it, they're experienced in this space in IO and into biology and they have a very aggressive development plan that we're really quite excited about.

In addition, this strategic collaboration marks some important differences from our prior collaborations in that, we have the opportunity to combine this bispecific with certain agents in our portfolio, which is really exciting for us. In addition, upon approval, we have the opportunity to co-promote. So we're really excited about the FDA recent clearance of this IND, and we'll be looking forward to making further announcements about the clinical progress of this molecule. Now beyond these most recent advancements, Garo has mentioned that we expect to present data on AGEN1181, which is making significant progress in the clinic.

And that data -- those data release will be based upon cohorts, disease-specific cohorts that we've now been expanding upon. So we'll certainly, we have Dr. O'Day here with us today, and we can answer questions about this program. Additionally, as we have -- we and others have shown, when you add CTLA-4 as PD-1, we see this with 1181. We also see this with bal/zal, particularly in one of our most advanced programs in cervical cancer. We expand the response rate and duration of response. And we're really excited to be presenting an update on our clinical program of bal plus zal in patients with refractory cervical cancer at ESMO this year. So the titles have been announced, and we'll have a mini oral presentation there. We're quite enthusiastic about.

Now on MINK Therapeutics, Garo introduced this. We've submitted a confidential S-1 for a proposed IPO. What we can't say too much about this program, these programs, what I can say is what we've explained to you before. Now MINK Therapeutics, formerly AgenTus, is advancing invariant natural killer T-cells. These are actually a subset of T-cells in their allogeneic form and they carry both the capacity to modulate innate and adaptive immunity. They have the ability in cancer to directly kill tumors through tumor lysis. They modulate the tumor microenvironment. They suppress myeloid suppressor cells, MDSCs. They also recruit and activate T-cells and NK cells.

We believe that these cells have the potential to deliver the durability and memory responses of T-cells with the cytolytic power of NK cells. We have multiple clinical trials underway. We've announced those the progress from those programs, and these programs include taking these cells into patients with solid cancers. And in addition to exploring these cells alone in solid tumors, we'll also be evaluating these cells in combination with validated checkpoint modulating antibodies, such as CTLA-4 and PD-1.

We believe that these cells can build on the benefits that we've seen with CTLA-4 and PD-1, and we presented data previously, demonstrating in preclinical models where CTLA-4 and PD-1 are about 40% to 50% active. When you add iNKT cells into that combination, you see complete tumor eradication in a lung met model preclinically. So we will -- we expect to be presenting data later this year on our ongoing clinical programs in patients with multiple myeloma as well as patients, B cells in patients with severe ARDS secondary to COVID-19.

And finally, our VISION platform. We presented data on this platform a number of times. This is a tool that enables us to identify how the best approach is to design molecules to address biology. This platform also enables us to interrogate responses and identify ways in which we can predict patients who will respond to our therapies. We expect the combination of our biologic platform and our new and expanding compute capabilities to be able to identify patients with significant probability of determining who will respond to therapies before those patients go on therapy. This is an evolving platform, and we look forward to continuing to update you on the progress of this platform.

Now I'm going to turn it over to Andy Hurley to tell you about our commercial group.

Andy Hurley
Great. Thanks, Jen. I'm happy to report that we are making great progress in planning the U.S. commercial launch of balstilimab in advanced cervical cancer, ACC for short. We have identified and hired a highly experienced leadership team across the key commercial and medical functions, I'm very pleased with the collaboration and agility that the team has shown to develop a well-defined strategic and tactical launch plan. A launch is only as strong as the team driving it, and we have attracted top commercial and medical leaders to Agenus from across the industry to be a part of the continued build-out of the company.

Our launch planning for balstilimab in ACC has 2 main goals in mind. First, that every patient that can benefit from balstilimab has access to it with few barriers. We are leveraging innovative programs at launch to reduce or eliminate normal reimbursement hurdles that physicians often face when trying newly approved medications. And second, in line with its market potential, a cost-efficient launch, leveraging a targeted personal and nonpersonal promotion approach across mediums and channels that physicians have told us they prefer in our market research. COVID challenged every pharma company to rethink how to promote their products and provide medical education of physicians.

And from this, physicians determine how they want to receive information, now and in the future. And we will be leveraging these learnings and how we will bring balstilimab to the ACC market. To comment a bit further on the progress made in our launch planning, we have hired an experienced team of commercial leaders, including account directors that will be engaging with payers pre-launch to support widespread formulary coverage of balstilimab at launch. We have conducted extensive market research across a wide audience of physicians and payers to determine our product positioning and messaging for all key stakeholders.

We've built a data management infrastructure that will allow for deep and fast insights generation to enable us to react in real time to signals that we hear at launch. And this is where I've seen a lot of launches fail and not being able to be agile and quickly act on an insight that has happened in a market. We are spending a great deal of time ensuring that there are no silos in how we support our launch execution. We have partnered with best in industry vendors and agencies to support our reimbursement hub, creative marketing

campaigns, medical education, planning CRM platforms and other critical areas, and these vendor partners will be embedded within our teams so they can also support future launches, following the balstilimab launch in ACC.

However, the overarching goal of this launch is for it to be a foundational step for Agenus. It will serve as the catalyst to initiate the build of a fully integrated commercial infrastructure, which in turn would allow us to easily scale our teams and operational systems for future launches, maximizing the value of our vast pipeline. Specifically, as Garo and Jen mentioned, we are very excited at the possibilities for 1181 in big indications with high unmet needs. As much as balstilimab monotherapy could offer the small population of second-line advanced cervical cancer patients a therapeutic option, we could potentially see 1181 providing a much broader range of patients, life-changing outcomes. Potentially, a range of outcomes unmatched in recent IO history.

I've had the good fortune to have led and been a part of over 20 product launches in my career. I believe that the promise that 1181 has clinically and commercially is seldom seen in a career, and it is a big reason of what got me to come to Agenus. There are certainly exciting times ahead for Agenus and the patients we hope to help.

I'll now turn it over to Christine Klaskin to review our financial results.

Christine Klaskin
Thank you, Andy. We ended the second quarter of 2021 with a cash balance of $74 million as compared to $100 million at December 31, 2020. Subsequent to the quarter end, we received $200 million related to our BMS partnership. For the second quarter ended June 30, 2021, our cash used in operations was $56 million, and we reported a net loss of $84 million or $0.37 per share. This compares to cash used in operations for the same period in 2020 of $37 million and a net loss of $48 million or $0.28 per share. Noncash operating expenses for the second quarter ended June 30, 2021, were $30 million compared to $18 million for the second quarter of 2020.

Our cash used in operations for the 6 months ended June 30, 2021 was $98 million with a net loss of $138 million or $0.65 per share, compared to cash used in operations of $72 million and a net loss for the same period in 2020 of $94 million or $0.59 per share. We recognized revenue of $22 million and $42 million for the 6 months ended June 30, 2021 and 2020, respectively. This revenue includes related -- revenue related to noncash royalties earned, revenue recognized under our collaboration agreement, and in 2020, $14 million from an upfront license fee we received.

I'll now turn the call back to Garo.

Garo Armen
Thank you very much, Christine, and thank you once again for participating in our call. I will make a few closing remarks before I will turn it to the operator for questions.

Just to summarize, some of the highlights for the second half of this year that you may expect. As Jen mentioned, we have a PDUFA date for balstilimab monotherapy in December. And we're diligently working in preparation for all aspects of the final phases of what is required. As Andy mentioned, we're preparing diligently for commercial launch for second-line cervical cancer. But as you said, we're putting together an infrastructure so that we can capitalize on our leveraging for our future launches. We're going to be defining our strategy for bal/zal.

And as Jen mentioned, you can expect the exciting presentation at the upcoming ESMO conference. We will continue with our development for AGEN1181 with its strategy to transition our studies to an approvable study for 1181. And additional data presentations for our own pipeline of agents and partnered agents are also due in the second half. We will be advancing our AGEN1777, which is now Bristol-Myers' asset, it's the TIGIT program, into and through the clinic. We will be completing enrollment of various other programs, and I will not give you the specifics on what we expect with our iNKT program based on our confidential S-1 filing, which puts us in a quiet period. We will be progressing our commercial manufacturing capabilities for antibodies.

This is a very important aspect of our strategy. It will be critical for us to do this so that we can launch -- potentially launch 1181 as speedily as possible upon demonstration of compelling data, as Andy said, in patients who are otherwise not benefiting from immunotherapy or for that matter, any other therapy. We're also progressing with our sustainable supply of QS-21, which we believe is a very, very important agent, for both prophylactic as well as therapeutic vaccine adjuvancy. And as I mentioned earlier, we will be anticipating additional transactions, financial and corporate transactions in the second half of this year. Thank you again for your attention. And now we'll open to any questions you may have.

Jan Medina
Thanks, Myra, if you could open the Q&A, please?

QUESTIONS AND ANSWERS

Operator
(Operator Instructions)

Our first question comes from the line of Kelly Shi from Jefferies.

Kelly Shi
Congrats on the progress. I have 2 questions. So first one is what is your market strategy for bal monotherapy in second-line cervical cancer upon approval, given that a combo is probably not too far behind in the progress? And also, what are we going to hear media overall survival data from monotherapy trial? Does this data have an impact on your commercial strategy for mono versus combo? That's my first question. And my second question is, could you give us some color on the combo data at ESMO?

Garo Armen
Let me address the question top line, and then I'll turn it to my colleagues to get into the specifics. But remember that we cannot say very much about the ESMO specifics, otherwise, we'll simply be kicked out of the presentation, which had a very desirable outcome for us. Now so if you're patient, you will see the data with -- classified data as being very exciting. And getting back to your first question, as you know, combinations with IO therapies. Generally, and when I say generally, I'm talking about the great majority of the time.

Certainly, with the existing marketed products, I see better results than monotherapy. And when I say better results, we're talking about improved response rates but also very critically improved duration of responses, and that's typical of that. So in an ideal world, where everybody would accept these facts, we would imagine that the combination should be the desired path forward. But there are hurdles including regulatory hurdles in allowing for these combinations to be practiced. And so we will work very respectfully with the regulatory agencies in the U.S. and elsewhere to make sure that these combinations become the best options available for the appropriate patient population. But with that, Dr. Buell and Dr. Hurley, if you have any other...

Jennifer Buell
Sure. I'm going to turn it over to Andy to get started on your question, Kelly. Question number 1.

Andy Hurley
Yes. So thank you, Kelly. I looked at every launch as you have to really establish a foundation with the community, you're going to be targeting and bringing a product to and the balstilimab monotherapy launch allows for us to build those relationships, get to understand the marketplace, get to really understand the dynamics that are going to be needed for subsequent launches in that particular space.

So part of our strategy is really bringing a much needed therapy to that particular wide audience of physicians. And then in doing so, they're going to get comfort with balstilimab. And because if you're going to be bringing a combination that has balstilimab in it, and they already have comfort with the monotherapy option and seeing it really work where other agents may not have worked in the past, that is a good first step for us to really establish credibility in a marketplace that we're going to be looking to really make significant impact in. So I believe that's really what it is.

And I'll go back to the initial point that I made is the fact that we're not looking at launches in isolation. We're not looking at one versus another as our primary focus. Our primary focus is to build a fully integrated commercial infrastructure that we can pivot to whatever products we're looking to bring to market. And if the combination in cervical cancer looks promising, and we want to continue to explore it, then we'll have the necessary support, both on the in-house commercial leadership as well as the field presence to be able to really make that impact.

Operator
Our next question comes from the line of Mayank Mamtani from B. Riley Securities.

Mayank Mamtani
Congrats on the progress, and Andy, in particular for the new role with MINK. So maybe first couple of questions for Dr. O'Day. So for 1181, Can you just -- looks like it's not maybe at ESMO, maybe it's after. Just curious what sort of update we should expect in terms of you have a number of different tumor types, PD-1 refractory setting versus doing this in combination. And also like what number of patients you may have on the MSS colorectal cohort? That would be question number one.

Steven O'Day
Thank you for that question. We're very obviously excited about the 1181 program as we publicly disclosed this agent, which is a next-generation CTLA-4 has been engineered to be more active, both from a priming and memory point of view as well as depleting Tregs in the tumor microenvironment and having a better toxicity profile. So we continue to advance the Phase I/Ib program. As Garo said, we now have over 100 patients treated with either single agent 1181 or combination. We will be hopefully presenting this data by the end of the year at a major conference and we can't say more than that at this point.

Well, I think the take-home messages from this program to date have been, it's been designed to be a next-generation CTLA-4, and it's performing as such in the clinic, in the sense that tumors that historically have had little to no PD-1 or CTLA-4 activity. We've reported responses, particularly in cold solid tumors like MS stable colorectal cancer, ovarian as well as PD-1 resistance settings. So this is all very encouraging to us. And in terms of numbers around cohorts, again, that we have not publicly released updates on that, but look forward to doing that at a major meeting. But as you know, colorectal MS stable cohort is one of the cohorts that we are rapidly expanding in this trial and look forward to updating you further later in the year.

Mayank Mamtani
And then on the Bal monotherapy PDUFA, as you prepare for that, are there any parallels to draw from, for instance, the retifanlimab recent experience with FDA? Or are you expecting an AdCom by any chance?

Steven O'Day
The question's, are we expecting a?

Jennifer Buell
an AdCom.

Steven O'Day
AdCom. Okay. I think between now and the PDUFA date, you can expect that we are going to do a lot of work in communication with the agency, there are mandated inspections in the process and we're going through all of that right now. And I think out of respect to the process, we will not disclose the details.

Mayank Mamtani
Okay. Fair enough. And then maybe for Jen and Garo, I have a follow-up for you. But maybe, Jen, are you able to comment on sort of the patients dosed across solid tumors and COVID-19 ARDS. And what sort of territories have you been enrolling for the iNKT? And any color there?

Jennifer Buell
Mayank, we can't say too much right now for obvious reasons, given where we are in the process. But rest assured, we'll be aggressive with data releases as we have always been across the portfolio.

Mayank Mamtani
Great. And maybe for a Garo. Garo, as you look at scaling up a lot across R&D, G&A, CapEx, great to see this Vacaville facility coming online here in California, expanding your XOMA antibody efforts. I'm just curious, like how should we think about this going forward, especially if QS-21 adjuvant becomes something that would require investment. How would you think about expanding CapEx and obviously, continuing to fund the R&D pipeline there?

Garo Armen
Okay. So let me address that in several ways, and I don't mean to be complex about my answer, but just bear with me. Now if you look at the history, Mayank, of how we have managed our expenditures versus our cash balance. It has been done in a very orderly way, meaning at any given quarter, we have managed our cash outflows and cash inflows very well. Of course, the Bristol transaction that brought in $200 million and is expected to deliver another milestone this year in terms of cash infusion has provided a bit of a jump into our cash balances.

And I expect that in the second half of the year, we will have additional jumps in our cash balances. Now where do they come from? Several sources, in addition to corporate transactions, milestones, project financing transactions. In addition to those, we expect to fund some of our separated subsidiaries by means of outside capital infusion, and that will certainly reduce some of our cash burn associated with those businesses. That includes, for example, our MINK Therapeutics asset.

It also includes our QS-21 and related assets. You could also expect to see some asset sales, possibly in the second half of this year. And so if you add all of those things relative to unusual items, that will occur from time to time that will represent jumps, I cannot tell you on a quarter-to-quarter basis, what the impact of that will be. But I expect that we'll be able to manage our cash position so that we are left with a substantial cushion at the end of each period. So other than that, unfortunately, I cannot give you any more specific dollar guidance.

Operator
(Operator Instructions)

Our next question comes from the line of Matt Phipps from William Blair.

Matt Phipps
Just a few. Do you guys have any update on the timing of the bal/zal filing that you can give a little bit more clarity on ahead of the PDUFA for bal? Or do we have to really wait for that PDUFA to clear?

Garo Armen
I think on the bal/zal filing, Matt, we've said that we'll provide guidance on this in the second half of this year. Of course, it's going to be a function of us disclosing the data, the final data from that combination trial at ESMO and then deliberations with the FDA. So bear with us, once we get some clarity through both processes we'll give you a definition on the path forward. But with regard to the PDUFA date, I'll -- what was the question again?

Matt Phipps
No, that pretty much answers it. Then secondly, for 1327, your now wholly owned TIGIT monospecific antibody, do you still plan to move that into Phase I this year? Or just what are kind of the thoughts for that asset after the out-license of the bispecific?

Garo Armen
So clearly, the bispecific has advantages over the monospecifics and the data that we've generated so far is very suggestive that. However, having said that, can the monospecific antibody be an important reagent, just like PD-1 is an important reagent. For some of the other combination possibilities in our portfolio, the answer is most likely, yes. And so hence, we will advance this program with that in mind, and we -- I don't think we provided guidance on the exact timing of the IND filing. But bear with us, it will be within a reasonable period of time.

Matt Phipps
Okay. Then, Garo, as I look at your earliest stage pipeline disclosures, it does seem like there's a bit of a move to bispecific formats or kind of therapies. Is that -- do you think that is kind of a direction that you all are moving more broadly? I mean, obviously, the TIGIT, and then also the TGF-beta-Trap are kind of in that realm. So just curious if that's kind of where we should think about for the evolution of your kind of antibody-based platform.

Garo Armen
Thank you for that, Matt. I think that's a presumptuous assumption, meaning we have, bispecifics in our portfolio that have not been disclosed that have very, very exciting activity that we're seeing very early on. But we also have some phenomenal monospecifics that will be announced and one specifically will be filed to enter the clinic this year. And of course, with these agents, as you know, the immune system is like a symphony of a lot of activities.

Yes. Certain immuno-oncology agents have activity as single agents, but I think it's fair to say that the most exciting activity is being seen with the symphony process of agents. And so I think it will be very exciting for us to see from our own portfolio, combinations and so that will be generating very exciting data as we have seen using our VISION technology and other means in our preclinical development process. So very exciting. And very exciting, particularly, because we control the different components of the symphony, if you will.

Operator
There are no further questions at this time. You may continue.

Jan Medina
Thank you all very much for your attendance and listening to our update.