agenus

Agenus (NASDAQ: AGEN) Q3 2018 Earnings Conference Call

November 6, 2018 8:30 AM ET

Introduction and Forward Looking Statements in APPENDIX I

Garo Armen

Good morning

I will update you firstly on our substantial operational achievements, which are unprecedented certainly for a company of our size but also for the field of I-O. Second, I will provide the latest update on the status of our partnership discussions and third, I will discuss our financial status and our creative financing strategies that have allowed us to advance our programs while maintaining or growing our cash balances.

Recently **at ESMO,** we reported that of the 130 patients treated with our CTLA-4 and PD-1 antibodies, more than 60% have shown clinical benefit. These include durable responses, across multiple solid tumors including cervical cancer. Dr Anna Wijatyk, our VP of Clinical Development will cover our discussions with the FDA last week which have confirmed our path to a planned BLA filing in 2020.

Our discovery and innovation engine which has given birth to our lead clinical stage antibodies, CTLA-4 and PD-1 will have produced 12 IND filings by the close of this year; this is **an industry record. Our innovative portfolio includes first-in-class and best-in-class assets. Today eight of these programs are in the clinic and also advancing in combination trials.**

Next, I will address the status of our partnering activities. I will provide an update on this with as much transparency as possible, while continuing to respect the sensitivity of these discussions. Clearly, we had hoped that we could close on one of these transactions as early as 8 weeks following our last earnings call. However, things have taken a bit longer, simply because of process. Despite these delays, two of these prospects are now rapidly advancing towards closure.

As mentioned in prior calls, we have sought, and identified partners who are best fits to maximize value to Agenus, to them and to our respective shareholders. This includes companies with an understanding of the critical importance of our diverse pipeline that we have built to optimize the possibilities of achieving significant success with clinical trials and commercial activities.

It is important to note that we have also made substantial progress with our existing partnerships. We have met or exceeded all research, IND filing and commercialization milestones in our partnerships with Incyte, Merck and GSK. We triggered $14M in cash milestones from Incyte and Merck this year, for the initiation of phase 1 trials for LAG-3, TIM-3, and an undisclosed antibody candidate, all discovered by Agenus.

While we are progressing our programs and filing INDs at record pace, as well as progressing our partnership discussions to closure, we are also prudently satisfying our near-term cash needs. We closed this quarter with over $46M in cash. At our last earnings call we projected that we would be at or above last quarter's cash levels which was at $43M. We continue to manage our cash position prudently with an intent to minimize dilution to shareholders to bridge to a partnership transaction. As an example of this and subsequent to the end of the 3rd quarter, we announced the completion of a private financing of $40M with a single investor netting the company approximately $39.9M in additional cash. This will be reflected in our year-end numbers.

Since our last call, we also announced a royalty transaction with XOMA which involved the purchase of a minority interest in the royalties and milestones that we are eligible to receive from Incyte and Merck. We received $15.0 million at closing and retain the majority (67%) of all future royalties and 90% of all milestones from these products. Importantly, we remain eligible to receive up to an additional $445.0 million and $85.5 million in potential development, regulatory and commercial milestones from Incyte and Merck, respectively.

So overall, so far this year, our financial position was enhanced with $97M in cash milestones from our existing partnerships and strategically executed financial transactions.

Finally, as you may know, our QS-21 Stimulon adjuvant is a critical component of GSK's Shingrix vaccine. **Shingrix sales are substantially ahead of forecasts**, making additional milestones from our royalty transaction with HCR much more likely.

Agenus is positioned to file a BLA as early as 2020 to become a commercial company so that we can continue to drive innovation with speed; these are critically important drivers of success in order to deliver the next major breakthroughs in immuno-oncology. Our portfolio of first-in-class and best in class assets, including our next generation CTLA-4 and bispecific antibodies will be in the clinic in 2019. These we believe will define the next major breakthroughs in the field of I-O; a field which has been relatively dormant with the absence of new agents to drive the next set of advances.

Before I turn the call to Dr. Anna Wijatyk, I will provide a summary of our important operational achievements:

We set out to file 6 INDs this year and we are on track having 4 already filed and two slated to be filed by year end. These include LAG-3 and TIM-3 antibodies under our partnership agreement with Incyte. Today I am pleased to announce that we have recently filed an IND for our next generation CTLA-4 antibody.

We have briefly described our next generation CTLA-4, AGEN1181, in our last earnings call. This molecule we believe will have both potential efficacy and safety advantages relative to competitor molecules, including:

(1) Enhanced potency through increased potential for T cell priming and Treg depletion
(2) Broader benefit to a wider patient population, including the ~40% of patients who are unlikely to respond to first generation CTLA-4 therapies due to a genetic predisposition
(3) Improved safety, through Fc engineering to avoid common side effects of first generation CTLA-4 antibodies and enhanced therapeutic potential to enable a broader range of dosing options

Additionally, ***we are on track to file INDs for two of our first in class bispecific antibodies this year*****, which we have described during our last call as well***.*

Importantly, these two tumor microenvironment conditioning agents offer critical solutions to overcoming the limitations of current I-O treatments. You will hear more specifics on these compounds as they enter the clinic next year.

We are positioned to deliver meaningful clinical advances with innovation and speed. ***Our discovery platforms*** have enabled our 4 therapeutic classes including checkpoint antibodies, cellular therapies, neoantigen vaccines, and adjuvants. ***Our cell line development and manufacturing platforms*** enable a fast path to IND. I want to reiterate that these capabilities have contributed to our record breaking timelines to deliver **clinical grade material from research cell bank 2-3 times faster than industry average and deliver registration grade material at commercial scale from technology transfer to our commercial CMO, as much as 5 times faster than industry standards.**

We've demonstrated speed in our CTLA-4 and PD-1 programs by enabling the CMC readiness to support a potential BLA filing as early as 2020 -- just 4 years after our first-in-man monotherapy trial commenced.

As we secure our BLA filings, our Clinical Development and Regulatory teams are led not only by industry veterans, but also by innovative thinkers energized by our pipeline and capabilities. Dr. Sunil Gupta who you met during our last earnings call and now, Dr. Anna Wijatyk who will be speaking next. Anna joined Agenus following her tenure as Vice President Oncology & Global Development Lead in hematologic cancers at Shire. She has also held leadership positions at Bristol-Myers Squibb and Baxter. Dr. Wijatyk is an expert in delivering programs under accelerated timelines for regulatory approvals. ***Anna will now provide an update on the status of our lead programs and our recent interactions with the FDA which have confirmed our clinical path forward for a potential BLA submission in 2020.***

Anna Wijatyk

Thank you, Garo, I am excited to be part of the Agenus team advancing such an innovative portfolio and delighted to give an update on the progress of our lead CTLA-4 and PD-1 programs.

As Garo mentioned, **we have treated over 130 patients with our CTLA-4 and PD-1 antibodies separately and in combinations**. We have published widely on the pharmacokinetic and pharmacodynamic profile of our agents. We have also demonstrated that our agents are clinically active. Just a few weeks ago, we provided the latest clinical update at ESMO.

As monotherapy, our PD-1 agent, AGEN2034, showed a clinical benefit of 68% in evaluable patients with metastatic and/or locally advanced solid tumors. These data also include confirmed responses in 3 out of 7 evaluable patients with refractory cervical cancer.

Agenus has long understood the criticality of anti-CTLA-4. Today there is growing evidence that the addition of CTLA-4 to PD-1 therapy improves response rates and durability of responses in several solid tumors.

Agenus is unique in being one of few companies with both anti-CTLA-4 and anti-PD-1 antibodies in its own portfolio along with robust data showing their clinical activity.

Ours is the most advanced clinical stage combination with registrational potential in patients with 2L cervical cancer. We endeavor to expand the response rates and durability of responses beyond anti-PD-1 alone in this setting.

Our combination trial has completed dose escalation. We have initiated the expansion phase in patients with cervical cancer; our global enrollment is actively underway.

We presented an early glimpse of our combination data at ESMO and reported disease control in 44% of patients. In a data update since ESMO, we have shown improved disease control. **In fact, in patients with refractory solid tumors, we see a clinical benefit in over 63% of patients with ovarian, breast, and soft tissue sarcomas. Our clinical results also include an objective durable response in a patient with ovarian cancer.**

I want to emphasize that the follow-up period for this study has been shorter than for our PD-1 monotherapy trial, and therefore, we expect these data to mature further with additional follow-up.

The particularly pronounced clinical benefit we have seen in gynecologic cancers has generated the interest of the Gynecologic Oncology Group (GOG). This catalyzed our recent engagement with the GOG, with whom we are now collaborating to drive accrual in our Agenus-sponsored CTLA-4 and PD-1 trials. This is a group that has had a terrific track record including the approval of topotecan and Avastin for patients with cervical cancer.

During our last call, my colleague Dr. Gupta explained that the FDA Oncology division has been progressive and has acted to promptly approve products that provide substantial clinical benefit with relatively small trials. CTLA-4 and PD-1 antibodies have been such programs, with accelerated approvals granted for these products in less than 4 years after FIH studies.

We recently met with the FDA to review our data and discuss our plans to BLA.

Through our collaborative discussions, **we confirmed that we are positioned to take advantage of accelerated pathways for approval with relatively small numbers of patients and surrogate or short-term endpoints in our trials. We anticipate filing for accelerated approval as early as 2020.**

In summary, our CTLA-4 and PD-1 programs are advancing in 3 active clinical trials designed to take advantage of accelerated pathways for rapid approval. These trials include:

- PD-1 monotherapy in patients with refractory cervical cancer;
- CTLA-4 plus PD-1 combination that we anticipate will further expand response rates and durability of response in the same cervical cancer setting, and
- CTLA-4 monotherapy in patients who are refractory to PD-1 – representing a significant clinical need.

I am delighted to be associated with a company with such an exciting pipeline of products in the clinic and soon to be in the clinic. I will now turn the call once again to Garo.

Garo Armen

Thank you, Anna.

There are 13,000 new cases of cervical cancer annually and 4,000 deaths in the US alone. Our initiatives to advance programs in 2L cervical cancer exemplify our commitment to provide access to effective agents where current treatment options have limitations. At the same time, these efforts represent important commercial opportunities for us. This year alone, aggregate commercial revenue for antibodies targeting PD-1 and CTLA-4 is expected to reach $15B. We have defined several development paths, including in 2L cervical cancer, where we can make a meaningful difference to patients while capturing a portion of this very large market.

Next, Christine Klaskin our VP of Finance, will provide financial highlights.

Christine Klaskin

Thank you, Garo.

As Garo mentioned earlier, we closed this quarter with a cash balance of $46M. At the end of 2017 our cash balance was $60M, and at the end of the second quarter our balance was $43 million. As you can see from these numbers, we continue to manage our cash prudently ending this third quarter as we projected, with a cash balance above that of the end of the second quarter.

For the third quarter ended September 30, 2018, we reported a net loss of $34 million or $0.29 per share compared to a net loss for same period in 2017 of $37 million, or $0.37 per share. In the third quarter, we recognized revenue of $13 million which includes a milestone achievement and non-cash royalties earned.
For the nine months ended September 30, 2018, we reported a net loss of $113 million or $1.04 per share compared to a net loss for the same period in 2017 of $86 million or $0.88 per share. The increased net loss reflects reduced revenue during 2018 due to an accelerated milestone received during 2017 from Incyte and the 2018 loss on early extinguishment of debt.

I will now turn the call over to Garo for his closing remarks.

Garo Armen

Thank you, Christine.

In closing,

Our key milestones over the next 12 months are,

1. Complete accrual of our CTLA-4 and PD-1 trials. These results are expected to support our path to BLA and enable us to commercially launch our CTLA-4 and PD-1 antibodies within the prescribed timeline for I-O antibodies of 4 years from first in man to registration.
2. Advance new discoveries to patients, including our 2 first-in-class bispecific antibodies and our next-generation CTLA-4.
3. Initiate a combination trial of our neoantigen vaccine with our CTLA-4 and PD-1 antibodies.
4. Close at least one of our ongoing partnership discussions.
5. With AgenTus, we expect to complete a private placement as well as partnership transactions. We are advancing our lead AgenTus cell therapy program into the clinic and are on track to file an IND within the next 12 months.

We continue to expand our communications effort through significant visibility at major oncology conferences, high profile publications, and through the publication of our newsletter. The newsletter is published every other Monday and summarizes key advances in our progress and highlights details related to our differentiated capabilities. Along with this, we have also increased our presence in social media. We have bolstered our communications efforts to showcase our rare and diverse pipeline with 4 different therapeutic classes. The perception of investors seeing us as a vaccine only company is changing. However, those of you who have followed us will know that Agenus transformed in the last 4 years to become a diverse I-O company with unique attributes. We take responsibility for educating investors and others going forward, and we anticipate that our enhanced efforts and our performance will provide the impetus to understand our company better and generate a greater following by serious investors.

Thank You!

Appendix 1:

Introduction and forward-looking statements: Jennifer Buell

Welcome to the Agenus' third quarter financial results conference call. Before we provide an update, I would like to remind you that this call will include forward looking statements, including statements regarding our clinical development plans and timelines, partnership opportunities and timelines, and our financial position. 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. Anna Wijatyk, Head of Clinical Development, Dr. Sunil Gupta, Head of Regulatory and Pharmacovigilance and Christine Klaskin, our Vice President of Finance.

During this call, Garo will provide a corporate update, Anna will summarize our clinical progress and path to BLA and Christine will provide a financial review. We will then open the call for questions.