Sesen Bio – Business Update

CALL/PRESENTATION DETAILS
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CORPORATE PARTICIPANTS
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CONFERENCE CALL PARTICIPANTS
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TELECONFERENCE REPLAY
An archived replay of the teleconference will be available on the Sesen Bio website (https://ir.sesenbio.com/events/event-details/sesen-bio-business-update) for 90 days after the conference.

PRESENTATION

Operator: Thank you for standing by and welcome to the Sesen Bio Business Update Conference Call. At this time, all participants are in a listen-only mode. After the speaker's presentation, there will be a question-and-answer session.

(Operator Instructions)

I would now like to hand the conference over to your speaker today, Ms. Erin Clark, VP of Corporate Strategy and Investor Relations. Thank you. Please go ahead, madam.

Erin Clark: Thank you, and good morning, everyone. Welcome to today's conference call. Joining me today is Dr. Thomas Cannell, President and Chief Executive Officer. For today's call, we have about five minutes of prepared remarks and then we will open the line for questions and answers.

Earlier this morning, we issued a press release outlining some highlights that will be covered today. The press release to which we will refer is available on the Investor's 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 vary materially due to various factors, including those described in Sesen Bio's most recent annual report on Form 10-K, quarterly report on Form 10-Q and other SEC filings. These statements represent Sesen Bio's view 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.

And with that, I'll hand the call over to Tom. Tom?

Thomas Cannell: Thank you, Erin, and good morning, everyone. Thank you for joining us on relatively short notice.

The reason for our call today is that on Friday, February 12th, the FDA sent us an official letter, or filing communication, with 4 pieces of good news:

First, the FDA stated that they had completed their filing review, and they have accepted the BLA file for Vicineum. This is an important milestone for us.

Second, the FDA awarded Vicineum with a Priority Review Designation. According to FDA guidance, Priority Review is awarded to products that, if approved, represent a significant improvement in safety or efficacy, when compared to standard treatment. So, the FDA awarding us Priority, rather than Standard review, is meaningful.

Third, the FDA set an accelerated 6-month target approval date, or PDUFA date, of August 18, 2021, rather than the usual review time period of 10 months. The shorter review period is significant, and having the potential approval date set is invaluable for our commercial launch planning, which is already well underway. If approved, our current plans are to begin promotion to physicians and patients on August 18, 2021, and to have commercial product supply available in Urology clinics by the 4th quarter of 2021.

Finally, and probably most importantly, the FDA stated that they are not currently planning to hold an advisory committee meeting for Vicineum. This not only de-risks and streamlines the regulatory path forward, it eliminates what would have been a huge workload and cost burden for a company our size.

I will also note that since BCG was approved for first line treatment of NMIBC in the 1980s, only two products have been approved for 2nd line use: VALSTAR in 1998, and Keytruda in 2020. The FDA required an advisory committee meeting for both those products prior to approval.

Typically, an advisory committee meeting is held to assist the review division with interpretation, when questions or difficulties related to trial data arise. So, we have the potential to become only the 3rd product ever approved for BCG-unresponsive Non-muscle Invasive Bladder Cancer, and the first to do so without the FDA requiring an AdCom.

As I have said before, we have been meeting regularly with the FDA over the past two years, and it has been a very productive process. They have helped guide the proper submission of our pre-clinical, clinical and CMC manufacturing data, and through that process we have come to understand their position, and expectations, for potential product approval – which gives us confidence in the regulatory path forward.

In addition to the great news in the US, let me give an update on our 3 largest markets outside the US:

First, in Europe, we hope to submit the Marketing Authorization Application, or MAA, some time next month.

Second, in China, we hope to hear by April on possible approval of our IND by the CDE, which would be a huge step forward in a very promising market, which will be commercialized by our partner, Qilu.

Third, in the Middle East and North Africa, once Vicineum is approved in the US, you will start hearing regulatory updates from our partner, Hikma, as some Middle East countries can move fairly quickly after US approval.

It is important to note that you are seeing tremendous progress in our 4 biggest global markets: the US, Europe, China and MENA region, which represent over 80% of the total global opportunity for Vicineum. In other words, we have a laser focus where we can create the most value for patients and for shareholders.

Before I turn it over to Erin for Q&A, I want to close by thanking our 26 very dedicated employees, and a small group of very dedicated consultants, who have made this all possible. I could not be more proud of the team and all that they have accomplished, and I can honestly say that I have never seen such a talented and hard-working organization that is able to make progress with such speed, quality and efficiency. It is a privilege to be part of that team, as we work to fulfill our mission to save and improve the lives of patients.

With that, I will turn it back to Erin.

Erin Clark: Thanks, Tom. Operator, we can open the line for questions and answers.

QUESTIONS AND ANSWERS

Operator: (Operator Instructions) Your first question comes from the line of John Newman from Canaccord Genuity. Your line is now open.

John Newman: Hey Tom, good morning. Congrats on the execution here – really nice to see. I just had two quick questions for you.

It is looking more and more like the commercial landscape for Non-muscle Invasive Bladder Cancer could be comprised of Vicineum and Keytruda, just in terms of new products. I wonder how you see the marketing playing out there, especially given your experience previously at Merck – I believe you were there for over two decades and you are familiar with Keytruda.

The second question I had is about the balance sheet – curious as to how you think the current balance sheet sets you up for your commercial launch later in the year.

Thomas Cannell: Great. Thanks, John, and good morning. Thanks for those questions.

First, on Vicineum versus Keytruda – first of all, I want to acknowledge how valuable Keytruda is to patients around the world. Last year, Keytruda sold $14 billion – it grew by 30% and it helped save the lives of thousands of patients. I was at Merck for 27 years; I worked on the Keytruda program and I am proud of what my friends at Merck are achieving. By the way, I would like to congratulate Ken Frazier on his retirement. Ken was one of the great CEOs of this era, across industries.

Now, having said all of that, in this particular indication, NMIBC, it seems clear to us that doctors who actually treat Bladder Cancer believe that Vicineum has a superior product profile to Keytruda. They tell us the two products have similar efficacy, but that Vicineum has 3 huge advantages:

First, our clinical trial had an endpoint to measure Time to Cystectomy, while Keytruda did not. Our cystectomy data is very powerful; 76% of patients were cystectomy-free for at least 3 years. We know that is the most important attribute to patients.

Second, physicians tell us that Vicineum has a much better safety-profile, with roughly one-third the rate of serious grade 3-5 AEs and one-third the rate of discontinuation due to AEs that you see with Keytruda. Obviously, with the Checkpoint Inhibitors – given their mechanism of action – the concern is always going to be severe, immune-related adverse reactions, and Urologists are just not usually comfortable taking those emergency calls for those life-threatening AEs. So, safety is a big factor in our favor.

Finally, they prefer our route of administration, intravesical, to the intravenous administration, because it keeps the Urologist in charge of patient treatment. For many important reasons, Urologists do not want to refer patients to Medical Oncologists; they really want to keep treating the patient themselves, and Vicineum lets them do that.

This is all market research, John. You have to prove it in the marketplace, but I have a lot of confidence in our ability to out-maneuver the competition and gain market leadership in this indication. So, that is Vicineum versus Keytruda. Anything else on that, John, before I go to your second question?

John Newman: That answers the question, Tom. Thank you.

Thomas Cannell: The balance sheet – this is kind of an interesting one to me. We posted our J.P. Morgan deck on January 11th and Monica Forbes, our CFO, updated the balance sheet at that time. We finished 2019 with $48 million on the balance sheet, but we finished 2020 with $55 million on the balance sheet, despite the fact that there was no traditional financing.

I know investors were pleased. We got a lot of good feedback on that. They love to see the strong balance sheet, which will allow us to make the commercial investments that will drive strong launch uptake.

Our financing strategy, as we have said, is we have been able to utilize the ATM very carefully and selectively, and sign OUS deals with upfronts and milestone payments, so that we gradually strengthen the balance sheet and avoid the need for more dilutive financings.

We know our investors want us to have a strong balance sheet because they want us to win in the marketplace, but we know investors want us to be very careful to minimize dilution. By leveraging the ATM and finding sources of non-dilutive capital, we feel like we have done a good job keeping the right balance.

You will see later this week, we will add about 35 million of capacity to our ATM instrument, so that we can continue to use it as we have been, carefully and efficiently, from time-to-time over the coming months. This steady strategy is working well for us and our stakeholders, and we plan to stick with it. In fact, I know a lot of investors doing their diligence check the SEC 13F filings. Since establishing the ATM we have seen new, quality investors coming into the stock – Vanguard, Renaissance, Blackrock, Morgan Stanley – so this ATM instrument seems to work well for all investors and I think the strong balance sheet is a huge advantage for us going into our launch planning.

Does that answer the question, John?

John Newman: It does. Also, just curious, in terms of the partnership that you have in China, if there would be any potential for additional milestone payments in 2021? I just wanted to check on that.

Thomas Cannell: Yes, there are a couple. We have submitted the IND in China; we are waiting to hear back from the CDE on that. There is a milestone payment associated with the successful approval of the IND.

We have also said that we are going through the tech transfer process with Qilu. Some time over the summer we are hoping to complete that process and that is also associated with a milestone payment. There are a number of milestone payments and royalties beyond that, but those are the two closest on the short-term horizon.

John Newman: Great, thank you.

Thomas Cannell: Thanks, John.

Operator: Your next question comes from the line of Chris Howerton from Jeffries. Your line is now open.

Christopher Howerton: Hi, good morning. First, congratulations, Tom. I don't think you could have asked for a better scenario – so, really, congratulations to you and to your small team of just 26 employees. Really happy to see the good news.

Thomas Cannell: Thanks, Chris.

Christopher Howerton: Thinking of moving forward, if we can be forward-looking a little bit – to dovetail a bit on John's question, now that you have a clear path to a PDUFA date, what would be your commercial preparatory steps that you are going to take between now and then and any more color with respect to your go-to-market strategy? I think you did a nice job comparing obviously to Keytruda, but I think we could also consider Fergene, as well, in terms of that as potential competition. And of course, how the confirmatory trial may or may not impact that medium-to-long-term strategy? So that is one question.

The other question that I have, again, kind of forward-looking a little bit here, is what are some other opportunities that are in your pipeline, either for Vicineum or other potential opportunities that you and the team are considering?

Thomas Cannell: Thanks, Chris. I will talk a little about go-to-market strategy, talk a little about other emerging competition, like Adstiladrin, and then talk about the rest of our pipeline. Thank you for those.

We have talked about it before; we think there are three key customer segments in terms of go-to-market: Urologists, payers and patients.

For Urologists, we will obviously leverage the fact that our product, designed for second-line use, is the same treatment protocol as the BCG that they use for first-line use – same treatment room, same nurse, same catheter, same two-hour treatment period, etc. That is really valuable when your average patient is a male in his 70s, and not having to change a lot of things is a real factor in our favor. We will leverage the clinical profile, which shows the benefits for patients outweigh the risks.

We have chosen our Contract Sales Organization; we will announce that in the next month or so. Those reps will educate doctors on the product. We have also chosen our HUB Service partner, which we will announce soon, as well. It will really be a fun, go-to-market strategy around the Urologist prescriber.

Second of all, with payers, we think we have a great story there. We will leverage our Time to Cystectomy data, which shows the ability of Vicineum to reduce real-world costs. We will leverage the ICER report from December that showed that at $150,000 annual price for Vicineum, we still reduce overall healthcare costs by $100,000 by year 5. In the end, we hope to establish with payers that we improve patient outcomes, while reducing overall healthcare costs. We will find ways to contract with payers to share risk around that value proposition.

Finally, patients – I do include family and caregivers in there – we will work with patients to give them information to ensure a productive physician-patient interaction. We believe that if that conversation is productive, the patient will often end up being treated with Vicineum. We know – again, the average patient is a male, in his mid-70s – they often want to bring along their family and caregivers to help them understand what the doctor is saying. It is quite an intimidating conversation, so we want to equip the important stakeholders with the information they need, which we think we can do effectively and efficiently via digital and social channels. So, you won't see a lot of television

advertising like you do with Keytruda, but we believe that we will be more effective at reaching the right customer, with the right message through this targeted strategy.

In mid-May, shortly after filing the first quarter 10-Q, we will have an IR call where we introduce the commercial leadership team, and it is shaping up to be a really strong team. They will walk all of you through our go-to-market strategy in more detail.

Christopher Howerton: Sorry, Tom. Maybe if I could just sneak one in here – what is your commitment and/or strategy to hiring commercial personnel prior to an approval?

Thomas Cannell: It's a great question. We have said all along that we are very careful with our cash; we think a lot about the balance sheet. We are always trying to find the right balance between being careful with cash, but being fully ready for launch, so everything we do is stage-gated. The announcements today hit all our stage-gate triggers for commercial hiring, so you will start hearing about the leadership team as we bring them on board; we have already identified them. Like I said, we will start working now with our CSO partner, start hiring managers and reps, and we will start working with our HUB Service partner to hire Reimbursement Specialists and build all of those HUB capabilities.

This was our trigger and we have just over 6 months – 6 months and a couple days – until potential FDA approval, and so we now go full speed in terms of commercial planning.

Christopher Howerton: Great.

Thomas Cannell: Adstiladrin – it's a hard one. Fergene is a private company; they don't provide a lot of information. I would refer you to their website. They got a Complete Response Letter from the FDA and that information is on their website.

Gene therapy is tough. There are only 2 products that have been approved by the FDA – Luxturna for blindness, Zolgensma for Spinal Muscular Atrophy – and those were very specific indications, where there were simply no other treatment options. I think you are seeing all of the companies with recent manufacturing setbacks, such as CRLs, for gene therapy products: Sarepta, Voyager, Iovance, Bluebird Bio, and Fergene. It is a tough thing to manufacture a gene therapy product and to get full CMC manufacturing approval from the FDA. There is just no way to predict if there is a way around that CRL for them.

You have gene therapy and the gene therapy vector is what they call a modified-live virus, in this case for Adstiladrin, an adenovirus. For it to work, you have to infect healthy bladder cells with the virus. Patients are concerned about being deliberately infected with a virus, much more so since the COVID-19 pandemic. Patients hear about viral replication and mutation and they are just concerned. Then, once inside the healthy cell, the virus releases a new genetic code; it injects new DNA into the patient and patients are concerned about anything having to do with manipulating or introducing new DNA into their healthy cells. On paper, the product profile seems pretty good, but there are just a lot of manufacturing and real-world barriers and so, it is really hard for us to predict what happens with Adstiladrin.

Any other questions on that before I go to the pipeline, Chris?

Christopher Howerton: No, that's great and I look forward to the call in May.

Thomas Cannell: Thanks for the pipeline question. We have been so laser-focused on the current regulatory process for Non-muscle Invasive Bladder Cancer, but there are 6 other interesting areas that we are working on in terms of our pipeline.

First of all, beyond our initial indication for Non-muscle Invasive Bladder Cancer in BCG-unresponsive patients, we will be going after label expansion in less-than-adequate BCG. Right now, there is a hug unmet need because of the BCG shortage. Right now, second-line products, like VALSTAR and Keytruda can only be used after at least 7 doses of BCG and we would like to study patients who have only had 1 to 6 does of BCG and can't get more because of the shortage or intolerance. We have discussed this study with the FDA.

It is very possible that Vicineum is more efficacious in this patient population based on the data analysis of our Phase II and Phase III trials. The FDA said that if those trials results are positive, it could be possible to expand the indication section of the label and expanding that label would represent a sizeable opportunity – so, keep an eye on that less-than-adequate population.

Second of all, in this combination used with Checkpoint Inhibitors, we are especially interested in patients that have a partial response when treated with Vicineum, and again, that was 40% of our patients in Phase II above and beyond the 40% that had a complete response. We think the combination with Checkpoint Inhibitors is applicable in Bladder Cancer, but also other indications. As you know, we are doing a study with AstraZeneca's Durvulamab. AZ has been a very good partner, but we are certainly looking at doing combination studies with other Checkpoint Inhibitors, as well.

Number three is Squamous Cell Carcinoma of the head and neck. We have promising Phase I and II data. Head and neck cancer is an area of huge unmet need. Our next step there is to meet with the FDA for a pre-Phase III meeting – that is probably a Type B meeting – and to discuss the study design for a Phase III trial. That is probably 3-6 months after we get approval for NMIBC, but that's on the horizon.

Christopher Howerton: Tom, what is the route of administration here?

Thomas Cannell: Yes. It's a great question. It's intratumoral; so, it's injecting into the tumor, based on the size of the tumor. Some of the most interesting work that we saw in head and neck is when you inject the primary tumor with Vicineum, sometimes you will see regression or complete treatment of the secondary tumors. So, we think that our Phase I and Phase II data for head and neck helps to show our dual mechanism of action and how we are activating the patient's immune system, because you inject the primary tumor and you see efficacy against secondary tumors that weren't injected. That also shows why it could be very nice in combination with an IV Checkpoint Inhibitor; administer intratumorally with Vicineum, use the Checkpoint Inhibitor given IV.

The fourth area is we have a set of IV fusion proteins. As you know, Vicineum is only designed to be given intravesically or intratumorally – it can't be given IV. We have other proteins in the pipeline, what we call our deBouganin Program, with promising pre-clinical data that we believe could be appropriate IV drugs, which would allow us to target a completely different set of tumor types. We are anxious to get that program in the clinic, but we haven't guided on timing yet.

As you know, we also have an IL-6 Program for ophthalmic conditions, such as Diabetic Macular Edema. The IL-6 is identified as EBI-031, back from our Eleven Bio days, and it is from our AMP-Rx program. Roche is running the clinical trials. Phase I is right on track and we could be eligible for up to $240 million in milestones, as well as potential royalties, and there are, of course, buyout options as well. We are watching this one closely. I think it's a very promising IL-6 monoclonal antibody.

The sixth one that we just announced in December is the imaging agent. This agent allows surgeons to clearly visualize the edges of the tumor. It helps to ensure cleaner, clearer margins, which means you are able to remove the tumor in its entirety, which is the most important indicator of a successful surgery. So, you can imagine the value of a technology like this to a practicing surgeon. So, we have promising Phase I and II results, and as we have announced, after the US approval of Vicineum, we are anxious to work with our partner, LUMC, to get the next clinical trial going with the imaging agent.

I think those are 6 emerging areas of potential value. I will refer you to the
10-K that we'll file in mid-March, and we will provide more detail on all of those programs.

Chris, did that answer all of your questions? I'm trying to think if I missed any.

Christopher Howerton: Well, yes. I think that that's great. Obviously, there is a lot to look forward to, not only for Vicineum, but for other opportunities as well. Congratulations again, Tom, and thank you for taking the questions.

Thomas Cannell: Great. Thanks, Chris.

Operator: There are no further questions at this time. I will turn the call back over to Dr. Thomas Cannell, President and CEO of Sesen Bio.

Thomas Cannell: Great. Thank you, Anthony. Before we close, I want to give you all a sense of what you can expect from us moving forward.

In March, you can expect an update on our MAA submission in Europe. As you know, Europe is a very important market to us, and if all progresses well, we could be looking at product approval there in early 2022.

Also in March, we'll file our 10-K, we'll have an IR call at that time and we'll do something new on that call, as we've invited one of the top Key Opinion Leaders in the Uro-Oncology space to give a clinical perspective on Vicinuem. He'll discuss the mechanism of action, clinical trial data, and the real-world applicability of Vicineum in Urology Clinics that treat bladder cancer. That will be a great call – somewhere around March 15th.

In April, we should learn more about the status of the IND in China. Approval of that IND would allow our partner, Qilu, to begin a small clinical trial, which then triggers the regulatory process in China. China is also a very important segment, and you can expect quite a few updates this year.

In May, as I mentioned, we'll file our 10-Q for the 1st quarter, and have an IR call at that time. On that call, you'll get to meet members of our very talented commercial leadership team. At that point, we'll be 3 months from the potential FDA approval, you'll learn more about our go-to-market, and I think that will also be a very important call – somewhere around May 10th.

It is a busy and very exciting time for the company, and you can expect us to continue to be transparent and communicative. For Investor Relations, we follow a very simple formula: we tell you what we're going to do, we execute those plans, and then we tell you what we did.

With that, we will conclude today's call, get back to work, and look forward to talking to you all soon.

Thank you.