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Agenus (NASDAQ: AGEN) Q3 2019 Earnings Conference Call

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Executives
Garo Armen, Ph.D. – Chairman and Chief Executive Officer
Jennifer S. Buell, Ph.D. – Chief Operating Officer
Anna Wijatyk, M.D. – Head of Clinical Development and Operations
Christine Klaskin – Vice President, Finance

Jennifer Buell

Thank you operator.

[Our forward-looking statements and disclosures are available in our press release and our website.]

I am Jennifer Buell, Chief Operating Officer of Agenus and joining me today are Dr. Garo Armen, Chairman and Chief Executive Officer, Dr. Anna Wijatyk, Head of Clinical Development and Operations, and Christine Klaskin, our Vice President of Finance.

I will start this call by first asking Garo to provide you with the reality of Agenus today operationally and in the market place. I expect these facts as they are and what we have achieved will be eye-opening to you all.

Garo Armen

Thank you, Jen.

During our last quarterly call, I shared a visual with you [$AGEN outpaces in advancing IO discoveries]. This slide speaks to our R&D productivity and the fact that over the past 4 years in IND filings we have outpaced other I-O companies, large and small. Also important is the fact that all the INDs that have been filed, all 13 of them so far, represent inventions of Agenus.

PATH TO BLA

During this call we will update you on the progress we have made with our most advanced programs, our CTLA-4 antibody, *zalifrelimab* and our PD-1 antibody, *balstilimab*. We are targeting c**ommercializing** both agents in the first half of 2021 which means we will be filing INDs in 2020. Our first indication will be 2L cervical cancer. BUT and importantly, we are developing these two antibodies because they are **critically important agents** to be used **in combination** with many of our own **NexGen antibodies including bispecifics, in combination with our allogenic cell therapy for which our first IND is on track to be filed this year**; and also in combinations with our cancer vaccines which include our off the shelf phosphorylated antigen vaccines where we have a highly proprietary position. As you can see from our IND chart, we have generated 13 I-O agents which are ***all*** in clinical development presently.

MARKET DIFFERENTIATION AND SUCCESS

We expect that some of the NexGen agents in our pipeline can help expand the market opportunity for our PD-1 and our CTLA-4 antibodies. For example, to the extent that the combination of our NexGen CTLA-4 antibody plus our PD-1 antibody performs better than those in the market today, we believe our PD-1 commercial opportunity will be **substantial**….. and on that note, we plan to start our combination trial with our NexGen CTLA-4 and our own PD-1 this month.

In addition to the leverage our PD-1 and CTLA-4 antibodies provide us for our development strategy, we have been approached by several companies who have expressed their interest to access our agents to develop with their own proprietary products; The first of these transactions is expected to be finalized in the next weeks. Each one of these transactions will involve a modest upfront, cash milestones, and double-digit royalties.

I will now provide you with some insights into our ongoing cervical cancer trials. As we had promised, we have completed *required* enrollment of our PD-1, CTLA-4 combination trial and we expect to complete enrollment of our monotherapy trial with PD-1 by year end. We have completed the planned interim analysis of our combo trial and expect to complete the planned interim analysis of our monotherapy trial soon. We have shared the results generated from our interim analysis of our combo trial with our DSMB and based on both safety and efficacy signals they issued a recommendation to proceed to completion. I should also point out that in preparation for our potential BLA filing next year, we have produced commercial grade material for both antibodies.

PIPELINE OPPORTUNITY

I will now switch to some visuals and address questions we are asked frequently. The next visual representing the evolution of our pipeline in the past 4 years. Our pipeline in 2015 [Pipeline Growth] included 7 products. Since that time, we have created an extensive portfolio [Pipeline Growth] of checkpoint antibodies, allogeneic cell therapy and neoantigen vaccines. I believe our pipeline represents one of the most

comprehensive portfolios in IO today. It also allows us and our partners to explore optimal combinations without having to compromise based on limitations to access.

KEY QUESTIONS

One question we get asked relates to***, how are we able to manage so many programs given your limited monetary and human resources?***

Regarding human resources, I humbly believe we have built one of the best teams in the industry. They are inventive, smart, highly knowledgeable, very passionate about their work and hard working. Without them we would not have achieved all this…..we expect our team to be the key drivers of our continuing innovation and success.

Regarding monetary resources, I would like to draw your attention to the following visual. This speaks to our resourcefulness in ***having raised a significant amount of money, which has been in excess of $500M in the past 4 years*** alone. And we have not done a marketed stock offering for four and a half years.

We aim to continue to fund our future operations largely through these types of creative mechanisms until we achieve profitability.

Another question we often get is - **have we sold all rights to your pipeline**? The answer to that question is most certainly **NO**. this pipeline chart shows what we have partnered and what we have retained. All magenta colored products represent agents that belong to us 100%. ***Importantly***, we have also retained the rights to generate bispecific molecules with all of our proprietary targets. As we demonstrate clinical activity of some of our clinical stage I-O agents, we plan to keep more and more NA rights for Agenus and license XNA rights to others.

Lastly, I would like to show you 3 recent stock charts which have tracked our performance relative to other I-O companies, non-I-O larger biotechs and biotech and drug indexes.

As you can see while our performance is **substantially** better than essentially all others, our **absolute stock performance has been dragged down by the sector** and of course we are not satisfied with the absolute performance of our stock price. In addition to our continuing efforts to improve our communications and education, we have recently hired a IR and communications professional who will be known to st least some of you.

In spite of the fact that the sector has experienced unprecedented and explosive revenue growth in the past 5 years with the first two PD-1s and first CTLA-4 antibodies – expected to top $20B in revenues this year – recent trends have shed some doubts about the sectors ability to continue with the past momentum.

CATALYSTS

We aspire to return confidence to the high hopes for the sector with our performance near and long term. During 2020, we expect to generate clinical data on our following I-O agents and trials:

1. Clinical data on our PD-1/CTLA-4 combo trial in cervical cancer
2. Clinical data on our PD-1 monotherapy trial in cervical cancer
3. Clinical data on our NexGen CTLA-4 dose escalation trial
4. Clinical data on our NexGen CTLA-4 combination trial with our own PD-1
5. Clinical data from our tumor conditioning bispecific GS-1423, now licensed to Gilead
6. Clinical data on our bispecific AGEN1223 design to deplete intratumoral T regs
7. Clinical data on our differentiated CD137 antibody, AGEN2373

All of these developments are slated for the upcoming year!

R&D DAY

Finally, I want to let you know that on November 15, that is the following Friday, we are hosting an R&D Day in New York. The event will include an update on the field of I-O by experts Dr. Steven O'Day and Dr. Manuel Hidalgo, as well as presentations from the company on our lead CTLA-4 and PD-1 programs, our next generation CTLA-4 molecule, and our discovery engine and capabilities. It will be an informative event and available via webcast.

Now, Jen Buell, our COO.

Jennifer Buell

Thank you Garo. As Garo mentioned, this is indeed a very exciting time for us.

While the transformation of the company occurred only within the last 4 years, we are operating with the integration, agility and flexibility, of a team that has been together for decades. This is largely due to our shared passion to deliver high impact therapies and small, fast clinical trials, designed for rapid regulatory and commercial success and access to all of the patients who need it. We share a commitment to transform the experience that a diagnosis of cancer means for patients. I am excited for Anna to share details about our progress in the clinic.

Before doing so, I want to ***summarize*** highlights of our progress in 2019 with brief details on our critical catalysts:

OPERATIONAL PROGRESS/EXECUTION

This year, we made remarkable progress in our trials, which includes the completion of accrual into one trial and approaching completion of accrual in our second. The **interim**

analyses based on independent core lab review are underway; our available investigator reported data **underscore the clinical benefit of AGEN2034 as a monotherapy for patients with refractory cervical cancer AND the benefit of the addition of CTLA-4 to PD-1 to expand response rates and potentially the durability of these responses**. Anna will tell you more about these programs shortly.

We **advanced 4 novel discoveries to IND** and these discoveries are now advancing in the clinic, now generating validating data on the differentiated proof of mechanism of these potentially first/best in class agents. These discoveries include our **next generation CTLA-4, AGEN1181, our differentiated CD137 agonist, AGEN2373, our first-in-class Treg depleting bispecific antibody, AGEN1223, and GS-1423, a bifunctional molecule exclusively licensed to GILD and being developed by them.**

In summary, this year we have:

- Generated data on more than 250 patients with lead CTLA-4 & PD-1 programs;
- Completed enrollment and the planned interim analysis for one late stage trial designed to support approval we are on track to complete enrollment and the interim analysis for the second trial this year.
- We have advanced our next generation CTLA-4, AGEN1181 through several dose escalation cohorts and will start combinations imminently;
- We have advanced our differentiated CD137 agonist in early dose evaluation;
- Activated the clinical trial for our Treg depleting bispecific, AGEN1223;
- Advanced our allogeneic cell therapy into IND enabling for a filing this year and engaged regulators to enable rapid combinations with our allogeneic cell therapy and antibodies; and
- Announced 3 cash milestones in our Gilead collaboration approximating $23M and entered into an agreement to manufacture GS-1423 for Gilead for undisclosed financials.
- Finally, due to the blockbuster sales of GSK's SHINGRIX vaccine containing our proprietary QS-21 adjuvant exceeding $1.6 Bn (USD) in the first 9mos, we have extinguished our contingent financial obligation of $25.9M to healthcare royalty. As a reminder, Agenus is remains eligible to receive sales milestones of SHINGRIX of up to $40M which are likely to come next year based on current trends of Shingrix revenues.

Now, I will focus on our NexGen CTLA-4, our differentiated CD137 agonist, and AgenTus. To reiterate Garo's earlier point, all of these next generation agents show important added benefit with PD-1 and in some cases, CTLA-4 or both. Given the preponderance of data we have generated with our lead molecules, we are able to accelerate the combination with our novel agents quickly. This includes combinations with our allogeneic cell therapy.

First, to expand on Garo's introduction of our next generation CTLA-4, AGEN1181 it is designed to address the shortcomings of the first generation CTLA-4 and expand benefit to the majority of patients who otherwise experience low responses due to a genetic polymorphism. We have shared early clinical readouts of AGEN1181 with our

scientific advisors and plan to share these data more broadly as they mature and combinations with AGEN2034 commence. As Garo alluded to earlier, if AGEN1181 in combination with our PD-1 or others, outperforms currently available CTLA-4/PD-1 combos, it will be an extraordinary outcome for patients and all our stakeholders.

Second, our differentiated anti-CD137 molecule, AGEN2373 is in the clinic. This molecule was designed with important safety and efficacy advantages over competitor molecules. AGEN2373 is a fully human monoclonal antibody that boosts the immune response to cancer cells by enhancing CD137 co-stimulatory signaling in activated immune cells – both adaptive (T cells) and innate (NK cells) which makes it a highly attractive target for cancer immunotherapy. **Importantly**, the unique binding properties of AGEN2373 are designed to enhance efficacy while limiting systemic toxicity that has hampered the development of competitor molecules.

Before I turn the call over to Anna, I would like to give you a brief update on AgenTus, our cell therapy subsidiary. AgenTus continues to build on the progress we shared during our last call. Our proprietary allogeneic cell format is advancing to IND and the company's highest priority and focus is to deliver allogeneic cell therapy approaches with proprietary targets and combinations with Agenus antibodies to patients with solid tumors and hematologic cancers.

- To accelerate our efforts we have appointed industry veteran, physician, and financing expert Dr. Walter Flamenbaum as CEO. One of Walter's priorities is to bring our discussions on financing to a positive conclusion.

I will now turn the call over to Anna to give you a brief update on our most advanced trials.

Anna Wijatyk

Thank you, Jen and Garo.

- This year has indeed been very productive and exciting. I have had the pleasure to work with an extraordinary team to deliver real breakthrough outcomes in timing to complete enrollment in our trials designed to support BLA and in parallel advance **four novel molecules to the clinic in this year alone at the same accelerated pace**. As a matter of fact, similar to our accelerated pace shared in discovery and manufacturing, our clinical operations team is innovating to do the same in the clinic. In that regard, we have advanced from IND clearance to FIM faster than industry standards and in under 2.5 months.

- As Jen and Garo already mentioned, the progress on our lead molecules is very important to enable us to start the combinations with our Next Generation molecules. The first combination with our NexGen CTLA-4, AGEN1181 is expected to start this month and our PK and PD data are informing optimal dosing.

- **Now, our lead programs.** Our proprietary CTLA-4 and PD-1 antibodies, zalifrelimab and balstilimab are advancing towards a planned BLA filing in 2020. At the upcoming Society of Immunotherapy in Cancer (SITC) this year, we will present clinical data from our Ph1 expansion cohorts showing that balstilimab is well-tolerated and reveals immunologic and clinical activity in recurrent ovarian cancer that is more impressive than what has previously been reported in this population with other PD-1 antibodies.

- As Garo and Jen reminded, we are pursuing *balstilimab* as a monotherapy and in combination with *zalifrelimab* in patients with relapse/refractory cervical cancer. In the combination trial, we have completed our accrual requirements for a potential BLA filing and the interim analysis. Our data continue to support our conviction that this validated IO combination may impart meaningful benefit, including improvement in response rates and durability of response beyond what is available today for these patients.

- As a reminder, this is a disease that affects young woman. These women have failed earlier lines of therapy which in some cases include surgery, radiation, chemotherapy, and other agents, sometimes multiple combinations. When they progress there are very limited to no treatment options for these patients.

- We are working with a sense of urgency to deliver meaningful treatments to this vulnerable population. We believe that our first-generation agents both alone and in combination can do that. We are working with our clinical advisors and the FDA in our efforts to advance these products quickly. ***Therefore, while we planned to publicly disclose data on our interim analysis this year, we have been advised to do otherwise in order to protect the integrity of our ongoing trials and support our planned BLA submission in 2020.***

- I look forward to providing additional information at our upcoming RD Day on November, 15.

- Thank you. Now, I will turn it back over to Garo.

Garo

Thank you very much Anna and keep up the excellent work.

As I mentioned, our strategy is to balance between monetizing a portion of our discoveries every year, while increasingly keeping rights to north America for some of our very valuable assets. Earlier, I indicated that we expect to generate meaningful clinical data in the next 12 months on a significant number of both partnered and wholly owned programs. This we expect to help our efforts to monetize on ex-US rights with significant value consideration. This strategy will be tested with our 2nd generation

CTLA-4 antibody currently in clinical development with prospects of generating early but potentially meaningful clinical data in the next months.

Our ability to control key components of IO combinations under one roof – specifically, checkpoint antibodies, cell therapy, neoantigen vaccines and our QS-21 adjuvant - we believe is a key advantage in our ability to develop the right combination drugs and in our ability to price them affordably. All for the purpose of benefiting patients.

Before turning the call over to Christine for recapping our quarterly financial report, I wanted to summarize a few key points:

- We have an outstanding pipeline of novel and 2nd generation I-O agents designed to deliver substantial benefit to patients with cancer.
- We expect to become a commercial stage company with our PD-1 and CTLA-4 antibodies. First in cervical cancer with strategies to rapidly expand to other cancers particularly with our combination agents.
- We are emphasizing smaller, focused trials to achieve high response rates specifically targeting patients who are not being effectively served by today's first generation I-O agents.

In addition to the clinical readouts which I outlined earlier for 2020, here is what expect to accomplish by year end 2019 and into 2020:

- Complete our monotherapy PD-1 trial accrual and conduct our planned interim analysis for this trial for BLA filing. Both our monotherapy and combination trials are designed to lead to BLA filings for accelerated approvals.
- Complete dose escalation and commence combination trials of our 2nd generation CTLA-4 with our proprietary PD-1 molecule
- As I mentioned earlier, advance our differentiated/best-in-class molecules in the clinic, including advancing and generating clinical readouts with our differentiated CD137 molecule AGEN2373 and our selective Treg depleting bispecific, AGEN1223.
- Advance additional breakthrough discoveries and file at least 2 additional INDs in 2020
- Advance our allogeneic cell therapy programs and have AgenTus funded independently

And importantly we expect to complete additional BD transactions in 2019 and 2020.

Now I will turn it over to Christine Klaskin to provide financial highlights.

Christine Klaskin –

Thank you Garo.

We ended the third quarter of 2019 with a cash balance of $93 million as compared to $53 million at December 31, 2018.

Cash used in operations for the quarter ended September 2019 was $28 million compared to $25 million for the same period in 2018. Cash provided by operations for the nine months ended September 2019 was $13 million as compared to cash used in operations of $95 million for the same period in 2018.

For the third quarter ended September 30, 2019, we reported net loss of $46 million or $0.33 per share compared to a net loss for same period in 2018 of $34 million, or $0.29 per share. For the nine months ended September 30, 2019, we reported a net loss of $81 million or $0.58 per share compared to a net loss for the same period in 2018 of $113 million or $1.04 per share.

During the nine months ended September 2019 we recognized revenue of $116 million which includes revenue from our transaction with Gilead and non-cash royalties earned. This compares to revenue of $30 for the nine months ended September 2018. Through the third quarter of 2019 we also recorded $30 million of non-cash interest expense due to our transaction with HCR related to the sale of future royalties.

Garo Armen

Thank you, Christine and thank you all for your attention.