Q1 2018 Earnings Conference Call

May 7, 2018 11:00 AM ET

Introduction and Forward Looking Statements in APPENDIX I

Garo Armen

Good morning and thank you for joining us for our quarterly update.

We have had several very productive years including the substantial progress we have made in the past several months. These have been with our clinical programs as well as the substantial number of new discoveries that are about to enter the clinic. I will speak about these in more detail but in summary:

- We made a conscious decision several years ago to pursue two antibodies that have become the backbone of I-O cancer treatment today; these are antibodies that target PD-1 and CTLA-4. We have advanced them into the clinic individually and in combinations. So far, we have treated more than 100 patients and observed a number of responses which will be presented at ASCO this year
- We believe these backbone molecules are critically important and we plan on pursuing combinations of them, including with one another to achieve regulatory approvals. We also believe they will play an important role in combinations with our portfolio of novel antibodies, neoantigen vaccines and cell therapies.

How have we accomplished what we have thus far? Innovation and speed are the basis of our I-O business model with 5 INDs filed over the past 18 months, 6 INDs on track to be filed this year and 2 additional INDs planned in the 1H of next year. Our IND roster for this year includes bispecific antibodies that modify the tumor microenvironment in order to make the tumor more susceptible to immune attack. Tumor microenvironment modifiers are amongst the most desirable NextGen I-O approaches. We have at least two antibodies with uniquely desirable properties. In addition to the INDs I mentioned, we expect our cell therapy company AgenTus to also file its first IND for cell therapy next year.

Next, I will provide a partnership update. While I don't have an announceable development yet, discussions are advancing with various companies. These discussions range from several product-licensing deals to potentially much larger collaborations. Our expectations are to bring them to closure within the next 2-3 months.

With respect to progress on our existing partnership programs with Incyte and Merck, all are advancing and we expect additional milestone payments including some that will be payable this year.

Also, our QS-21 Stimulant has received increased interest as the most potent adjuvant available today. QS-21 is also an enabling component of our neoantigen cancer vaccine program that will be entering the clinic in combination with our own checkpoint antibodies soon.

As you are aware, QS-21 is a key component in the world's most efficacious shingles vaccine, SHINGRIX (with over 97% efficacy). SHINGRIX received approval at the end of last year and this year's revenue estimates have recently been revised to 3 times what they were earlier in the year. GSK's first full year revenues of Shingrix is expected to top $600M this year which is about the same as where Merck's Zostavax was tracking last year---after 15 years on the market. Our royalty transaction announced earlier this year has additional revenue milestone payments totaling $40M that are due to Agenus if specific revenue milestones are achieved.

Now, I will provide you with an update on our clinical and research programs:

- Last year we launched combination clinical trials of our proprietary CTLA-4 targeting antibody (AGEN1884) with our PD-1 targeting antibody (AGEN2034).
- **To date, we have treated more than 100 patients with our CTLA-4 and PD-1 antibodies separately and in combinations**. We presented compelling data on the pharmacodynamic activity of our anti-CTLA-4 and anti-PD-1 antibodies at AACR; at ASCO this year there will be clinical data presented on our CTLA-4 and PD-1.
- In our trials with both compounds we have seen partial and complete responses in some patients with advanced cancers. **We plan to develop, register, and launch our CTLA-4 and PD-1 antibodies**.

- This year, aggregate revenues, for antibodies targeting CTLA-4 and PD-1, are expected to be $15B. Hence, we believe that despite the current players, our antibodies represent a significant commercial opportunity for Agenus.
- Very recently, we shifted our strategy for first approval to cervical cancer from lung cancer. We will be developing the combination of our own two antibodies for cervical cancer. The reasons for our strategy shift include increasingly crowded lung cancer opportunities and Merck's recent data with Keytruda in combination with chemotherapy in 1L NSCLC that has set a higher bar for any future approvals.
- PD-1 has also emerged as an important driver of improved efficacy when used in combination with standard of care, chemo, or radiation. We are opportunistically exploring such combinations with our own PD-1 and CTLA-4 antibodies.
- **We continue with our commercial launch readiness efforts**. We have supplied our clinical programs and have successfully manufactured commercial grade CTLA-4 and PD-1 antibodies. We acquired our California manufacturing facility 3 years ago and it has proven to provide us with independent, speedy and cost-efficient manufacturing capabilities today.
- **This year, we are also planning triple combination studies of our proprietary vaccine in combination with both our CTLA-4 and PD-1**.

So far, I have discussed our antibodies that are in the clinic, and touched on our future clinical and product registration plans. I will now shift to our pipeline, that includes a slate of exciting I-O agents expected to enter the clinic soon.

- **Our novel pipeline is advancing.** As I mentioned earlier, we are on track to file 6 INDs this year and additional 2 INDs in the first half of next year. Amongst them is our NextGen CTLA-4. Our scientists have discovered a novel mechanism that enhances the function of CTLA-4. We expect these findings to be published shortly. With this feature, our NextGen CTLA-4 is designed to deplete Tregs and improve T cell priming. We, and an increasing number of other experts in the field, believe that depleting Tregs is critical to overcoming the limitations of current I-O treatments and successfully depleting Tregs could expand the market for current treatments significantly.

- **We are also planning IND filings for our bispecific agents this year**. These AGENUS bispecific antibodies are designed to selectively deplete intratumoral regulatory T cells as well as condition the tumor microenvironment. We believe these compounds address tumor escape mechanisms in solid tumors as well as hematologic tumors, such as B cell lymphoma.
- **Cell therapy has shown life-saving potential for patients and has created significant value for shareholders.** However, current approaches have limitations that are well-known; including manufacturing and logistical challenges, and very high costs of production.
- We believe, AgenTus, our cell therapy company has the technologies and capabilities to potentially address these limitations. **Last week, Dr. Andy Hurwitz presented at PEGS Summit in Boston, MA**. Specifically, our proprietary platform has generated high quality T Cell Receptor (TCR) libraries designed to target solid tumors. In addition, our allogeneic cell format is designed to address manufacturing and logistical challenges, scalability, as well as costs.
- We also have a very exciting targeting mechanism for both vaccines and cell therapy. It is our proprietary library of phosphorylated targets designed to optimize efficacy with improved safety; potentially with an off the shelf targeting mechanism.
- One of the most compelling advantages for our Cell Therapy business includes access to de novo discovery platforms, core capabilities in bioinformatics, structural and computational biology, molecular and cell biology, and importantly, a pipeline of validated checkpoint antibodies and bi-specific tumor microenvironment conditioning agents to rapidly develop first-in-class combinations. All of these are capabilities we possess in-house and give us the ability to innovate and advance programs rapidly.

    - In summary, given our long history in the field of Cancer Immunotherapy and the key acquisitions we have made in the past 4 years, along with our extraordinarily talented team we have transformed Agenus into a company with one of the most exciting and extensive pipelines in the field. Also, importantly, our capabilities have generated our exciting pipeline and we are now advancing next generation opportunities beyond those slated to enter the clinic soon.

- As I alluded to earlier, we believe, and other experts believe, that new mechanisms, such as the ability to modify the tumor microenvironment, will be the drivers of next generation successful treatments and cures for cancer patients. We believe we have amongst the best product pipeline to accomplish this. In addition, our ability to combine these molecules with first generation I-O antibodies, our neoantigen vaccines, cell therapies, and adjuvants, provide us unique advantages in I-O field, which is rare.
- In fact, knowledge of these capabilities, and our pipeline, have been the drivers behind the partnership interest from companies we are in discussions with today.

Thank you for your time and interest in our company. We look forward to your questions at the conclusion of our discussion.

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

Christine Klaskin –

Cash and cash equivalents were $52.3 million at March 31, 2018 compared to $60.2 at December 31, 2017.

For the first quarter ended March 31, 2018, we reported research and development expenses of $29.4 million as compared to $32.6 million for the same period in 2017. Our net loss for the three months ended March 31, 2018 was $54.3 million or $0.53 per share compared to a net loss of $17.1 million or $0.18 per share for the first three months of 2017.

This increase in net loss in the first 3 months of this year was due to several onetime items as well as noncash charges.

These items, in aggregate, effected this year's quarter unfavorably and prior year's quarter favorably. In the first quarter of this year, we recorded a loss on the extinguishment of our debt and had increased non-cash charges. Whereas, during last year's 1st quarter, we recorded a large accelerated milestone payment received from Incyte.

Notwithstanding these items, our total R&D and G&A expenses were lower for the first quarter of this year compared to the first quarter of 2017.

I will now turn the call back to Garo

Thank you, Christine. Now, I'd like to turn it back to the operator to begin questions.

APPENDIX I

Introduction and forward looking statements: Jennifer Buell

Thank you. Welcome to the Agenus' first quarter financial results conference call. Before I continue, I would like to remind you that this conference call will contain forward-looking statements, including without limitation statements regarding the Company's development and commercialization plans and timelines.

These forward-looking statements are subject to risks and uncertainties disclosed in more detail in our most recent filings with the U.S. Securities and Exchange Commission, and that could cause actual results to differ materially. These statements speak only as of the date of this call and Agenus undertakes no obligation to update or revise these statements, except to the extent required by law.

All forward-looking statements are expressly qualified in their entirety by this cautionary statement. When evaluating Agenus' business and securities, investors should give careful consideration to these risks and uncertainties. As a reminder, this call is being recorded for audio broadcast.

Joining me today are Dr. Garo Armen, Chairman and Chief Executive Officer and Christine Klaskin, our Vice President of Finance.

During this call, Garo will provide a corporate update and Christine will provide a financial review. We will then open the call for questions.

About Agenus

Agenus is a clinical-stage immuno-oncology company focused on the discovery and development of therapies that engage the body's immune system to fight cancer. The Company's vision is to expand the patient populations benefiting from cancer immunotherapy by pursuing combination approaches that leverage a broad repertoire of antibody therapeutics, proprietary cancer vaccine platforms, and adoptive cell therapies (through its AgenTus Therapeutics subsidiary). The Company is equipped with a suite of antibody discovery platforms and a state-of-the-art GMP manufacturing facility with the capacity to support early phase clinical programs. Agenus is headquartered in Lexington, MA. For more information, please visit www.agenusbio.com; information that may be important to investors will be routinely posted on our website.

About AgenTus Therapeutics, Inc.

AgenTus Therapeutics, a subsidiary of Agenus, is a preclinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of breakthrough "living drugs" to advance potential cures for cancer patients. AgenTus employs naturally-derived and engineered receptors, specifically T cell receptors (TCRs) and Chimeric Antigen Receptors (CARs), designed to supercharge human immune effector cells to seek and destroy cancer. AgenTus also aims to advance adoptive cell therapy formats which would enable off-the-shelf living drugs. AgenTus has locations in Lexington, MA and Cambridge, UK. For more information, please visit www.agentustherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding Agenus' development plans, timelines, and anticipated milestones. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recent Quarterly Report on Form 10-Q or Annual Report on Form 10-K filed with the Securities and Exchange Commission. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.