Sesen Bio – Business Update

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WEBCAST REPLAY
An archived replay of the webcast will be available on the Sesen Bio website (https://ir.sesenbio.com/events/event-details/sesen-bio-1q-2021-business-update) for 60 days after the conference.

PRESENTATION

Operator: Good day and thank you for standing by. Welcome to the Sesen Bio Quarter 1 2021 Business Update call. At this time, all participants are in 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, Ms. Erin Clark, VP of Corporate Strategy and Investor Relations. Please go ahead.

Erin Clark: Thank you, and good morning everyone. Welcome to our first quarter Business Update call.

On today's call we will discuss our operating results for the first quarter ended March 31, 2021, as well as an update on the commercial readiness progress to date ahead of our target PDUFA date of August 18, 2021.

Joining me on today's call are Dr. Thomas Cannell, President and Chief Executive Officer, Dr. Chad Myskiw, Executive Director of Supply Chain, 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, quarterly report on form 10-Q 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.

With that, I will turn the call over to Tom. Tom?

Thomas R. Cannell: Thank you, Erin, and good morning everyone. Thank you so much for calling in and participating in our business update today.

Please turn to **slide 3**, which is a summary of the 3 key takeaways for our call today. First, Vicineum has a unique and compelling value proposition, especially when it comes to its potential to improve patient outcomes, while reducing overall healthcare costs. Second, we believe we have a clear regulatory path forward, with potential approval in the US in August of this year, and in Europe in early 2022. And finally, given the substantial unmet need in bladder cancer, and the highly differentiated clinical profile of Vicineum, we project a significant global commercial opportunity.

Please turn to **slide 4**. If you have been following us for a long time, like many of you have, you know we always start our presentation with the patient journey to make sure we are focused on realizing our mission to save and improve the lives of patients.

It is important to understand the unmet medical need in bladder cancer through this lens, not only to understand why there is such a significant patient need for a product like Vicineum, but also to understand why we believe prescribing physicians will prefer Vicineum versus available agents.

An important takeaway from this slide is that the Urologist plays a key role guiding the patient through their journey. Most medical decisions, including treatment choice, will be decided by the patient and their Urologist, and we will talk about why that is important in a few minutes.

Please turn to **slide 5**. This shows our anticipated regulatory timeline for our four biggest global markets; we continue to make progress across each of these key regions.

In the US, the team is laser focused on responding to information requests, site inspections, and preparing for the late-cycle meeting with the FDA in July. We continue to be encouraged by what we have found to be an engaging and collaborative review process.

As you may recall, the late-cycle meeting was originally scheduled in June, but due to delays scheduling site visits outside the US, caused by the pandemic, we are now planning for that meeting in mid-July.

You can see we remain on track for our target PDUFA date of August 18th, and our current plans are to begin promotion to physicians and patients upon potential approval in August, with commercial product supply available in Urology clinics by the fourth quarter. Given the market dynamics in this market, we would expect signs of early commercial success by mid-2022.

In Europe, we achieved an important milestone with the conditional acceptance of our proprietary brand name, Vysyneum. In addition, the EMA notified us that the MAA submission was found to be valid, and that the review procedure has officially started with potential approval in early 2022.

Next, in China, the IND was approved by the CDE (Center for Drug Evaluation), which triggers a milestone payment from our partner Qilu Pharmaceutical. It also enables Qilu to conduct the proposed clinical trial to assess the efficacy and safety of Vicineum in patients in China, and we expect the first patient to be dosed in that trial next month.

Finally, in the MENA region, we continue to work closely with our partner, Hikma Pharmaceuticals, to submit Marketing Authorization Applications in 2021 in key markets, with the first wave of potential country approvals for Vicineum in the MENA region as early as 2022.

Turning to **slide 6**, just a reminder that while our planned tradenames in the US and Europe will be spelled slightly differently, they will be pronounced the same: *Vicineum*. We would expect most countries outside the US and Europe to utilize one of these two spellings.

Turning to our brand strategy - we believe we are positioned to launch a best-in-class therapeutic that will improve patient outcomes, while reducing overall healthcare costs. Given the differentiated value proposition of Vicineum, we expect that Vicinium will become the market leader in the non-muscle invasive bladder cancer market in late-2022, on a path to realize global peak sales of $1-$3 billion dollars.

Turning to **slide 7**, you can see a high-level view of our customer engagement strategy.

First, we have identified about 300 national and regional Key Opinion Leaders, or KOLs, where a very high level of engagement is warranted. For these customers, we will deploy Medical Science Liaisons with the full support of our Medical Affairs department. We will also engage some of those KOLs as speakers at a variety of company-sponsored and independent conferences and programs.

Next, I want to mention our reimbursement support strategy. Vicineum is going to be a buy-and-bill product, and we will be selling directly into the Urology clinic. Given this, it is critical that we have the right support to ensure clinics are reimbursed for Vicineum, and that we provide helpful resources to patients as they go through the reimbursement process.

Next, from a sales force perspective, there are about 2,000 high-prescribing physicians our sales force will target. We recently announced a partnership with the leading Contract Sales Organization, Syneos Health, who will provide logistical support in the hiring and deployment

of the sales force. The sales force will include 35 representatives across 4 geographic regions. This will enable reps to see each target, on average, a couple of times a month, with a very reasonable investment in terms of operating expense.

Finally, there are also some high prescribing physicians who are located in more rural locations and are harder to see, but it still makes sense to interact with them virtually. For targets located at these sites, we will use inside sales reps to efficiently reach these prescribers.

Overall, we are confident in our customer engagement strategy. Bladder cancer is a highly concentrated market and we believe we have developed an approach which will lead to strong product uptake and sustainable growth.

Please turn to **slide 8**, which highlights the results of our market research of Vicineum relative to Keytruda. When we show high prescribers of bladder cancer the profile for Vicineum, and for Keytruda, they say that they would choose Vicineum over 80% of the time, because they view Vicineum to have advantages in terms of safety, ease of integration into their clinical practice, and overall physician interest in using the product.

Physicians have a very favorable brand image of Keytruda, and therefore, when physicians choose Vicineum over Keytruda 80% of the time, that strongly positions us for a successful launch.

With that, I will hand the call over to Chad.

Chad Myskiw: Thanks Tom. If everyone can please turn to **slide 9**. Given the complexity of manufacturing biologics, we've purpose-built a very reliable and robust supply chain with world-class manufacturing partners. Our current supplier for drug substance is Fujifilm, and for drug product, Baxter. Both of these CMOs (Contract Manufacturing Organizations) are industry leaders with a long history of manufacturing excellence and a strong regulatory track record with the FDA and other regulatory authorities.

To strengthen our existing supply chain, we are currently transferring the Vicineum manufacturing process to Qilu Pharmaceutical, our partner in the Greater China region, to add them as an additional source of drug substance and drug product supply in the future. Qilu has a very large and experienced manufacturing team and already supplies commercial products to the US, so we feel very good about bringing them on board.

For third-party logistics and specialty distribution services, we are working with Cardinal Health in the US; Cardinal is one of the most well-respected and capable players in this industry. They have significant expertise in cold-chain logistics and deep relationships with the Uro-Oncology community, so we feel very confident we can leverage the experience of our supply chain partners to support a world-class launch of Vicineum.

Turning to **slide 10** and the manufacturing process for Vicineum, which is produced via E. coli fermentation. The general approach of using microbial fermentation to manufacture recombinant proteins was pioneered by Genentech in the 1970s with Insulin, and continues to be widely used to manufacture peptides and small proteins, such as antibody fragments. This system is very well understood and well characterized. The specific process that you see here is the proposed commercial process and was developed by Sesen Bio throughout clinical development and then transferred to Fujifilm and Baxter. Fujifilm manufactures the drug substance, so that is all the steps up to and including bulk drug substance formulation. This material is then sent to Baxter for drug product manufacturing, which is just a fill-finish and they will also do the labeling and secondary packaging and serialization of the product.

One **slide 11**, we've highlighted what we see as some of the key advantages of the manufacturing process for Vicineum in comparison to other biologics and gene therapies. We are using microbial fermentation - a well-understood system that has and continues to be used to manufacture many recombinant proteins. The reliability of this system reduces the

risk of manufacturing issues than can lead to supply shortages, and the non-muscle invasive bladder cancer space is very sensitive to supply issues, given the ongoing BCG shortage and manufacturing problems with past products, such as Valstar. Because microbial processes tend to be shorter and less complex than mammalian systems and since we do not have any process intermediates or conjugation steps, as you have with antibody-drug conjugates, we expect to achieve a competitive cost-of-goods. Finally, having such strong manufacturing partners leads to a reliable and robust supply chain to support the launch of Vicineum.

With that, I'll turn the call over to Monica.

Monica Forbes: Thank you, Chad.

Please turn to **slide 12** for a few financial highlights. We significantly strengthened our cash position in the first quarter, ending with approximately $110M in cash and cash equivalents. We also saw a strong increase in stock price and market cap versus year-end 2020. With a strong balance sheet, we believe we are well positioned to continue to build for a successful launch ahead of the potential approval of Vicineum in August of this year.

Turning to **slide 13**, as we prepare for commercial readiness in the US, we continue to manage our balance sheet through stage-gated investments, which are focused on our highest priority initiatives, such as supporting the regulatory process in the US and Europe and the commercial launch of Vicineum in the US, illustrated by the dark blue bars.

We also continue to strategically raise capital to strengthen our cash position, as shown on the dark purple bars. I will remind you that, given our strong cash position, as of April 1st, we shut down our ATM for April and May. We will reactivate the facility no sooner than June and will continue to operate it on a periodic basis consistent with our historical practice with the goal of minimizing dilution and decreasing the need to do a large, dilutive financing event.

With that, I will turn the call back to Tom. Tom?

Thomas R. Cannell: Thank you, Monica. Please turn to **slide 14**, which is a summary of the 3 key takeaways for our call today.

First, Vicineum has a unique and compelling value proposition, especially when it comes to its potential to improve patient outcomes while reducing overall healthcare costs. Second, we believe we have a clear regulatory path forward in both the US and Europe. We continue to work closely with the regulatory agencies as we approach upcoming milestones. Finally, given the substantial unmet need in bladder cancer, and the highly differentiated clinical profile of Vicineum, we project a significant global commercial opportunity.

With that, we will open it up for questions. Ruby?

QUESTIONS AND ANSWERS

Operator: (Operator instructions). Your first question comes from the line of John Newman from Cannacord.

John Newman: Tom, good morning and thanks for all of the updates. I just wondered if you could comment a bit on the design of the Phase III studies that were run for Vicineum and the reason I'm asking is whether you would expect Full Approval or Accelerated Approval, given that when I look back at the guidance it seemed to me, at least, like the design for you studies I think was consistent with Full Approval – obviously that will be up to the FDA – I'm just curious if you could comment there?

Thomas R. Cannell: Yes, thanks, John. It's a great question. Obviously, it's very topical, because last week, the FDA had ODAC meetings or Advisory Committee meetings discussing the Accelerated Approval pathway. So, you're right - in the February 2018 guidance, the FDA says that for Carcinoma in situ, you can conduct a single-arm trial, and

that you would be eligible for either Full or Accelerated Approval and they said we'll make that call during the review process.

We had our first pre-BLA meeting in June 2019, and again, there was a lot of good news there. We had a clear regulatory path forward, and the FDA gave two pieces of guidance: they said, we expect that you'll need an Advisory Committee meeting, and we'll expect that you're on an Accelerated, not a Full Approval pathway, which means you'll need a confirmatory trial. So, that's how we've been kind of planning things, and that was the guidance we gave at that time.

Obviously, we feel like as the data comes together, it just keeps looking better and better. So, it was really good news in February of this year when the FDA said oh, it appears that an AdCom will not be required, and we don't have one scheduled.

What they haven't weighed in on yet - we probably won't learn until right around the PDUFA date, August 18th - is whether they'll require an Accelerated Approval, which means a confirmatory trial, which was their previous guidance, or whether they're prepared to give Full Approval. So still, our guidance is the same based on what the FDA told us during the pre-BLA meeting; our guidance is that we expect Accelerated Approval, and we're ready. We have a protocol written. We're ready for a confirmatory trial if that's their decision. That would be great news; that would be a great event for us to get Accelerated Approval in August.

But there is the chance of the upside scenario, where we actually get Full Approval, and so that's something we'll all just be watching for as we approach the PDUFA date. Did you have a follow up question, John?

John Newman: I did, actually. So, it's interesting. I'm just wondering - just in your view - what will change in terms of the views on the Company once Vicineum hits the market? Just curious as to what investors might learn over time, when Vicineum, or if Vicineum is approved, and in the market that could sort of, in your opinion, change your views on the trajectory of Sesen?

Thomas R. Cannell: Yes, it's a good question, and we get that a lot. I will - since this is all about forward-looking statements - remind everyone of slide 2, especially the risks and uncertainties. We've guided that we believe, based on the comprehensive Monte Carlo simulation, that there's an 80% probability of Vicineum having peak sales of $1 to $3 billion and you can use whatever PE ratios you want, but if we're right, the company value has the potential to be much higher than our current market cap. Right?

So if that happens, John, then I think the market will have learned and really come to understand three things. First of all, I'd say it's the the powerful role of Urologists, which I alluded to talking about the patient journey. Then, the clear understanding of the three key drivers that motivate them, all of which play in the favor, I think, of Vicineum.

First, Urologists make decisions based on medical drivers, and especially the benefit-risk profile; they're looking for product that delivers the best efficacy with the least safety risk. We believe we're the clear winner versus Keytruda in that regard, because we have comparable efficacy, and a much better safety profile.

Second of all, Urologists make decisions on emotional drivers; it's well understood that they're very loyal and committed to their patient. They do not want to refer to another doctor like Medical Oncology, because they're concerned that other specialties do not adequately understand bladder cancer, and if the Urologist chooses Vicineum they get to keep treating

the patient. If they choose Keytruda, someone else will probably treat their patients. So, we think the emotional drivers are a big factor that the market will come to understand.

Then, finally, it's the business drivers. It's important to understand Urology clinics make their money through treatment rooms and diagnostic tests. If that Urologist chooses Vicineum, their Urology clinic gets to keep treating the patient and running diagnostic tests every three months including cytology, cystoscopy, and biopsy. On the other hand, if they choose Keytruda, the academic medical center, the Medical Oncology practice, derives that business benefit. Again, to this point, I believe that Urologists are always going to do the best thing for the patient - always make their decision based on medicine first - but if you can choose the best product for the patient, the treatment adoption will be accelerated if that is a more profitable approach for the clinic and the doctor.

So, I think there's a lot for the market to understand about the Urologist and the medical, emotional and business drivers that we think will really shape the treatment of non-muscle invasive bladder cancer.

The second thing, John, I think is - and we've talked about this, there's a good backup slide on this - the virtuous cycle that's created when you have the advocacy of all three customer segments: patients, payers, and physicians. This is pretty rare for new product launches to have advocacy from all three segments, and here’s why that's important: the stronger the advocacy from patients and their families, and the more they ask for a new product, the more likely the doctor is to prescribe that product. That phenomenon has been well documented.

The stronger the advocacy of physicians and Key Opinion Leaders, the more likely that payers will add the product to formulary and reimburse the product fully. Remember, it is mostly physicians that sit on these Managed Care P&T (Pharmacy and Therapeutics) committees, so that physician view really matters. Then the better the reimbursement is from payers, the lower the out-of-pocket costs for patients, and the better the patient access to therapy. I think when all three groups are advocating, the stronger the feedback loop is, and that can drive, I think very strong, early and sustainable uptake. That's the second phenomenon, I think is the interplay and the virtuous cycle between the different customer segments, and I think that's fairly unique in our situation.

Finally, I think something that people aren't completely paying attention to yet is just how lucky we are to have Keytruda as our primary competitor. Keytruda is arguably the most important Oncology product in the modern era. I mean, as you know well, John, they grew 30% last year, with sales at $14.4 billion. I haven't seen your projections, but many analysts project it to surpass $20 billion, and become the bestselling pharmaceutical product of all time, and I believe it has the best brand image of any Oncology product.

Keytruda is indicated for 19 types of cancer and in one of those, NMIBC, we believe we are better than them. We believe we will surpass Keytruda to become the market leader in NMIBC. I think, as you know, the real strength of our company is the commercial and marketing expertise, and when you see the dominant market leader in one single area, it has a transformational effect on your brand image and the value of your company. So, from a commercial marketing perspective, it's a very important phenomenon.

Anyway, we think we've got the best situation for a new product launch to be positioned against one of the most important Oncology products of all time. I believe by the time we launch our next indication, potentially for head and neck cancer, that that will be a whole different ballgame.

What should investors be watching for? Watch the role of Urologists and what motivates them, watch the virtuous cycle between physicians, payers and patients, and watch the market share battle between Keytruda and Vicineum. Obviously, after August, we'll structure our presentation so that's easy to follow. Any follow up on that, John?

John Newman: No, that's great. Thank you, Tom.

Thomas R. Cannell: Thanks, John.

Operator: Thank you. Your next question comes from the line of Roger Song from Jefferies. Your line is open. You can ask your question.

Roger Song: Great. Thank you, Tom, for taking the question. Maybe just a quick follow up on John's question earlier. So obviously, if you can get the Full Approval in August, there will be a real kind of upside. But, just tell us a little bit about the logistics, because, as far as I know, you've seen from the last the guidance, you may need to start the confirmatory study before the PDUFA date or maybe just finalize the protocol. Probably you already got some additional kind of guidance from FDA if you need a confirmatory study, and obviously, you are having kind of back and forth with the FDA right now, so tell us a little bit what we should. What is going to happen before the approval decision in terms of the confirmatory study, your site inspection, and the late cycle meeting?

Thomas R. Cannell: Yes. That's a great question. I think, as I've said before, it's definitely the FDA's preference that you launch your confirmatory trial right around the time of approval. So, we had a Type C meeting with the FDA; we agreed on the protocol synopsis and the overall approach. As we've talked about, we plan on targeting the less-than-adequate BCG population - that is patients that have had only one to six installations. So, we will be ready to go. We have a team to put together a clinical trial oversight team. And as we move through the process, if it seems increasingly likely that it's Accelerated Approval, we'll be ready in the third quarter to launch a study.

I will say even if they don't require a confirmatory trial, it's something I want to do anyway - to do that clinical trial in the less-than-adequate BCG population. We have data to suggest that Vicineum is even more effective in patients that have had less exposure to BCG. It also puts us on a path toward hopefully someday first-line therapy, with or without combination therapy, depending on how we design the trial. So, even if we don't need the confirmatory trial, we do intend to do a study in that patient population.

That's kind of the thinking right now, Roger, and then what I would say is, if we learn more at the late-cycle meeting, which is mid-July, then obviously we'll disclose that and we will come out and make sure that investors know what the update is there.

Did you have a follow-up, Roger?

Roger Song: Yes, I do have one follow-up. So first of all, thanks for the color. My next question is related to the financials, understanding you're contracting a CSO to do the sales. So just tell us a little bit about what is the level of the ramp up in terms of SG&A? And what is the pace since you have $110 million in the bank? And what is the current cash runway?

Thomas R. Cannell: Yes, yes, that's great. I'll just talk about the ramp up of the contract sales organization, I'll let Monica speak to what we think that cost is per annum for a contract sales organization of that size. So we've said publicly, it's 35 representatives, and up to 10 Reimbursement Specialists. We have got the National Sales Director hired, as well as the VP of Sales. We're in the process of and close to finalizing all the Region Sales Directors and

then we're getting ready to go with the representative interviews, and then training. So, all of that will happen throughout the spring, in getting those representatives ready to be out there in August. Same thing with the Reimbursement Specialists and the concierge call center that we will set up to support patients through the process. We have a lot of experience with Syneos; I've worked with them in the past and this is really their area of expertise. They can find talent, have a very expeditious recruiting process, and then train those representatives, and they're going to be ready to go. That's kind of how we're thinking about the roll out of the contract sales organization.

Monica, I'll just let you talk about OpEx in regard to that.

Monica Forbes: Sure, thanks, Tom. Hey, Roger.

We haven't guided specifically on what our cash burn will be once we stand up the sales force and build the full commercial team, but we have said with regards to the CSO and the number of representatives that we will hire, we expect roughly $10 to $15 million on an annual basis, for that part of the commercial team. Then I think you also referred to our cash balance. Just with regards to the cash balance of $110 million at the end of the first quarter, we do expect that, again, although we're not guiding on cash burn, we do expect the $110 million to be sufficient to fund operations through the fourth quarter of this year.

Roger Song: Great. Awesome. Thank you. That's all for me.

Thomas R. Cannell: Thanks, Roger.

Operator: Thank you. Your next question comes from the line of Arthur He from H.C. Wainwright. Sir, your line is open. You can ask your question.

Arthur He: Good morning, everyone. Thanks for taking my question. This is Arthur for RK. I just had a one question regarding the manufacturing part. So, as we know, there's an industry-wide backlog for FDA conducting the on-site inspection. I just wonder if these onsite inspections also required for the approval for Vicineum and how the communication is between you guys and the agency regarding that issue? Thank you.

Thomas R. Cannell: Yes, I'll just answer that at a high level, and then I'll check with Chad to see if he wants to add anything on top of it. Again, as the FDA prepares for the late-cycle meeting in mid-July, obviously, they're doing their clinical and their manufacturing site inspections. As we mentioned, because of the pandemic, which again, there was just something in the Pink Sheets that there's been delays kind of across the board in the FDA getting out; but, we do feel confident that they'll have all of those wrapped up in time so that we can have a good, really productive late-cycle meeting in July and are still on a pathway for potential approval in August of this year. And again, as you can imagine, the most important of those site inspections would be at Fuji, which is our bulk, drug substance manufacturer, and that's where probably 90% of the overall complexity and the work is around manufacturing. We feel very confident; Fuji was with us when we had the Type B meeting with the FDA in terms of demonstrating analytical comparability, and they're a world-class manufacturer with a real good track record with the FDA from a regulatory perspective. So, we feel good about how that's going, recognizing the site inspections have been a real challenge for the agency since the pandemic hit.

Chad, anything you want to add to that?

Chad Myskiw: No, Tom, I think you answered that very well.

Thomas R. Cannell: Great, thanks. Arthur, do you have another question or a follow up?

Arthur He: No, thank you. Thank you for the color. Thanks.

Thomas R. Cannell: Thanks, Arthur.

Operator: Thank you. At this time, there are no further questions on queue. I would now like to hand the conference over to our President and CEO, Dr. Thomas Cannell.

Thomas R. Cannell: Thank you, Ruby, and thank you, everyone, for your good questions today and your interest in Sesen Bio. I'd also like to thank take this time to thank our employees. You know, we only have roughly 30 employees, and they're just doing herculean work in bringing this product to market and being prepared for manufacturing and supply chain and all the commercial prep that's underway.

So, I just want to thank the team for everything they're doing; it's just an outstanding effort and they're working so well. You will be hearing again from us soon. Thank you again to all of our investors for your interest, and please stay safe and have a good week. So with that, that concludes our call for today. Thank you all very much. Ruby, I'll hand it back to you.

Operator: Thank you. This concludes today's conference call. You may now disconnect.