Sesen Bio – Business Update

CALL/PRESENTATION DETAILS
Date: March 15, 2021
Time: 8:00 am EDT

CORPORATE PARTICIPANTS
Dr. Thomas R. Cannell, Sesen Bio, Inc. – President, CEO & Director
Monica Forbes, Sesen Bio, Inc. – CFO
Erin Clark, Sesen Bio, Inc. – VP of Corporate Strategy & IR
Dr. Neal Shore, M.D., FACS, Carolina Urologic Research Center – Medical Director

CONFERENCE CALL PARTICIPANTS
Brian Clifford, Schonfeld Strategic Advisors LLC – Investor
Christopher Lawrence Howerton, Jefferies LLC, Research Division – Equity Analyst
John Lawrence Newman, Canaccord Genuity Corp., Research Division – Principal & Senior Healthcare Analyst Swayampakula Ramakanth, H.C. Wainwright & Co, LLC, Research Division – MD of Equity Research & Senior Healthcare Analyst

TELECONFERENCE REPLAY
An archived replay of the teleconference will be available on the Sesen Bio website (https://ir.sesenbio.com/events/event-details/march-business-update-conference-call-neal-shore-md-facs) for 90 days after the conference.

PRESENTATION

Operator: Thank you for standing by and welcome to the Sesen Bio March 2021 Business Update. 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, 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 our March 2021 Business Update call.

Joining me on today's call are Dr. Thomas Cannell, our President and Chief Executive Officer and Monica Forbes, our Chief Financial Officer. In addition, we are joined by Dr. Neal Shore, Medical Director for the Carolina Urologic Research Center, in Myrtle Beach, South Carolina. Dr. Shore is an internationally recognized expert in Urologic Oncology and is a practicing Urologist at the Atlantic Urology Clinic. Dr. Shore has a consulting relationship with us and he was also an investigator in our Phase II and III clinical trials for Non-muscle Invasive Bladder Cancer. Dr. Shore is here today to provide a clinical perspective of Vicineum and answer questions after our prepared remarks.

For those of you who have accessed this call via the webcast, we are sharing a presentation and we will be advancing the slides automatically. For those of you calling in, you can find the slides in the investors' section of the company's website at sesenbio.com. In addition, earlier this morning we issued a press release outlining some of the highlights that will be covered on the call today.

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.

Please turn to **slide 3** for a summary of key progress over the last 90 days. It is a transformative time for the Company and many of you have been following us for a long time and are aware of our Investor Relations' strategy, which is to tell you what we're going to do, execute those plans flawlessly and then tell you what we did. If you're signed up for email alerts, you received an email with an 8-K filing or press release each time one of the events on this slide occurred. We are very pleased with the progress to date and anticipate more good news in the coming months.

Turning to **slide 4**, I am happy to introduce Dr. Neal Shore, an influential Key Opinion Leader and leading Bladder Cancer clinical trialist. He is the National Director of Urology Research for 21st Century Oncology and maintains a busy, large Urology group private practice.

Looking at **slide 5**, you can see that not only is Dr. Shore a consultant and clinical investigator for Sesen Bio, but he has extensive experience across many Bladder Cancer programs. This breadth of experience provides a unique perspective in terms of clinical meaningfulness for Urology products.

With that, I will hand the call over to Dr. Shore. Dr. Shore?

Dr. Neal Shore: Thank you, Erin for that generous introduction, and good morning everyone. It is a pleasure to join the call today and share my clinical perspective in the area of bladder cancer.

Let's turn to **slide 7**, and I would like to begin by talking about the patient journey, which you see nicely woven in and out for the patient and for the physician too. Personally, I have been diagnosing and treating patients with bladder cancer for nearly 30 years now, and like so many cancers, it is a very heterogenous disease; we have some patients with low-grade and some with high-grade cancer, but we do have a proportion of patients who have aggressive disease. The journey can be complicated in how we ideally monitor them and the complexities of treatment. It can be stressful, both to patients and physicians. It can be humbling, especially when we are not making the ideal decisions at the right time.

Most of us who treat bladder cancer – Urologists, Medical Oncologists, even Radiation Oncologists as well – we are always trying to come up with the most innovate and effective approaches to optimize patient care and avoid two key issues. One is disease-recurrence for our high-risk Non-muscle Invasive Bladder Cancer patients, as well as progression, which means the disease progresses through the lining of the bladder into the muscle. Very importantly – we hear this phrase used very frequently – is maintaining quality of life, which we all want to do, especially as it relates to our Bladder Cancer care.

I'd also like to highlight on the slide the critical role of the Urologist. Invariably, patients are referred to the Urologist at the onset of demonstrating blood in the urine, and this can be visible blood in the urine or what we call gross Hematuria or macroscopic Hematuria, or it can be microscopic blood in the urine that is seen under the microscope on urine analysis. It is the Urologist who initiates and oversees the various diagnostic tests and these include an ever-expanding role of urinary biomarkers. The classic one we use is Cytology, but then, really Cystoscopy and Biopsy. Urologists use Cystoscopy looking inside the Bladder the way Cardiologists use a stethoscope, and that is really one of the key facets to Urologic expertise in evaluating for Bladder Cancer and ensuring the diagnosis of Non-muscle Invasive Bladder Cancer when we do a biopsy, as opposed to invading into the muscle. It is at that point where we make a decision as to intravesical therapy, and the gold-standard for years now has been BCG. We have had various degrees of success and optimization utilizing BGC strategies, whether it is half-strength, full-strength, third-strength, and the different schedules. We have learned quite a bit over the years, but nonetheless, we have to do the best we can to explain this to patients and how we pick intravesical therapy to avoid progression and recurrence.

So if you look at the bottom right part of the slide, there are realistically 3 choices for patients who no longer respond to BCG or, what we call, BCG-unresponsive.

The first thing is, we can say, okay, we did the appropriate Level 1 evidence for a BCG intravesical regimen; it didn't work. And now we have to offer you, the patient, radical cystectomy, which, in other words, is removing the patient's bladder and creating a form of urinary diversion. Later on in the program, and with some additional slides, I'm going to tell you why – and it's probably obvious to many of you who are not in the health care world of treating patients, but this is not a very appealing choice to have one's bladder removed.

We can, at this point, for BCG-unresponsive patients, refer them to a medical oncologist with the 2020 approval of a checkpoint inhibitor given intravenously, Keytruda, which is also generically known as Pembrolizumab. Now, most of the administration of Pembrolizumab for BCG-unresponsive Carcinoma in situ patients is administered by Medical Oncologists. Frankly, I administer it, and I'm trained and comfortable on administering various and all approved checkpoint inhibitors, but I think I'm really quite in the minority right now. A big part of that is the Urologist's comfort level and understanding in managing what are classically described as immune-related adverse events, which are very unique to all of the class of checkpoint inhibitors, the PD blockers.

Third, we can use other intravesical agents, such as different forms of chemotherapy. But really, hopefully, in the future, we're going to be able to use Vicineum.

At this point, we will move over to **slide 8**. This explains the mechanism of action of Vicineum and why I'm certainly hopeful it will become a treatment option for patients.

On the left-hand side, we see that Vicineum directly kills cancer cells; creates an apoptotic effect by inhibiting protein synthesis. It does this initially by binding to epithelial cell adhesion molecule, or the acronym EpCAM, which allows it to selectively attack cancer cells while limiting the impact on healthy cells, and that's always important when you try to avoid off-target side effects.

An additional and augmented aspect of the Vicineum mechanism of action involves the stimulation or the activation of the patient's immune system. We know that Vicineum causes immunogenic cell death, which results in the release of other antigens or neoantigens. When the T cell is presented – the normal population of white blood cells that fight off infection and cancer, that's the T cell – with these neoantigens, it leads to further activation and proliferation. These T cells are then able to recognize and attack the cancer cells. This is sort of T cell cellular proliferation.

For me, what is particularly compelling about this mechanism of action is that it leads us to contemplate the scientific hypothesis that Vicineum may have an additive effect when used in combination eventually with checkpoint inhibitors. Interestingly, a really exciting Phase I clinical study is being conducted at the NCI [National Cancer Institute] to test this scientific hypothesis; it's combining Vicineum with a well-described checkpoint inhibitor, Durvalumab. I'm really enthusiastic to see how those results turn out.

Please turn to **slide 9**, and this shows the clinical profile of Vicineum. You can see by looking at this slide that Vicineum appears to have a very favorable patient profile on the left relative to the safety profile on the right side. Invariably, patients, when I discuss therapies with them – Bladder Cancer, Prostate Cancer, Kidney Cancer – one of the first questions is: "well, what are the side effects, doctor? So what's the benefit? What's the risk profile?" I think this is really true of all of my colleagues, not really just in Urology, frankly, but in Medical Oncology as well, both community-based and academic-based.

Importantly, the FDA emphasizes that their decision-making approval of biologic agents is to review the benefit-risk profile. So with that, the FDA has recently awarded Vicineum Priority Review, and they stated that they're not currently planning to hold an advisory committee meeting for Vicineum. I think that these decisions reflect very favorably on the clinical profile for Vicineum. Additionally, when I think about that and the rigor that the FDA takes to these processes, it is really tremendous, especially given where we've been through many recent approvals and during the pandemic.

But also, when I think about this, I think patient outcome for these high-risk NMIBC patients is extremely important – efficacy outcomes – and you can see that at the bottom left of the slide. In the Phase III clinical trial, Vicineum was shown to allow 76% of patients to remain cystectomy free – in other words, not losing their bladders and requiring a diversion, a very major and complex surgery – out to 3 years. The overall survival, or what we sometimes abbreviate the OS, of 2 years, was 96% for patients on therapy with Vicineum versus a background, general population of 94%, both matched for age and gender. So, when we talk about saving and improving the lives of patients, these are really critical and meaningful endpoints and metrics.

Please now turn to **slide 10**. Let me further discuss with you radical cystectomy, because I think it really helps to review the cystectomy data and put it in a perspective. Off of that, what's the role of the bladder? The bladder is essential to normal voiding urinary function for men and women; it is actually also fully integrated with both reproductive and sexual function. So, it seems pretty clear, obviously intuitive, you want to keep your bladder intact because of all of those important life factors. The other part of removing the bladder, or what we call in the surgical parlance radical cystectomy, is a challenging operation. It is actually the operation that led me into Urology. It is quite an important operation. There's a lot of great anatomical dissection, and then one has to essentially – beyond removing this vital organ – create a substitute for urinary diversion. One can imagine how technically complicated and arduous this procedure can be and how one needs a lot of training and a lot of volume to continue one's surgical skills to get great results.

For example, in women, you don't just remove the bladder, but you also remove the female reproductive organs, involving the uterus, the cervix and part of the vaginal wall. In men, we not only remove the bladder, but we remove the prostate and the seminal vesicles and all aspects of the urethra.

For me, having done many, many radical cystectomies throughout the course of my training and my career in Urology, you do see the intraoperative, the short-term and long-term postoperative complications. I think for patients, they recognize when doing a little bit of reading that they want to do everything and anything they can to preserve their bladders.

When we recommend a cystectomy, it's not a glib decision point in the patient journey. So, logically and not surprisingly, more than 50% of patients will just say, even though it's the appropriate gold standard for life preservation when they have an aggressive form of the cancer – BCG-unresponsive, high-risk NMIBC – they want other options. They oftentimes will refuse surgery. Some of these patients may not be really good surgical candidates for the anesthetic risk, the blood loss risk and the complications that are involved.

That brings me to why we're here: I really think that we need alternatives for BCG-unresponsive patients, and that's where a drug such as Vicineum, with the data that we're presenting, could be an exceptionally important option in real-world clinical practice.

Please turn to **slide 11**. This looks at the time to cystectomy for patients who responded to Vicineum at the 3-month interval versus those who did not. What you see here is that if you're an initial responder to therapy, the average patient in our studies was cystectomy-free for over 1,000 days, for nearly a 3-year period.

So, if you don't respond, then your option at that point would be for your Urologist to recommend bladder removal or cystectomy; 40% to 50% of patients will have a cystectomy in those next 2 years, which is consistent with those patient preferences I mentioned earlier.

I think the important point here is that in this comparison, it helps to adjust for both potential patient and physician preferences regarding cystectomy and it allows us to think about the benefit of novel intravesical advances of therapy, such as Vicineum. I think this is really significant and will be greatly appreciated by not only patients, but clearly by my Urology colleagues.

Please turn to **slide 12**. This is a slide from the Phase II study that Erin mentioned earlier. I was an investigator in this trial as well. In the Phase II, we did perform bladder mapping, and it helped us to identify patients who had a partial response to therapy, which was defined as a reduction in tumor size or no change in tumor size.

I like this slide because it really represents – one might describe – more reflective of real-world experience and shows what we see in clinical Urologic practice. Often, when testing an investigational clinical trial product – a therapy – we'll see that patients are responding to a therapy, but they haven't yet reached a complete response. The CR, is usually the clinical endpoint of a trial, and if we don't get to that, per FDA guidance, we have to discontinue the therapy. But, in the real-world and clinical practice, if a partial response to therapy is observed, I think many physicians would consider maintaining therapy to see if the patient ultimately would continue to progress to a complete response. So, there is the sort of nuance of understanding trial endpoints versus real-world practical application.

Back to a point I made earlier on Vicineum, and assuming this – the NCI trial, which is combining Vicineum with Durvalumab, a well described and approved checkpoint inhibitor in other forms of cancer, including Bladder Cancer – demonstrates an additive or synergistic effect, I think many Urologists will consider adding the checkpoint in combination with Vicineum, taking advantage of the multidisciplinary team and involving their Medical Oncologists. I think this is pretty cool; it's something to watch for in the future as the trial reads out.

Please can please turn to **slide 13** right now. This is a data cut which I find very promising. In my clinical practice, context matters. What I say to a patient has to be personalized to their own specific experience and stage of treatment. It still informs us of the importance, so to speak, of the art of medicine.

What you see on this slide is, if you have a complete response at 3 months, that these patients had a 42% chance of staying disease-free for another year. It allows us to better have that patient-physician shared decision-making discussion and level set on expectations accordingly; I think that's really important when you're thinking about radical cystectomy as still being the standard of care. If they remain disease-free at 6 months, the story is a bit different; their prognosis has actually improved. With our trial data, it suggests they have a 56% chance of staying disease-free for another 12 months. The prognosis keeps improving, the longer they keep responding.

This a nice discussion to have with patients and their families because we're trying to provide hope for bladder preservation. It's important to remember that the patient's journey with their Bladder Cancer does require vigorous, rigorous, long- term follow-up and clinic visits with cystoscopies, potential biopsies. There can be the need for ongoing therapies, but these therapies have to be evidence based – they have to be credible. The data on slide 13 resonates to me, and I believe it should resonate in a well-articulated discussion with patients, their families and their caregivers.

Up until now, I've talked a lot about efficacy and outcome. Let me shift gears a second. Let's talk about safety. Looking at the Phase II data, the product, Vicineum, to me clearly seems safe and well tolerated. Ongoing in further discussions with the FDA, from the Phase II, we increased the dose of Vicineum for the Phase III trial. For patients on maintenance, for example, it resulted in doubling of the dosing frequency. Despite the increased dosing and increasing the intensity of the dosing schedule, Vicineum remained safe and well tolerated in our Phase III trial readout. It didn’t appear to show any increase in any severity of adverse events; that, to me, is very reassuring. There didn't appear to be any age-related increase in adverse events. Again, very important because the Bladder Cancer patients tend to be elderly; often times that increases the level of their frailty. So, that's just a global demographic regarding Bladder Cancer.

Please turn to **slide 15**. This summarizes a really interesting report by the Institute for Clinical and Economic Review, the acronym is ICER. It's a 213-page report. You can see the link at the bottom of the slide.

ICER has a really well-deserved reputation as one of the most important watchdog groups on pharmaceutical pricing in the US. To me, they're sort of analogous to the U.K. version of the NICE. I appreciate the analysis that they perform because it supports and encourages value-based care, which has been a mainstay proposition desire for all the urologic organizations that I've been involved with, from LUGPA [Large Urology Group Practice Association] to AUA [American Urological Association] to SUO [Society of Urologic Oncology]. We have to reduce healthcare costs in the United States. As in many disease states, these costs are really becoming prohibitive for optimal patient care.

Therapeutic developers can be frustrated, I think, by the ICER report because sometimes negative analyses can impact the pricing of medications. Nonetheless, I think this was a really informative report. As you can see on the slide, their report was very favorable to Vicineum. They voted 8-to-3 in favor of Vicineum and estimated that the Vicineum therapy would project, if approved, to decrease cumulative health care costs by about $100,000 by year 5.

I'm encouraged by that as we move more and more away from volume-based to value-based health care; it potentially augurs another competitive advantage for Vicineum, if it achieves approval. I don't think there's any doubt at this point in time that my colleagues and patients want medications at a lower cost that will facilitate adoption of new therapies.

Finally, on **slide 16** – if you could turn there, please – let's look at the clinical trial data for Vicineum as it is juxtaposed to clinical trial data for the recently approved Keytruda. Congratulations to them getting approved and for their ODAC and resolution in January of 2020. It was really kind of amazing that, that was able to be performed in-person prior to the developing of the pandemic.

These are data that come from the FDA. As you can see, the 2 products have very similar CRs, complete responses, at 3, 12 and 18 months. Vicineum has the time to cystectomy data, which I just talked about, while Keytruda didn't have cystectomy data as an endpoint in their registration trial.

I think, perhaps, the biggest difference between these agents is the safety and tolerability where it really does appear that there's an advantage for Vicineum based upon the data that's been published and presented. Regarding the mode of administration, this does fit greater into the wheelhouse, so to speak, for Urologists as a general statement. Urologists are very comfortable with intravesical therapies, which allow them to maintain their role in the patient Bladder Cancer journey, and it is Urologists who will continue to be at the forefront.

Let me hand it back to Erin at this point. Happy to take questions later.

Erin Clark: Thank you, Dr. Shore, for that great talk. Next, I will turn the call over to our CFO, Monica Forbes, to provide a financial overview. Monica?

Monica Forbes: Please turn to **slide 18**. With the recent critical decisions made by the FDA regarding our regulatory path, we are positioned to launch a product that we believe has the potential to be best in class with projected global peak revenue of $1-$3 billion.

I would like to remind you that in addition to a potential synergistic marketplace where there is alignment between patients, payers and physicians, in terms of their advocacy for a product, the market is also highly concentrated with roughly 30% of physicians treating about 75% of patients.

We believe this will allow us to have a very focused and efficient sales force of roughly 35 specialty sales representatives and about 10 reimbursement specialists via a contract sales organization, which we plan to deploy shortly before launch. This assumption translates to an estimated $10 to $15 million investment on an annualized basis while achieving the reach and frequency levels necessary for a successful launch.

We have also learned the importance of caregivers in the treatment decision-making process. A high percentage of the time, the caregiver is a spouse, child or grandchild, and because of this we are developing 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.

It is for these reasons that we believe we are positioned to launch Vicineum into a marketplace that enables a strong uptake and, equally importantly, product growth, which is supported by an efficient commercial model. We believe all of this translates into lower opex, stronger operating income growth, and a shorter path to corporate profitability.

Next on **slide 19**, as we continue to strategically prepare for commercial launch it is critical for us to understand the range of alternative futures for peak global sales. To inform our assessment, we completed a Monte Carlo simulation with four key inputs for the US market: eligible patients, peak market share, number of year-one doses that a patient will receive, and pricing. For the regions outside of the US, we use a multiplier that accounts for prevalence and price relative to the United States.

We feel that from the low end to the high end of the range, we have captured 80% of the variance in terms of valuing peak revenue for Vicineum at $1-$3 billion.

Additionally, we remain focused where we can create the most value for patients and for shareholders, and we continue to make tremendous progress in our 4 biggest global markets, which represent over 80% of the total global opportunity for Vicineum. Highlights include the acceptance of the BLA for Vicineum by the FDA with a PDUFA date of August 18th in the US, and the submission of our MAA in Europe earlier this month. Then, in China and the MENA region, we signed recent partnerships, and as part of both of those agreements we are eligible for milestones and royalties.

Please turn to **slide 20** for a few financial highlights. In January, we issued an update on our year-end cash position of $55 million in cash, cash equivalents and restricted cash as of December 31, 2020. As you can see, we have significantly improved our financial position in the first two months of 2021, with estimated cash and cash equivalents of approximately $98 million as of the end of February 2021.

We have been able to steadily strengthen our balance sheet leveraging non-dilutive capital from our OUS partners and efficient and strategic use of our ATM, while avoiding a traditional financing event. This balance of funding sources allows us to minimize dilution while we continue to build value for our shareholders, which is represented by the changes in stock price and market cap you see on the slide.

We've also been slowly cleaning up our warrant structure, and as of February, have fewer than 1.5 million warrants remaining. This of course significantly reduces the potential for future dilution from warrant exercises.

Turning to **slide 21**, we continue to manage our balance sheet through stage-gated investments which are focused on our highest priority initiatives, which are represented as the dark blue bars on the graph, while strategically raising capital to strengthen our cash position, as shown on the dark purple bars. This balance of managing opex in a disciplined manner and efficiently using the ATM will allow us to begin funding the US commercial launch anticipated for later this year.

Finally, please turn to **slide 22**. We filed our preliminary proxy statement earlier this morning, which includes the proposals for shareholder vote at the 2021 Annual Meeting. It is important to note that the proposals are designed to align with the guidelines from the two leading, independent proxy advisor firms, ISS and Glass Lewis, whose roles are to provide guidance to investors on corporate governance and responsible investment solutions.

When drafting our proposals, we considered not only the appropriate benchmarks for the average company of our size and stage of development, alignment with guidance issued by Glass Lewis and ISS, but most importantly what we believe to be in the best interest of all stakeholders. So, when looking at the proposals, and specifically the proposal to increase the number of authorized shares, we believe an increase of 200 million is a reasonable amount to comfortably support future investment in strategic initiatives, which we believe to be in the best interest of Sesen Bio and our shareholders. For instance: funding the US launch of Vicineum, which is intended to create revenue and contribute to achieving profitability, attracting and retaining valuable talent, and establishing and expanding strategic partnerships and relationships.

Importantly, we have not requested an increase in the number of authorized shares since the Company went public 7 years ago in 2014, and we believe the requested increase will provide us with the flexibility necessary to execute on our strategy as we transition into a commercial, revenue-generating company. We are hopeful this may be the last time the Company needs to request additional shares, as we believe this increase will be enough for us to achieve corporate profitability, which is our most important short-term goal.

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

Thomas Cannell: Thank you, Monica, and good morning everyone.

Please turn to **slide 24**, which shows our anticipated regulatory timeline for the US and Europe. We have made a lot of exciting progress, and the company is at an inflection point in our transformation into a full-scale commercial organization. In the US, our BLA was accepted by the FDA under Priority Review and, if approved, our current plans are to begin promotion to physicians and patients in August, and to have commercial product supply available in Urology clinics by the fourth quarter.

In Europe, we recently announced the submission of our MAA [Marketing Authorization Application]. This is a significant milestone for one of the largest regions in terms of unmet need for NMIBC. Our next step will be to start the pricing and reimbursement process with Health Technology Assessment groups like NICE. We believe we have a compelling story for these economic analyses given our clinical dataset. We would then anticipate potential approval in Europe early next year.

Turning to **slide 25**, as we prepare for commercial launch, our brand vision is very clear. We believe we are positioned to launch a best-in-class therapeutic that will improve patient outcomes, while reducing overall healthcare costs. We aspire to be the leader in the Non-muscle Invasive Bladder Cancer market in 2022, and we project a significant global commercial opportunity, with peak sales of $1-$3 billion.

It is important to note that the forecasted revenue opportunity Monica reviewed earlier, and that you see here, only accounts for our core program: BCG-unresponsive NMIBC – and does not include potential business adjacencies and pipeline assets, which I will discuss more on the next slide.

Please turn to **slide 26**. We believe there is significant potential for Sesen Bio beyond our core program. We are currently laser-focused on regulatory approval and a world-class launch, but we plan to steadily progress into other important business adjacencies to support sustained and profitable growth of Sesen Bio. Our pipeline plans include stage-gated investments, based on financial and regulatory triggers, and we plan to share more on these important business adjacencies later in the year.

Please turn to **slide 27.** We covered a lot of ground on this call, and Erin, Monica and Neal did a great job providing very helpful information on the potential opportunity for Vicineum.

In the end, our story remains very clear: 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. 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 the call for questions. Operator?

QUESTIONS AND ANSWERS

Operator: (Operator instructions). Our next question comes from Brian Clifford with Schonfeld.

Brian Clifford: Hi, good morning.

Two questions: one for Dr. Shore and one for Monica. Dr. Shore, maybe could you just give us a sense of what percentage of your patients would be considered eligible for treatment with Vicineum? And then, can you talk to maybe how that might change the practice of Urologists? Is this – give us a sense of how – just given the price tag you were talking about and the economics, how this could really change the practice?

And then for Monica, could you give us an updated share count?

Dr. Neal Shore: Sure. Happy to answer that. I appreciate the question.

Yes, it can vary depending upon your volume of these patients that you see. I think one of the things that was referenced in the presentation that you saw with the consolidation of Urology Practice in the United States – groups aggregating, especially the larger groups, and as well as the academic centers – we're seeing much, much higher volume concentrated in a lesser percentage of broadening larger practices. So, if you have a large volume based upon a large number of providers – physicians and advanced practice providers, nurse practitioners, physician assistants – you see a lot of Bladder Cancer. About 75% of these patients who come in right out of the gate have what's described as Non-muscle Invasive Bladder Cancer. A good third to a half of those will have high-risk features: carcinoma in situ, high-grade papillary disease, T1 disease, which is a disease that goes through the basement membrane sort of just almost touching into the muscle or, what we call, the lamina propria of the basement membrane.

When we treat these patients with traditional standard of care BCG, the induction course and then maintenance course, unfortunately, close to 50% of these patients are going to progress. So, these numbers can really add up dramatically and quickly.

What we've done over the course of time as we give inappropriate recurrent administrations of BCG when the data doesn't support doing it – additionally, on top of that now, we have a global BCG shortage – and so patients then are put into clinical trials or they will get a radical cystectomy, or they just want something. So, they may get some intravesical chemotherapies that don't have Level 1 evidence for benefit through a well-conducted Phase II and Phase III study.

To answer your question, it's a very significant percentage of the patients who present with high-risk NMIBC. Nearly half will end up requiring treatment, whether it's a cystectomy or additional intravesical therapy after they've undergone BCG treatment.

What's exciting to me, too, is how we're going to address BCG-naive patients in the future and looking for other alternative intravesical applications. And I think that's an interesting and exciting area for further research with Vicineum.

Thomas Cannell: Great. Thanks, Dr. Shore. We'll hand off – Monica, the other question was on share count. We'll hand that one to you.

Monica Forbes: Great. Thanks Brian.

You'll see on both the Form 10-K that we filed this morning on the face of the document and also in the preliminary proxy, as of March 8, we had 168 million shares outstanding, plus we have roughly 15 million to 16 million additional shares reserved for employee incentive programs and to a lesser degree, warrants. So, on a fully diluted basis, roughly 185 million.

Thomas R. Cannell: Any follow-up questions, Brian, or is that good for you?

Brian Clifford: No. That does it for me.

Operator: (Operator Instructions) Our next question comes from Swayampakula Ramakanth with H.C. Wainwright.

Swayampakula Ramakanth: Good morning. This is RK from H.C. Wainwright. A real quick question for Dr. Shore. Thanks for explaining your thoughts regarding Vicineum. How – or when in the journey of a patient does the radical cystectomy come up as a treatment methodology in consideration?

Neal D. Shore: Yes, sure. A patient will present with high-risk Non-muscle Invasive Bladder Cancer and again, there are sort of 3 buckets: carcinoma in situ, high-grade papillary disease, and T1 lamina propria invasion. Or, if they come in the 20%, 25% who present with muscle-

invasive disease, if they're already muscle-invasive disease and they don't have on imaging evidence of disease – significant disease outside of the bladder, specifically lymph nodes above the pelvic outlet – then they are right away direct candidates for bladder removal, radical cystectomy.

The former group, the high-risk NMIBC – the standard of care is to start them on BCG, assuming they can tolerate BCG, and the overwhelming, supermajority of patients clearly can, but there are some side effects to it. Nonetheless, they get the induction course, they get maintenance, or they get sometimes a second induction course.

At the end of the day, if they respond, it's great. We continue them on maintenance BCG therapy. But a very significant percentage, depending upon the data and the meta-analysis – could be 30% to 50% of patients with high- risk NMIBC – will become unresponsive to their BCG administration. That's where we've been historically in this conundrum of patients saying, "Okay, now you're saying, take my bladder out doctor, but don't you have anything else?"

In January, Pembrolizumab received approval based upon their Phase II study of Keynote 57 for CIS, and so, they have that option versus cystectomy. Certainly, what I'm hopeful for – and I can guarantee you everyone in the Urologic community is hopeful for and patients, too – is another option that can offer patients avoidance of having their bladder removed. Succinctly, an intravesical therapy is highly appealing to the Urologists who don't traditionally give parenteral intravenous systemic therapy for Bladder Cancer.

Thomas Cannell: Great. Thank you, Dr. Shore. RK, did you have a follow-up or anything else?

Swayampakula Ramakanth: No, no, I'm good.

Operator: Our next question comes from Chris Howerton with Jefferies.

Christopher Lawrence Howerton: Hey there. With respect to Keytruda, what would be kind of the expectations in terms of the Urology community getting a certificate to administer Keytruda? And what would be the expectations around the palatability of those training procedures? And I guess, maybe I have a follow-up after that with the confirmatory study.

Thomas R. Cannell: Great. Dr. Shore, I'll hand that one to you.

Neal D. Shore: Sure. Happy to take it. So, it's an interesting use of the word certificate. We don't really have this notion of giving out certificates of training once we complete our formal training, known as Surgical Urologic Residency and/or a Uro-oncology Fellowship. There are ongoing advances in surgical technique and therapies throughout all of Urology and all of cancer, so it falls upon organizations, and they come in many different shapes and forms. What I've dedicated much of my career to is educating my colleagues, both in the community and in academia to say: Urology needs to expand its treatment armamentarium. That said, when the checkpoint inhibitors came out in 2016, we now have 5 approved in Urothelial Cancer. Recently, there have been 2 withdrawals that you're probably well aware of for frontline metastatic Bladder Cancer.

But that said, the development and understanding of adverse event management specific to any new therapy, whether it's in Prostate Cancer, for example, in the androgen receptor blocker or a new radiopharmaceutical or a checkpoint inhibitor in Bladder Cancer or Kidney Cancer, it's incumbent upon Urologists, Medical Oncologists, Radiation Oncologists to take courses and read the literature, and they can be non-CME [Continuing Medical Education] or CME-provided courses. I've been proud to be part of many of those to try to expand comfort and expertise and knowledge in therapies because then that opens up access to patients.

But, as you can probably imagine, there's a person-power shortage in Urology and Medical Oncology. There's this expansion of health care requirement, expansion of the elderly

population, or what oftentimes is called the graying of America or the silver tsunami. So, there's just only so much bandwidth that urologists have. They really have always been very comfortable with anything that's endoscopic, which is another way of saying, inserting a tube, a catheter or a scope through the urethra and into the bladder. I think that's a relatively noncontroversial statement to make. So, I think that's been one of the challenges so far with the adoption of Keytruda since its approval in January 2020.

Christopher Lawrence Howerton: Okay. Well, yes, that's very clear and, I think, consistent with what we've heard from other Urologists as well. Tom, I wasn't sure if this was asked yet, but I am looking forward to hearing maybe your view and Dr. Shore's with respect to the reevaluation of the accelerated approval of checkpoint inhibitors.

Obviously, more broadly in Oncology, but I think salient to this conversation is for Bladder Cancer. How does that affect your view of the commercial opportunity? What are some of the things that you're going to be looking for there in terms of their reevaluation? Then, I'll also note that Europe for accelerated approval – is there any risk to your reevaluation in terms of risk-benefit down the road?

Thomas Cannell: Great. Thanks, Chris. Well, Dr. Shore alluded to this a bit. Maybe I'll answer it, Neal, and then I'll hand it back off to you for any additional comments.

Just a little background for everyone who's not following this closely. The FDA has instituted its accelerated approval program to allow for earlier approval of drugs that treat serious conditions, that fill an unmet medical need. As everyone knows, we've guided since our pre-BLA meeting with the FDA in 2019 that we expect an accelerated approval pathway for Vicineum.

For products which receive FDA accelerated approval, companies are required to conduct a study to confirm the anticipated clinical benefit. These studies are known as Phase IV confirmatory trials. If the confirmatory trial shows this drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place to remove that indication from the product label.

As some of you have seen in the news, the FDA has been conducting a thorough industry-wide review of its accelerated approval program, and recently, as Dr. Shore mentioned, 2 companies have issued press releases in the Bladder Cancer space. AstraZeneca announced the voluntary withdrawal of Imfinzi, which is Durvalumab, and the indication is for advanced or metastatic Bladder Cancer in the US, as it did not meet its post-marketing requirements. It does not impact other FDA-approved indications for Imfinzi. Then, Roche announced its voluntary withdrawal of the US indication for Tecentriq in prior platinum-treated metastatic Urothelial Carcinoma, which also does not affect other FDA-approved indications.

Chris, to answer your question, I think it means 2 things for us: first, if you look at our competitive scan in the IR deck, we had been assuming that Tecentriq and then Durvalumab would be new checkpoint inhibitors that we'd be competing with in NMIBC. So, this probably lowers their probability of success and is yet another delay of potential competitors.

Then second, it shows why we've been working so carefully with the FDA on the design of our Phase IV confirmatory trial to make sure we meet our primary endpoints. As we disclosed in late 2019, we are targeting a less-than-adequate BCG population for our confirmatory trial with primary endpoints of complete response rate and duration of response. Based on analyses from our Phase III study, we believe that Vicineum should be even more effective in this patient population, which has been exposed to less BCG. So, we remain confident we'll hit the endpoints in our confirmatory trial and gain traditional approval at that time.

Dr. Shore, would you like to add anything to that?

Neal D. Shore: No. I think that was perfect. Well stated. No, I have nothing more to add.

Thomas Cannell: Great. Thank you. Chris, any other follow-ups or other questions?

Christopher Lawrence Howerton: Yes. Maybe just a quick kind of housekeeping one. With respect to that confirmatory study, anything about its conduct or initiation that would affect the BLA process or PDUFA?

Thomas Cannell: Great question. What we would like to do is initiate the study right around the time of FDA approval, and I think that's the preference of the agency as well. So, we've had a Type C meeting with the FDA to discuss the protocol synopsis. We'll have a follow-up meeting with them later this spring to review the entire study protocol, and then we want to be ready to go for the first patient fairly close to the time of approval and get that study underway.

Operator: Our next question comes from John Newman with Canaccord.

John Lawrence Newman: Dr. Shore, thanks for spending some time with us this morning. I'm just curious, Dr. Shore, if you could talk to us about your perception as to how most Urologists decide when to refer to a Medical Oncologist? Obviously, it's probably going to be different for each physician, but I'm just curious as to what it is that triggers that? And whether perhaps having more therapeutic options would potentially delay that referral? Thank you.

Dr. Neal Shore: Thanks for the question. It's a really interesting question because there's a spectrum of how different Urologists, depending upon their understanding of the disease state, will utilize intravesical treatment or suggest cystectomy, depending upon their training.

If you have been well trained to do cystectomy or you have a colleague within your organization, your practice, then you will probably have a much quicker trigger to advise patients to go to cystectomy. Given the caveats of what I described earlier, that it's quite a morbid and life-altering decision and surgical undertaking, but nonetheless, it can be life-saving, which is clearly important. So that would be one camp of urologists, certainly, those who have that surgical expertise at their realm, but nonetheless, patients don't want their bladder removed; I mean they just don't, if they could do anything to help it.

Now, the other group of Urologists who may not have that access to great outcomes or the better outcomes, even the best outcomes, have significant morbidity and mortality associated with it, will continue to try intravesical options that don't have necessarily Level 1 evidence of benefit – so continued, repeated courses of BCG, which have been shown to not benefit patients, or they'll go with some Phase II data of intravesical therapies that have shown some evidence of success, specifically chemotherapies involving Gemcitabine and Docetaxel. There’s the approved agent known as Valrubicin that got approved years back, but honestly, its efficacy benefit is rather minimal. I don't know how much it's really being used today; I think it's being used rather minimally.

There are clinical trials, of course. And so if – indeed, if Vicineum does get approved, it will be a first-in-class if it can get out there some time this year, as Tom and Erin went through the time line. I hope that answers your question.

We see a spectrum. We see a spectrum of less-than-optimal recurrent intravesical treatment, and then we see some of our colleagues who have access to clinical trials to try to stave off cystectomy, but do it in a way that's prudent and rigorous in monitoring patients, so that they don't progress and/or they'll go to cystectomy.

Thomas Cannell: Great. Thanks, Dr. Shore. John, did you have another follow up? Great. Then Shannon, are there any other questions in the queue?

Operator: We have a follow-up question from Brian Clifford with Schonfeld.

Brian Clifford: Thanks for taking the follow-up. Great. Tom, maybe can I just get a comment on your thoughts on the capitalization of the company here, the $98 million in cash you have? Should we expect a significant increase in the burn rate this year? Are you going to continue to beat the ATM? How much room do you have on that? Do you have enough – are you well capitalized for the near or an intermediate term here?

Thomas Cannell: Yes. Thanks, Brian. It's a great question. As Monica presented, we're really delighted with the progress we've made. We started the year with $55 million cash and cash equivalents on the balance sheet. We now, as of March 1, had $98 million. And as Monica mentioned, I think we've been able to do that very efficiently through nondilutive capital, such as OUS upfronts and milestones, as well as very efficient and careful use with the ATM. So, we're in a very good position. This is significantly more money on the balance sheet than the company has ever had since we went public about 6 or 7 years ago, which you need to have in the year of a commercial launch.

We feel well positioned. We're in a very good place with a strong balance sheet. That gives us lots of optionality, and so we really feel confident going into the launch phase right now. But of course, we'll still pay close attention to any possible strategic options that are out there. Brian, did you have a follow-up or any other questions?

Brian Clifford: No. That's great.

Operator: I'm currently showing no further questions at this time. I'd like to turn the call back over to Dr. Thomas Cannell for closing remarks.

Thomas Cannell: Great. Thank you, Shannon. First of all, I want to thank everyone for a very productive discussion today, a great call. I want to thank Monica, Erin and Chad, Rachelle and Dr. Shore for all the work they've put into making this a great call.

I also want to thank all the Sesen employees who are working so hard, getting so much done, and making so much progress on our journey to help save and improve the lives of patients.

And finally, thank you to our investors. This is obviously an exciting time for the company. There will be a lot of news coming your way. Until then, I hope you all have a great week. That concludes our call today, and I'll hand it back to you, Shannon.

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