Q4 2019 Sesen Bio Inc Earnings Call

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Eleven Biotherapeutics March 2020 Business Update Conference call. (Operator Instructions) I would now like to hand the conference over to your speaker today, Erin Clark, VP of Corporate Strategy & Investor Relations. Thank you, and please go ahead, ma'am.

Erin Clark, Sesen Bio, Inc. - VP of Corporate Strategy & IR

Thank you, and good morning, everyone. Welcome to the Sesen Bio March 2020 Update Call to discuss our fourth quarter and full year 2019 financial results as well as an update on the regulatory progress and commercial opportunity for Vicinium.

Joining me on today's call are Dr. Thomas Cannell, President and Chief Executive Officer; Dr. Chad Myskiw, Senior Director of Strategic Planning, CMC; and Monica Forbes, our Chief Financial Officer.

Earlier this morning, we issued a press release outlining some of the highlights that will be covered on the call today. The press release and the slides to which we will refer are available in the Investors section of the company's website at sesenbio.com. I would like to remind you that today's discussion will include forward-looking statements related to the company's current plans and expectations, which are subject to risks and uncertainties. Actual results may differ materially due to various factors, including those described in Sesen Bio's most recent annual report on Form 10-K and other SEC filings. These statements represent Sesen Bio's views as of this call and should not be relied upon as of any future date. Sesen Bio undertakes no obligation to publicly update these forward-looking statements.

The company's annual report on Form 10-K will be filed later today with a risk factor describing how public health outbreaks or epidemics, including the recent COVID-19 coronavirus pandemic, could adversely affect our business, including, but not limited to, our ability to commercialize and raise capital. The company has not yet experienced any business disruptions as a result of the coronavirus. With that, I'll turn the call over to Tom.

Thomas R. Cannell, Sesen Bio, Inc. - President, CEO & Director

Thanks, Erin, and thanks, everyone, for joining us this morning. Please turn to Slide 3, which shows you an outline of our story for today's call. First, there is a huge unmet need in bladder cancer. Not only does bladder cancer have a tremendously high disease burden, but it is also the most expensive cancer to treat in the United States, with a significant impact from both radical cystectomy and disease progression. Second, we believe Vicinium has a unique dual mechanism of action, which helps to explain both the favorable efficacy and favorable safety profile. Third, recent market research results, which we will share later in the call, support what we believe to be a significant market opportunity. And finally, we made tremendous regulatory progress in 2019, and based on our most recent meeting with the FDA, we feel like we have a clear regulatory path forward to complete our BLA submission this year.

Now please turn to Slide 4, which shows the journey for a patient that has been diagnosed with non-muscle invasive bladder cancer. Each year, roughly 80,000 patients are diagnosed as having bladder cancer. And as you can see on the slide, after the initial diagnosis, patients often face recurrence and progression, which drives the projected $6 billion burden on payers this year in the U.S. alone. It is important to note that the patient goes through the majority of this journey with the urologists. Patients are usually referred to a community-based urologist early in the diagnosis process. That same urologist takes them through multiple BCG treatments and continues to see the patient every 3 months for diagnostic tests, which means, often by the time BCG has failed, that physician has been treating patients

for years. So it is easy to see why the urologists would be reluctant to refer the patient to a surgeon or a medical oncologist, if they feel they are able to manage ongoing treatment with an intravesical medicine themselves.

Please turn to Slide 5. Based on preclinical studies, we believe Vicinium has a unique and compelling dual mechanism of action. The first mechanism is through direct cell killing. Vicinium selectively targets and kills bladder cancer cells, while generally leaving healthy cells alone. We believe that the favorable safety and tolerability profile of Vicinium is due to the selective targeting of cancer cells. The fact that Vicinium generally leaves healthy cells alone, differentiates it from most available agents, including BCG and chemotherapeutic agents such as VALSTAR, which indiscriminately attack both cancer cells and healthy tissue.

But even more interesting is what we believe occurs with the second mechanism. Because Vicinium causes immunogenic cell death, it appears that DAMPs and neoantigens are released. This results in T cell activation and proliferation, and T cells have been able to recognize cancer cell neoantigens and attack the tumor. Therefore, the tumor may be killed through both Vicinium and an antitumor adaptive immune response, which we believe may explain the strong and durable efficacy results we are seeing in our clinical data. These 2 mechanisms are very familiar to physicians, and I can tell you that both key opinion leaders and high-prescribing urologists tell us that they think this dual mechanism of action is unique and important in terms of making a treatment choice.

Please turn to Slide 6. As you can see, we believe Vicinium has a differentiated clinical profile with a strong benefit risk rationale. Looking at the efficacy data, you can see the initial patient response at 3 months is very positive for patients with carcinoma in situ and those with papillary disease. You can also see that this appears to be a durable antitumor response in both patient types. Perhaps our most impressive data is related to our time to cystectomy, which not only has a clinical benefit which physicians are drawn to, it has a huge quality of life benefit for patients and a very important ability to reduce health care costs for payers.

In our Phase III data, 76% of patients were able to avoid radical cystectomy for at least 3 years, and we're not aware of any competitive data that comes close to that.

Turning to safety and tolerability, we believe Vicinium is highly differentiated versus available and pipeline agents. Vicinium is administered intravesicaly, which means the bladder lining itself protects the body from systemic exposure. This is one of the reasons that the FDA and prescribing urologists prefer local intravesical medicines like Vicinium over systemic intravenous therapies. Most adverse events are mild and transient, and there appear to be no age or dose-related increase in adverse events.

In fact, we hear from investigators that sometimes patients who are being treated with Vicinium think they're receiving placebo because they are tolerating the treatment so much better than they tolerated previous therapies.

Turning to Slide 7. As most of you know, Keytruda was approved for non-muscle invasive bladder cancer by the FDA in January of this year. From a regulatory perspective, we think this is a very good sign for Vicinium and improves our regulatory probability of success given the similar efficacy profiles for the 2 products. It then begs the question around the commercial opportunity and what treatment choices we would expect physicians to make between the new branded agents. We know there are approximately 1,500 urologists who treat about 75% of non-muscle invasive bladder cancer patients. We conducted 3-minute interviews with a subset of 34 urologists from this group. These physicians were randomly selected, and physicians who participated in our clinical trials were excluded to avoid bias.

Turning to Slide 8. During the interviews, we shared the latest profile for Keytruda based on their FDA advisory committee briefing book and their updated product label, relative to the latest profile for Vicinium based on the data we submitted to the FDA last December as part of our BLA submission. First, you can see the 2 products have very different mechanisms of action. In addition, Keytruda has a more limited indication than we are projecting for Vicinium, is given intravenously and is generally administered by a medical oncologist.

Then turn to the clinical data on Slide 9, you can see the similar efficacy results for Vicinium and Keytruda, the impressive time to cystectomy results that are only available for Vicinium and the more favorable safety profile for Vicinium. And just a reminder that these data are for market research purposes only and not intended for any promotional purpose.

So turning to Slide 10, we asked physicians to rank the profiles of Vicinium and Keytruda on a scale of 1 to 10 for a variety of attributes. You can see that physicians believe the 2 products profiles have comparable efficacy. They consider Vicinium to have a better safety profile. They view Vicinium as being much easier to integrate into their current treatment practices, and they indicated a greater overall interest in Vicinium relative to Keytruda.

Turning to Slide 11. When physicians are given the choice of the new branded agents or radical cystectomy, they choose the branded agents about 80% of the time. And then when you ask them to choose between the Vicinium profile and the Keytruda profile for their high-risk non-muscle invasive bladder cancer patients, they choose Vicinium over Keytruda, roughly 80% of the time.

On Slide 12, we asked physicians for the reasons they generally prefer Vicinium over Keytruda, and they offered 4 explanations. First, from a patient perspective, they prefer to maintain ownership of the patient journey rather than referring to the medical oncologist for Keytruda or the surgeon for radical cystectomy. There is a lot of loyalty between bladder cancer patients and the urologists, and this is an important factor. Second, they like the favorable profile of Vicinium, which demonstrates comparable efficacy to Keytruda with a better safety profile. In addition, urologists are compelled by the strong time to cystectomy data for Vicinium. Third, they mentioned the ease of integration, given that the product profile of Vicinium has the same treatment profile as BCG. For patients, this means they can drive to the same treatment center, talk to the same urologists and the same nurse, which create continuity of care, which is important to patients and physicians. Finally, physicians talk about negative psychologic effects of referring patients to a medical oncologist. Patients who are referred to medical oncologists have to go to a new building, often a large medical academic center, and these patients feel that going to the intravenous treatment center means they will be treated as a patient with a serious disease, which can result in a more difficult patient experience. So to summarize, we are very pleased with the way high-prescribing urologists reacted to the profile of Vicinium relative to the profile of Keytruda. These results are highly consistent with what we have been hearing from key opinion leaders, and we believe this indicates the potential for a successful launch with rapid uptake and growth of Vicinium.

Turning to Slide 13. I mentioned that 1,500 urologists write the bulk of the prescriptions in this category, which will allow us to have a very focused and efficient commercial model. After conducting 5 rounds of market research with urologists, we feel like we know the customer well and estimate that we'll deploy roughly 40 to 50 sales representatives shortly before launch. We plan to utilize a contract sales organization, which we hope to select by the end of this year. We have also learned the importance of caregivers in the decision-making process, most of whom are women, and we have clear plans for digital and social strategies that will not only help to inform and empower these important caregivers but will also be an efficient and scalable commercial approach.

On Slide 14, we have also conducted multiple rounds of payer research and spoken to over 20 payers, both commercial and Medicare. We've been pleasantly surprised by the most common pricing benchmarks and the limited restrictions to reimbursement that seem likely.

Based on our research to date, we believe that there is potential for significant reimbursement and advocacy by payers for the appropriate use of Vicinium.

Overall, we are pleased with the progress in our commercial planning and the understanding of customers we have gained to date. We believe we have an insightful commercial plan that will help us realize the full market opportunity for Vicinium. And as I have mentioned previously, the commercial spend will be carefully stage gated and triggered by events such as the FDA accepting our BLA and a successful ADCOM, if one is required.

At this time, I'd like to hand the call over to Dr. Chad Myskiw for a review of our regulatory process and path forward.

Chad Myskiw, Sesen Bio, Inc. - Senior Director of Strategic Planning

Thank you, Tom. Turning to our regulatory update on Slide 15. We made incredible progress in 2019, including completing all the FDA meetings required to initiate our BLA submission. In the first half of the year, we aligned with the FDA on demonstrating analytical comparability between our clinical and commercial drug supply. This was our desired outcome as it meant we would not have to run an additional clinical trial to demonstrate comparability as can be required with a change in the site of manufacturing.

In first half of 2019, we also completed our clinical pre-BLA meeting in which we reached agreement with the FDA that our 12-month clinical data was sufficient to support a filing and to move forward under the accelerated approval and rolling review programs.

In the second half of 2019, in support of accelerated approval, we discussed the confirmatory trial with the FDA, and we plan to enroll patients who have received less than adequate BCG, which creates the opportunity for future label expansion in patients earlier in the treatment paradigm. Lastly, late in the year, we completed our CMC pre-BLA meeting, where we received FDA feedback on the requirements for Module 3 of the BLA, which details CMC. These activities culminated in the initiation of our Vicinium BLA submission to FDA under rolling review on December 6 of last year. So this means that all of our clinical and nonclinical data have been submitted to and are under review by the FDA. We now have to complete Module 3 and the related manufacturing activities to finalize the BLA submission.

Turning to Slide 16. We've detailed out a timeline of the next year of critical CMC activities, and how they relate to the completion of our BLA submission and potential approval date. As you know, we manufactured Vicinium at our facility in Canada for clinical trials, but this site would not be able to provide enough supply to meet the significant global demand in non-muscle invasive bladder cancer. Also, this therapeutic space has been plagued by drug supply shortages, which reinforces the need to have reliable expert manufacturing capabilities at scale. As such, we made the decision to identify world-class CMOs with the necessary production capacity, regulatory experience and track record. So we've now partnered with Fuji for bulk drug substance production and Baxter for drug product fill and finish. As is typically required by FDA for companies who are changing their site of manufacturing, we need to

complete 3 consecutive process performance qualifications, or PPQ runs, at Fuji and Baxter to demonstrate analytical comparability between clinical and commercial drug supply.

We will also be collecting the long-term stability data required for shelf life dating of Vicinium for commercial use, not only from PPQ runs, but from the previously completed commercial scale GMP runs executed at both CMOs.

We expect to complete all these CMC activities, and finalize the BLA submission in the second half of 2020. Working forward from that date, we anticipate an ODAC meeting and potential approval in the first half of 2021. With that, I'll turn the call over to Monica.

Monica Forbes, Sesen Bio, Inc. - CFO

Thanks, Chad. Please turn to Slide 17. We finished 2019 with approximately $48 million in cash and cash equivalents, which we believe is sufficient to fund our strategic priorities into 2021. As we noted on our last call, our resources are focused on completing the VISTA trial, finishing the regulatory activities required to complete our BLA submission this year, including a successful tech transfer, and limited prelaunch commercial spend for the U.S. We ended the year with 106.8 million shares of common stock outstanding or $136 million on a fully diluted basis. And importantly, the company carries no debt. With that, I will turn the call back to Tom. Tom?

Thomas R. Cannell, Sesen Bio, Inc. - President, CEO & Director

Thanks, Monica. Please turn to Slide 18. To summarize, there is a huge unmet need in non-muscle invasive bladder cancer, and we believe the strong advocacy of stakeholders will help us gain approval and have a successful commercial launch. Vicinium has a highly differentiated product mechanism of action and clinical profile, and the positive market research results actually exceeded our expectations. We believe there is a sizable commercial opportunity, and more importantly, a significant opportunity to save and improve the lives of many patients. And finally, we are confident in the regulatory path forward.

With that, we'll open up the line to take your questions. Operator?

QUESTIONS AND ANSWERS

Answer – Operator: (Operator Instructions) Our first question comes from the line of John Newman with Canaccord.

Analyst: John Lawrence Newman, Canaccord Genuity Corp., Research Division - Principal & Senior Healthcare Analyst

Question – John Lawrence Newman: Tom, I just had 2 questions this morning. The first one is, I'm wondering if you could talk about how the Keytruda data that were utilized for approval in non-muscle invasive bladder cancer were different in the United States versus outside the United States? I think when I was looking through the data, I noticed that, especially in the efficacy, that was a little bit different. I wondered if you could talk a bit about that?

Answer – Thomas R. Cannell: Yes, great. Thanks, John. So if you look at the briefing book for the FDA advisory committee meeting that was held in December of 2019, there was a significant disparity between the Keytruda overall data where they saw overall a 41% complete response rate, and then the data in the U.S., where they saw roughly a 31% response rate. I believe there were somewhere between 35 and 40 patients in the U.S. arm. They were actually asked that question of the ADCOM, and Merck didn't have an answer at that time, they had no comment. The only thing we can possibly interpret from the data is in the U.S., it's often the case that there's much more BCG before they get to the second-line agents. And certainly, as you know, we've seen with our own data that we're even more efficacious in patients that have less exposure to BCG. So in any case, even with the weaker U.S. date of the FDA, the ADCOM had a positive vote and the FDA approved it. But we do think a strength of our study is that our U.S. arm had a 40% complete response rate, which was almost identical to our global numbers. So we feel that we have even, in some ways, a stronger position in terms of the comparative efficacy versus Keytruda. Does that answer your question, John?

Question – John Lawrence Newman: Yes. And I just had 1 additional question regarding the manufacturing and the analytical comparability steps for Vicinium. Could you just walk us through the stability data that the agency will be looking for in terms of the filing there?

Answer – Thomas R. Cannell: Yes. I'll start, and then Dr. Chad Myskiw is much more of an expert. But you can -- if you go to Slide 60 on our backups, we tried to kind of just give everyone a sense of the key things that the agency will look for. And these are actually global standardized set of benchmarks for analytical comparability. So first of all, there's the analytical release testing. Second of all, biophysical characterization, looking -- which is looking at the structural characteristics of the protein. Then third of all, there's forced degradation studies, so that they kind of -- they look at stress conditions like temperature extremes. And then finally, the stability studies, which are, they look at the long-term storage conditions to look at the stability of the protein. So at a high level, those are what the agency will

look for, consistency between the clinical supply we used in Phase II and Phase III that, as Chad mentioned, was manufactured at our Canada site versus the commercial supply that's being manufactured by Fuji and Baxter. Let me just stop and see. Chad, anything you want to add to that?

Answer – Chad Myskiw: Yes, sure, John. So the one thing that the FDA said at our FDA meeting as well was that if we can demonstrate analytical comparability, which we expect to be able to do, that we can leverage historical stability studies from our clinical trial. So once we demonstrate comparability, we had a 4-year shelf life for Vicinium in clinical trials, and so we expect to be able to leverage that. What we will do is simply provide all of our stability data to the FDA. We've completed commercial scale GMP runs at each of our CMOs last year and the blocks are also on stability. And so we'll be submitting all that data and as well as the PPQ stability data to the FDA for their determination.

Answer – Operator: And our next question comes from the line of Chris Howerton with Jefferies.

Analyst: Christopher Lawrence Howerton, Jefferies LLC, Research Division - Equity Analyst

Question – Christopher Lawrence Howerton: Great. I guess, for me, I just wanted to find out what if any modifications you're considering with respect to the pandemic and the CMC operations that you have? So that's 1 question. And another question that I have is just kind of what the status is of the confirmatory trial and when that might get started?

Answer – Thomas R. Cannell: Yes, great. Thanks, Chris. That's 2 great questions. So first of all, if we could just talk a minute more about the impact of COVID-19. And Erin made a quick comment at the start, and we do talk about a little on our 10-K that will be released. But I mean, obviously, the first thing we're thinking about is just the health and well-being of our employees, the surrounding communities, patients and health care professionals. We're taking that very responsibly, very seriously. We are executing risk mitigation strategies. And as Erin mentioned, at this time, the company has not yet experienced any business disruptions. Probably for a company like ours, the 3 biggest risks we think about are the clinical trial risks, the regulatory process risk and then the manufacturing risk, which was kind of the bulk of your question. But I want to start with the other 2. So regarding clinical trial, we do have the benefit right now that all of the patients have gone through the 12-month mark. We did our last data cut in May of last year, and our clinical and nonclinical data have been submitted to the FDA. So the good news is there's no worry about for us in terms of patient enrollment, in terms of getting our drug approved. The second thing has to do with regulatory. A lot of questions about whether it might slow down the process by not being able to meet with the agency face-to-face. But so luckily for us, as Chad presented, we had 4 face-to-face meetings last year, 2 on the clinical program, 2 on CMC. We don't foresee any additional face-to-face meetings with the FDA between now and approval. The only possibility might be an ODAC, but that would be in 2021 prior to approval. So we don't see any regulatory impediments. We are having regular teleconferences with the FDA. We just had a productive session about 2 weeks ago. And then in Europe, we're going through the EMA scientific advice process, as we've mentioned. And there, that's all being done via written as well as teleconference, and we have a teleconference coming up with the EMA as well. So I think we're in good shape on regulatory. And then finally, on supply chain, our -- the team has been in close contact with our CMOs, Fuji and Baxter, as well as our distributors that distribute the consumables and the inputs into the manufacturing process. So far, they feel -- they remain confident in their ability to remain fully operational in terms of the PPQ runs and to maintain business continuity. So at this time, there doesn't appear to be any big regulatory or any big manufacturing risk.

Then you asked, Chris, a question about the confirmatory trials. So the -- as you know, we're going through the process for accelerated approval, which means we will initiate a confirmatory trial prior to approval. So right now, we're projecting possible approval in the first half of 2021. So that would be the time when we would want to get the patients, the study enrolled prior to approval.

That's usually what the FDA likes to see to make sure that the study is underway before they give the approval. So we would still plan on the confirmatory trial starting in the first half of 2021.

Answer – Operator: And our last question comes from the line of Swayampakula Ramakanth with H.C. Wainwright.

Analyst: Swayampakula Ramakanth, H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst

Question – Swayampakula Ramakanth: This is RK from H.C. Wainwright. So most of my questions have been asked. Just wanted to see between now and the finalization of the BLA, are you -- do you have any further meetings with the agencies? And would we hear anything as and when some of these data come out from the manufacturing runs?

Answer – Thomas R. Cannell: Yes. Thank you, RK. So yes, we're doing -- as Chad mentioned, we're doing a pre-PPQ run. We're just finishing that up at Fuji and then Baxter. I'm hoping sometime in the second quarter once we've

collected all the data, I'll come out and give everyone an update in terms of how analytical comparability looks versus that pre-PPQ run. We do have another IR call plan for the May time frame, so that might be -- if I have it by then, I'll be sure and share that. We don't have any planned face-to-face meetings with the FDA. We will continue to talk to them. We correspond regularly with them, electronically as well as teleconferences. And so I think the next big discussions as once we submit the BLA, and they accept the BLA file, then we'll be talking to them, asking about whether or not an ADCOM is required. So that's probably -- the next big discussion is, as you know, the FDA accepts the file in 60 days of the BLA being submitted. And then that sets off the next set of choices. You get -- you find out whether you've got priority review or not, and you find out whether or not you'll need an ADCOM. So those are probably the next big upcoming discussions, RK.

Answer – Operator: And that concludes today's question-and-answer session. I would now like to hand the call back
to CEO, Tom Cannell for closing remarks.

Answer – Thomas R. Cannell: Great. Thank you. So I want to thank everyone for calling in today. I mean, I know these are very busy times for everyone, so we really appreciate your interest and all the great questions. I'd like to thank our dedicated employees who have worked incredibly hard to advance Vicinium to this stage of development and for the brave patients who have allowed us to be part of their journey. Our next IR call, as I mentioned, will probably be in about 2 months. And as always, you have our commitment to continue to communicate in a timely and transparent manner as we work toward bringing a product to market that has the potential to save and improve lives. With that, thank you very much for your support and we will conclude our call today.

Operator?

Answer – Operator: Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You
may now disconnect.