Jefferies Virtual Healthcare Conference

PRESENTATION DETAILS
Date: June 4, 2021
Time: 8:30 am EDT

CORPORATE PARTICIPANTS
Dr. Thomas R. Cannell, Sesen Bio, Inc. – President, CEO & Director

CONFERENCE CALL PARTICIPANTS
Chris Howerton, Jeffries LLC – Equity Research Analyst

WEBCAST REPLAY
An archived replay of the webcast will be available on the Sesen Bio website for 60 days after the conference.

FIRESIDE CHAT DISCUSSION

Chris Howerton: Hi, everyone. Thank you so much for joining us for the final day of our Virtual Healthcare Conference this year. My name is Chris Howerton, part of the Jefferies Biotechnology Research Team. I've got to say I'm very pleased to be hosting a conversation with the next company, Sesen Bio. On behalf of the company, we have Dr. Tom Cannell. Thanks for joining us, Tom.

Dr. Thomas Cannell: Good morning, Chris.

Question – Chris Howerton: The CEO, I should point out, as well. You earned that, my friend. Okay, well, we have some exciting times coming up for Sesen, I must say. So, the PDUFA (Prescription Drug User Fee Act) is very soon for Vicineum. When is that again?

Answer – Dr. Thomas Cannell: The PDUFA is August 18th. That is the target approval date. And, yes, there is a lot going on.

Question – Chris Howerton: Fantastic. So, we got an approval that is a long time coming and, certainly, a lot of work for you and the team. With that kind of tantalizing set up, what is your 30-second elevator pitch for Sesen these days?

Answer – Dr. Thomas Cannell: I think the first step for Sesen is to launch Vicineum for carcinoma in situ (CIS). We believe we have a product that is superior to the market leader, which is Keytruda. We think we have comparable efficacy, a better safety and tolerability profile, and really the preferred mode of administration, which is intravesical. We believe that, by roughly a year after launch, we will become the market leader in this very sizeable market.

But that is really just the start. Then we believe there are add-ons for combination— such as PD-1s. We think we'll move earlier along the continuum— first to less-than-adequate BCG (Bacillus Calmette-Guérin), and then ultimately to first line. Beyond bladder, we already have Phase 1 and 2 data in head and neck. We believe that is the next area we will move into.

It all starts with the launch. If we are able to get FDA approval in August, we really think we can build from there and have a very promising future.

Question – Chris Howerton: Fantastic. Basically, we have a drug on the precipice of approval in bladder cancer. It has a differentiated profile – certainly with delivery and safety. And the efficacy is as good or better than the market leaders. That is a pretty good pitch, in my view.

Okay, so with the PDUFA just a few months away, are there any more updates that we can expect from you and the team between then and now?

Answer – Dr. Thomas Cannell: Yes, a lot happens between now and the PDUFA. I just got back from Boston last night. We were doing our last of nine inspections with the FDA. It was our corporate inspection. We have done clinical site inspections, manufacturing inspections. It is important to get those done because for a lot of companies, during the pandemic, those have been rate limiting. We feel good about that.

Coming in mid-July, we will have our late-cycle meeting with the FDA. So, we are in June now and the FDA is wrapping up the review. They will send us a briefing book in early July. In mid-July, we will have that late-cycle meeting, and probably put out a press release after that – pre-market, the next day, as we do.

And then we are heading toward the PDUFA date of August 18th, recognizing that we have priority review, and there have been several priority review products that have been approved two to three weeks earlier than the PDUFA. By the time you get to August you are just watching. If we are able to get approval, it could come at any time. And then we go into the full launch mode.

Question – Chris Howerton: Okay, fantastic. That's so funny – when you were coming back from Boston, were you with the FDA folks on the same train going back toward DC?

Answer – Dr. Thomas Cannell: No, I wasn't. I was by myself on that one. But we were with them for several days up in Boston – a very high-quality FDA review team and a very productive discussion.

Question – Chris Howerton: Okay, fantastic. So, here is a curious one we have been getting from investors: "Tom on the last the call said he was excited about being in a market with a market-leading drug like Keytruda. What did [he] mean by that?"

Answer – Dr. Thomas Cannell: I've been getting that question a lot as well. Before Keytruda got approved, patients only had two choices: Valstar, which is hardly used at all, and radical cystectomy, which is very undesirable. Most patients choose not to go through that radical surgery. So had we launched into that market, we would have beat two undesirable options, and it is kind of hard to know how well you can really do.

There is a marketing saying: "if you want to be a billion-dollar brand, beat a billion-dollar brand." I started my career as product manager for Zocor. It was a little cholesterol reducing drug that was third to the market. The analysts thought it would be $300 to $500 million. But Mevacor was a billion-dollar brand and Pravachol was a billion-dollar brand. We were able to beat them, and Zocor went on to be a five-billion-dollar brand. And I do not think that would have happened if we were not beating a major product.

It is a fundamental marketing principle. Keytruda last year sold $14.4 billion. It is growing at 20 or 30 percent a year, so this year it will be a $17 or $18 billion drug. If you can beat them in just one indication, I think it changes the way payers, physicians, patients and investors think about the company. So, we feel lucky to be lined up against Keytruda.

Chris Howerton: It's interesting. That wasn't necessarily the answer I was expecting, to be honest with you. I was thinking you might say that the mechanisms are orthogonal and are a lot of reasons to combine them together. So that is what I thought you were going to say.

Dr. Thomas Cannell: Well, I think it will complement Keytruda or another checkpoint inhibitor. But first we want to be the first-line therapy, and then we will add on the checkpoint inhibitor.

Chris Howerton: I don't know that I have heard you say that in public before – that you want to be a first-line therapy. I, of course, totally agree, but I do not recall you saying that in public before. So that is awesome. I love to hear it.

Dr. Thomas Cannell: Yes, we talk about the evolution. We are going to be in adequate BCG, where patients have had at least seven instillations. We want to move to less-than-adequate BCG – one to seven instillations of BCG. We know physicians and KOLs (Key Opinion Leaders) want us to move to first line. The big thing we are working with is payers. There is no point to moving to first line if you cannot get reimbursement. So, it will be along a continuum. We are going to have to bring payers with us. But that is definitely the ultimate goal: to be first line and then have checkpoint inhibitors you can add on to that.

Question – Chris Howerton: Very good. So, I guess the other one – there has been some uncertainty in terms of whether or not there might be an advisory committee (AdCom) for Vicineum. That is, I guess, put to bed at this point. Is that fair?

Answer – Dr. Thomas Cannell: Yes, the FDA in February said that they do not plan on having on an AdCom. Now, the FDA can change their mind on anything at any time. But it seems to be going well the way it is. As you know, we would be the third agent with this indication. Valstar had two AdComs. They failed on the first one.

Chris Howerton: Is that right?

Dr. Thomas Cannell: Yes, in 1998; it was a while back. And, you know Keytruda had one AdCom in December of 2019 and it was a mixed vote. It is kind of a big deal if FDA decides that we do not need an AdCom. They had previously guided that they thought we would, but that was before they saw the BLA (Biologics License Application) and all the data. I think it's a real nice acknowledgement of the benefit-risk profile of the product.

Chris Howerton: And this, in my opinion, is also an evolution of the regulatory space, too. I think there was a lot of, "what do we do to demonstrate clinical benefit?" They worked with industry and added this pretty detailed guidance, which you guys have kind of worked through. And I think it is a nice demonstration of your team's ability to work closely with the regulators, in my view.

Dr. Thomas Cannell: It is such a good point. The guidance over the last five years has changed dramatically, especially since February 2018 when the FDA came up with more formal NMIBC (non-muscle invasive bladder cancer) guidance. We have a really strong regulatory and clinical team and they've been able to evolve with the agency. I think that has made all the difference. There have been dozens of products that have tried to get approval for this indication – I think, often, they miss the nuances around FDA guidance. I am really proud of how our team has stuck with the FDA every step of the way.

Question – Chris Howerton: Yes, totally. So, I guess let's speak of nuances then. One nuance I think that is lost on a lot of people is that Keytruda's pivotal trial design – correct me if I am wrong – only included patients who were either ineligible for cystectomy or refused cystectomy.

Answer – Dr. Thomas Cannell: That's right.

Chris Howerton: Talk to me about that. How it is different than your trial?

Dr. Thomas Cannell: They took a little bit of an easier path. It is only for patients who absolutely can't or won't have the surgery and then as kind of a last resort you give an investigational drug.

We took a little bit of a different path – kind of the all-comers. So, whether or not you can have cystectomy, you can still choose Vicineum if you want. I do not think it will change the way the labels look. I think we will have very similar labels. But I think KOLs and the physicians who have followed it – it could end up with us being viewed more as the primary first-line agent, and Keytruda being more niche for add-on or last resort. I think it is going to be a benefit for us in the long run.

Question – Chris Howerton: Okay, that makes sense. Let's talk about label. The initial label you would like to see is very similar to Keytruda within this indication? What are some features that would be particularly attractive in your view?

Answer – Dr. Thomas Cannell: I mean the ideal label is full approval. It is the same indication – a level playing field in terms of indication with Valstar and Keytruda to show comparable efficacy in the clinical data. And I think the real differentiator is the Warnings and Precautions section. If you look at Keytruda now, there are like three pages of life-threatening immune-related AEs. The safety and the Warnings section is so prominent. The idea for us is that we are given intravesically. The bladder wall protects the body from the medicine.

If our warnings are more about perforated bladder or bladder surgery like TURBT (transurethral resection of bladder tumor) or irritable bladder – if they are more constrained to the bladder in terms of safety warnings and precaution information, I think that is really going to resonate with physicians and that is going to drive their treatment choice.

Question – Chris Howerton: Right, right. I did want to dig in a little bit to what you said there that the ideal label would be a full approval. You and I have discussed a confirmatory trial several times. So, I guess, what is the reconciliation between those two ideas?

Answer – Dr. Thomas Cannell: When we had the pre-BLA meeting in 2019, it was really good but the FDA had two specific pieces of guidance. One, they thought we needed an AdCom, and that has obviously changed since then. The other is they thought it would be an accelerated, not full, approval, which means you need to do a big confirmatory trial. As time has gone on and we have submitted the BLA and have had a lot of discussions with them on it—we are still guiding on accelerated approval with confirmatory trial, but as I mentioned on the last call, there's an upside scenario now where we get full approval.

And that is really good for us. Not only does full approval give physicians more confidence, but, for a small company like ours, doing a big confirmatory trial is expensive, and there is a lot of work. It allows us to keep a laser focus on a world-class launch. And it takes out a lot of opex (operating expense), making our path to profitability quicker as well. There are a lot of benefits in that upside scenario. But we are still guiding for accelerated approval until we learn more from the agency.

Question – Chris Howerton: And when might you learn more information? Is that the kind of thing that would be at the late-cycle review meeting?

Answer – Dr. Thomas Cannell: Much like the AdCom, the FDA can change their mind any time they want. It is their regulatory process. But we might get more insight in mid-July.

Chris Howerton: I mean, you are painting the FDA as quite capricious. I think what I would say, maybe, is that they can attain new information that might alter their previously stated desires or whatever.

Dr. Thomas Cannell: Well, I mean it with great admiration. They are great professionals. If you look at their guidance, when they talk about the late-cycle meeting, they always say, 'we retain the right to change our minds at any point; we are not making final guidance.'

Chris Howerton: Yes, I hear you. Totally. And I think one of the underappreciated features [of the FDA] is they see a lot of information we will never see. I think it is just important to kind of trust that they will do the right thing for patient safety.

Dr. Thomas Cannell: Yes, they will. If they do approve it, they have something called the summary basis for approval. At the same time that they would post our new label for approval, they would post the summary basis. And that will give you a lot of insight into the data we have shared with them. It is really their way of saying, 'here's why we approve the drug.' I encourage people to look at that. It is always really rich with valuable information.

Question – Chris Howerton: Awesome. One topic related to either a confirmatory trial or a label expansion trial – when you think about the ultimate opportunity for Vicineum, you have been pretty vocal about seeking partnerships. How important is thinking about the view of a partner and what the design of that confirmatory or label expansion trial might look like?

Answer – Dr. Thomas Cannell: Well, I think there are two dimensions as far as partnerships. We will be looking for partners to do combination trials with—so companies that have a checkpoint inhibitor. Then there are also partnerships outside the US. For some of those markets, they may need to do a confirmatory trial and we might work closely them.

If you need to do [a confirmatory trial] in Japan, China, Europe, wherever – if you have one global confirmatory trial, it gives a lot more statistical power and lets you be more efficient. So, as we bring on partners, that is one of the things we are talking about – do you think you will need a confirmatory trial and do you want to participate in a global study?

Question – Chris Howerton: All right. Before we talk about outside the US, I think we are both preparing and assuming that the drug will be approved and launched soon. So, let's talk about that commercial opportunity. First and foremost, when would you expect the product to become commercially available if approved on the PDUFA?

Answer – Dr. Thomas Cannell: If we are approved in the August timeframe, we expect product to be available in the fourth quarter. We are still talking to the agency and trying to finalize the label. Once we agree on that label, then we need to ship that and finalize all our packaging. As you know, our fill-and-finish and all our secondary packaging is done by Baxter in Germany. Then we need to print off those labels,

package them up, and ship them off to Cardinal, our distributor. That takes just a period of time and that is why I always guide product availability in the fourth quarter.

Question – Chris Howerton: Okay, how do you see the commercial opportunity? I think you talked about CIS as the initial label.

Answer – Dr. Thomas Cannell: What we see for products like this in oncology and biologics is a little bit of an S-shaped curve. I would expect in the fourth quarter, as we are shipping to sites, they are identifying patients who have failed BCG and helping those patients get reimbursement at a time when you have a temporary J-code and to prior formulary approval by the health plans. I would expect fourth quarter to be probably less than $5 million in revenue – pretty conservative.

In the spring, what you will see is we get a permanent code, and we are added to formularies. By mid-year, what you will start to see is early commercial success. On that trajectory, you are surpassing Keytruda late in the year. And then you are really on a path to being a $1-3 billion drug, which is what we have projected. So, the S-shaped curve is what you will see over the next twelve months or so.

Question – Chris Howerton: That makes sense. You recently updated us on your contract sales force. Can you tell us a little bit about that?

Answer – Dr. Thomas Cannell: Yes, we hired our VP of Sales, Lisa LaMond, who is terrific. We have got the National Sales Director, the four Regional Sales Directors. We are doing recruiting and have started interviewing. We will make hires in early July and those representatives will start training in late July. We have said we will have about 35 representatives in the US. So far, it is really a strong team. We are really happy with our partner, Syneos. Those representatives will be out there ready to go in August. So, that part is coming along.

For all of the payer work, as you know, we have hired Pattie Drake as Chief Commercial Officer. She is one of the top commercial leaders I have ever worked with. She is hiring a great team. She just hired Steve Barbera who has a lot of Uro-oncology experience in market access. So those plans and our interactions with payers are really starting to come together, as well as the plans to help patients get reimbursement. The team is really doing great work. It is really a top-notch commercial team. It will be fun to watch the launch.

Question – Chris Howerton: Okay, fantastic. A little bit earlier we talked about who would be prescribing this – either a Urologist or an oncologist. For those who may not understand the nuance here – what are you talking about?

Answer – Dr. Thomas Cannell: Most of the prescribing of BCG, which is the first line treatment for NMIBC, is the Urologist or Uro-oncologists, which means they have some advanced training in oncology on top of the Urology specialty. We estimate that there are roughly 2,000 of those Urologists in the US that do the bulk of the prescribing. The Urologist usually has that patient referred as soon as the patient has blood in the urine – very early in the diagnostic process. And it is the Urologist that uses BCG.

Then, Urologists will have the choice to keep treating the patient using Vicineum, or to refer to medical oncologists who would use Keytruda. But we think there are a lot of reasons – there are clinical reasons, emotional reasons and even economic

reasons – that the Urologist will prefer Vicineum to referring for Keytruda. So, we feel really good about that target specialty.

Question – Chris Howerton: Interesting, yes. That makes a lot of sense.

I've never asked you this. Let's fast forward five years. Vicineum is the first-line or one of the first line monotherapies. You guys want to hit it as a combo with a PD-1, an intravenously prescribed drug, that would also be a first line therapy. What are your thoughts on that scenario?

Answer – Dr. Thomas Cannell: You look at the checkpoint inhibitors now – they can be dosed every six weeks. I think in the scenario where you add on a Keytruda, the Urologist keeps managing the treatment; they keep managing the patient. The patient just goes over every six weeks for an IV infusion of Keytruda and comes right back to the Urologist. That is how I think the add-on therapy would work.

Question – Chris Howerton: Yes, and by that time, Keytruda will have been on the market for quite some time, so there would be a lot of familiarity.

Very good. Maybe in the last minute or so that we have here – what can you tell us about your current finances? Outside of the PDUFA, are there any key dates you want us to pay attention to?

Answer – Dr. Thomas Cannell: In terms of the finances, the balance sheet – it is very strong. As Monica Forbes, our CFO, presented on our earnings call, we finished the first quarter with about $110 million in cash. That is by far the strongest position we have ever had from a cash perspective. That allows us to really finance off the ATM (at-the-market facility) very efficiently in a way that minimizes dilution. We can carefully strengthen the balance sheet without hurting the growth of the stock or [causing] dilution. We are in a very strong position. We have the cash runway through the end of this year. I feel like we are really well-positioned for the launch in that regard.

Dates beyond that – we have not guided, but there will be a lot of other things happening. Stay tuned. Nobody really gets to go on vacation this summer because there will be a lot happening.

Chris Howerton: All right. Well, that is certainly something I am very excited for. Personally, I will take at least one week of vacation. I think I deserve it. But I encourage you to get your team in the office and get that thing launched. It is really strong. Thanks again for joining us. Really appreciate it.

Dr. Thomas Cannell: Thanks, Chris. And have a great day everyone.