agenus

Agenus (NASDAQ: AGEN) Q4 2018 Earnings Conference Call

March 14, 2019 8:30 AM ET

Introduction and Forward-Looking Statements in APPENDIX

Jennifer Buell

In 2018 our discovery efforts yielded six IND filings. We also concluded an important employing **collaboration with Gilead** which resulted in an upfront **cash infusion of $150 million followed by the receipt of another near-term milestone of $7.5 million** which we announced yesterday. We expect to achieve other near-term milestones this year which would trigger additional payments from Gilead and our other partners.

Regarding our plans to become a commercial company in the coming years, we have **advanced our lead CTLA-4 and PD-1 antibodies in two trials** designed to meet accelerated approval pathways by the U.S. FDA. **We ended the year with over $200 million of pro forma cash including the cash payment we received from Gilead earlier this year**. We also announced the launch of a product specific financing mechanism designed to provide funding for the expanded development, commercialization and distribution of our anti-PD-1 antibody AGEN2034. Garo will expand on these developments in just a bit.

Looking forward in 2019 we expect to continue on the momentum we have built during 2018. More specifically,

- We expect to file additional INDs for novel agents.
- We expect to commence clinical trials with several novel I-O agents that are designed to address mechanisms currently not addressed with available therapies.
- We expect to generate clinical data and we also expect additional partnership transactions.
- Most importantly, we expect to make substantial progress with our clinical trial enrollment in preparation for an FDA filing for product approval.

One of our marquee programs is our potentially best in class **next generation anti CTLA-4 molecule**. This is AGEN1181. AGEN1181 is an antibody with unique attributes, which, we believe, can be breakthrough I-O treatment for patients with cancer. In addition, AGEN1181 can potentially be a best-in-class combination agent to substantially expand the commercial potential of our PD-1 antibody.

I will now turn the call over to Garo to provide additional details on our accomplishments and our plans for 2019.

Garo Armen

Thank you, Jen and thank you all for joining us this morning. As Jen mentioned, we had a year of important advances. We continue to innovate and discover novel agents which have been the key catalysts for our internal development programs as well as our partnered programs. We have advanced our agents into and through the clinic. We are enrolling patients in our PD-1 and PD-1plus CTLA-4 trials designed for accelerated approval by the U.S. FDA.

We have reached important partnership milestones and received payments from our existing partners and very importantly, we have entered into a partnership with Gilead, which as Jen said resulted in a cash infusion of $150 million followed by an additional payment for a near term milestone which we announced yesterday.

In addition, we made **progress with our AgenTus cell therapy programs**. Presently we are **on track to file our first cell therapy IND** later this year. We also expect to complete our first round of financing for AgenTus and we are in early partnership discussions.

It is also important to note that one of our innovations, **QS-21** has been a key driver for the successful launch of **GSK, Shingrix vaccine, with its first-year revenue in 2018 exceeding $1 billion**. We have designed our pipeline of innovative and next-generation immuno-oncology agents to deliver substantial benefit to patients with cancer. Hence our strategy is to pursue smaller trials to achieve clinical proof of principle with high response rates and cures, specifically targeting patients who are not being effectively served by today's first-generation immuno-oncology agents.

What this means is that if we deliver on these objectives, clinical trials required for approval will enroll fewer patients and be quicker to achieve results. We're entering the period in the biopharmaceutical industry where success is being increasingly driven by speed and innovation. This is akin to the present-day drivers of the technology sector. **Our in-house capabilities from novel target discovery all the way to GMP manufacturing have made it possible for us to be able to file 13 INDs for Agenus discoveries of novel agents in about a three-year time span including some of the filings contemplated for this year.**

In a new world in which obsolescence rates may be rising, such capabilities to innovate in speedily advanced programs we believe will be key among the key requirements for success. Our speed and innovation have also been key to our ability to enter into important partnerships with Gilead, with Incyte, with Merck, and with GSK. We expect additional partnership transactions to be an important part of our strategy going forward. However, given the productivity of our discovery engine, we also expect our pipeline of innovation to be driving our own commercial ambitions and strategy.

Our growth portfolio of antibodies, vaccines and cell therapy provide us with the ability to derive optimal combination treatments for patients. In our experience, we know that

cancer is a very complex disease and a one size fits all solutions have not been and will not work. Therefore, our strategy has been to design and use all available tools in our portfolio in our efforts to conquer cancer.

I will now summarize some of the specifics of our 2018 accomplishments.

- We ended 2018 with a cash balance of $53 million subsequent to which we received $150 million from the Gilead transaction. And we announced another $7.5 million in payments from a milestone we achieved a few days ago.

- Data from our most advanced clinical trials involving CTLA-4 and PD-1 continue to demonstrate clinical benefit in the majority of patients treated.

- We confirmed with the FDA that our lead clinical trials are designed for accelerated path to our first BLA filing. We will expand our market opportunity for PD-1 by pursuing expanded cancer indications using combination strategies with our own internal immuno-oncology molecules.

- We advanced our best-in-class molecule with IND filings, these molecules include our next generation CTLA-4 which is AGEN1181 and first-in-class bispecific molecule AGEN1223, both of which I will review in more detail in a bit.

Recently, we disclosed our plans to launch a novel financing mechanism which we call **BEST**. **This offering is being done under Reg D in compliance with the SEC rules. The purpose of BEST is to provide project specific financing. We're planning to deploy the proceeds from BEST later on this year and early next year to expand the development and commercial upside of our PD-1 antibody, AGEN2034 beyond our cervical cancer programs.**

We have the ability to use our first or second generation CTLA-4 antibodies in combination with our PD-1 antibody. Thus, enhancing our competitive advantage and enhancing the market potential of our own PD-1.

Now I will provide the details on our partnerships with Gilead and its implications for us and perhaps for them as well. The Gilead transaction marked an important strategic and financial milestone for us. Gilead's commitment to immune-oncology and their choice of Agenus for a collaboration speaks to the capabilities we have built over the past years. We believe that having Gilead as a partner to advance several of our best-in-class molecules will help accelerate their development and potentially bring breakthrough therapies to patients faster.

As I mentioned, our collaboration with Gilead provided us with an upfront cash of $150 million and potential milestone payments of an additional $1.7 billion. Yesterday's announcement of an additional $7.5 million in milestone payments represents the first of several near-term milestones we expect to receive. Through our collaboration, Gilead received exclusive rights to AGEN1423, a first-in-class bispecific antibody designed to block two powerful resistance mechanisms in the tumor microenvironment. The IND for this molecule was recently accepted by the FDA which means it can now proceed to clinic.

Gilead also received the exclusive option to license AGEN1223, a first-in-class bispecific design to eliminate regulatory T cells from tumor microenvironment and AGEN2373, a CD137 agonist. Gilead may acquire rights to these two programs following early proof of mechanism demonstration with an options figure of $50 million for each program. In our existing partnerships with Incyte and Merck, we received several milestone payments last year for the clinical advancement of LAG-3, TIM-3, ILT4. These molecules were discovered at Agenus and continue to advance successfully.

Last year we met with the FDA to discuss the approval path for our lead CTLA-4 and PD-1 programs. We concluded that we are positioned for accelerated pathways for approval with relatively small numbers of patients and surrogate short-term endpoints. **We anticipate filing for accelerated approval by as early as 2020. To that end our accrual in these trials for both PD-1 monotherapy and combination studies with our CTLA-4 antibody has been steadily progressing and tracking to be complete by approximately year end.**

It is heartening to see the benefits for our CTLA-4 and PD-1 antibody in our trialed patients in several different tumor types are showing responses including some with long lasting durable and even potentially curable responses.

Finally, as Jen mentioned at the opening of the call, while there are more than a dozen active clinical trials with first generation molecules discovered at Agenus, our next generation pipeline comprised of first and best-in-class molecules is now entering the clinic. These include our enhanced CTLA-4 molecule AGEN1181 and our first-in-class bispecific molecule AGEN1223.

For the purposes of this call, I will focus on **AGEN1181** with just a few points. We made a discovery that revealed we could significantly enhance functionality and antitumor immunity with antibody engineering. Our experts went to work and engineered this enhancement into AGEN1181, our next generation anti CTLA-4 antibody. Based on preclinical data, we believe this molecule represents an important breakthrough in the field. Based on this molecule shows that it has enhanced immune activation and tumor fighting activities. It was designed to specifically boost cancer killing immune cells and very importantly, to defeat cells that block the immune system's ability to kill cancer.

AGEN1181 has the potential to be effective in a wider patient population than the first-generation molecules. And importantly, AGEN1181 may significantly expand the commercial potential of our own anti PD-1 antibody when used in combination. This could differentiate the Agenus I-O portfolio from others, including some of our leading competitors. In fact, AGEN1181 has generated considerable excitement among key opinion leaders and we expect to dose our first patient in the next several weeks.

Now, I will turn the call over to Christine to provide financial highlights and I will be back to sum up the call.

Christine Klaskin

Thank you, Garo. As Garo mentioned, we closed 2018 with a cash balance of $53 million followed by the $150 million received from Gilead earlier this year, thus heading into 2019 with approximately $200 million. At the end of 2017, our cash balance was $60 million and at the end of the third quarter of 2018 it was $46 million. For the fourth quarter ended December 31, 2018 we reported a net loss of $49 million or $0.40 per share compared to the net loss for the same period in 2017 of $35 million or $0.35 per share.

In the fourth quarter, we recognized revenue of $6.5 million which includes non-cash royalties earned. For the year ended December 31, 2018 we reported a net loss of a $162 million or a $1.44 per share compared to a net loss for the year ended 2017 of $121 million or a $1.23 per share. The increased net loss reflects reduced revenue during 2018 due to an accelerated milestone received during 2017 from Incyte, the 2018 loss on our early extinguishment of debt and increased non-cash interest on our liability related to the sale of future royalties.

I'll now turn the call back to Garo for his closing remarks.

Garo Armen

Thank you, Christine. In closing, we expect the following key catalysts for 2019.

- Complete accrual of our PD-1 and CTLA-4 lead programs by year end to deliver our BLA as early as 2020.
- Expand the commercial market access of our lead molecule in indications beyond cervical cancer fueled by our best mediated capital initiatives.
- Initiate first-in-class combinations with our next generation CTLA-4 our proprietary PD-1 molecule.
- Advance additional breakthrough discoveries and file at least three additional INDs this year.
- Advance our next generation best-in-class molecules into the clinic including 1181 and a selective Treg depleting by specific AGEN1223.
- Advance our cell therapy program and have AgenTus funded independently in anticipation of our public offering later this year or next.

Lastly, we continue with our enhanced communication strategy through our own participation at major oncology conferences with high profile publications and through the publication of our Agenus Newsletter. Agenus News is published every other Monday and reports on Agenus advances as well as provides the necessary education to help enhance the reader's understanding of this exciting field. As you are aware, we have also increased and continue to increase our presence on social media. We are committed to

our mission of delivering for our patients and for all our stakeholders. Our efforts and staying power over the last 25 years speaks to this commitment.

We thank you for your staying the course and joining us on this journey.

Appendix

Introduction and forward-looking statements: Jennifer Buell

Thank you, operator, and good morning. Before market opened today, Agenus issued a press release to provide a corporate update and financial results for the fourth quarter and full-year ending December 31, 2018.

Today's call is being webcast and will be available on our website for replay. 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 remainder, 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 and Christine Klaskin, our Vice President of Finance.

Today we will review our 2018 accomplishments and outline our plans for 2019. We have set ambitious goals for 2018. We accomplished our key objectives, and, in the process, we made important contributions to science, to patients and for our partners.