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SERES THERAPEUTICS, INC.

(Name of Registrant as Specified In Its Charter)
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The following is a transcript of a presentation by Eric D. Shaff, President and Chief Executive Officer of Seres Therapeutics, Inc., at the Canaccord Genuity Growth Conference on August 13, 2024.

John Newman: Good afternoon, everyone. Thank you very much for joining us at the 44th Annual Canaccord Genuity Growth Conference here in sunny Boston today. I'm John Newman, one of the biotech analysts here at the firm. We are very excited to have Seres Therapeutics with us today, and the CEO, Mr. Eric Shaff. Eric?

Eric Shaff: John, thank you for having us at this year's conference. Good afternoon, everybody. It's great to be here. I appreciate everyone's patience with our technical difficulties. It's a great time to be in person to talk about Seres, to talk about the microbiome on the heels of our announced Vowst transaction with Nestlé, and ahead of our upcoming SER-155 data readout.

Eric Shaff: Seres is a company developing novel bacterial therapies for life-threatening infections in medically vulnerable patient populations. Infections in these patients are frequent, they're serious, they can sometimes be fatal, and they certainly are costly to the healthcare system. And we have a track record of regulatory and clinical success initially focused on C.difficile infection, but we believe that our core technology platform can be applied to a variety of additional indication areas. So again, we're pleased to be here with you today to talk about the difference that we have made in patients' lives, and our plans to continue to make that difference in patients' lives going forward.

Eric Shaff: Now we will be making forward-looking statements in today's presentation, so I would refer you to our 10-Q that we filed today. And in fact, we actually have two pages of disclaimers, and I would note that there's important information relating to our transaction, our expected transaction with Nestlé. This is made available to you on 8K that we filed today and it will be available going forward.

Eric Shaff: So, at Seres, we live and embrace the idea of transforming patients' lives using consortia of bacteria as therapy. There has certainly been a notion historically that there was harmful bacteria, there might be neutral bacteria, but the idea that bacteria and the health of the ecosystem of bacteria in your body, and in particular in your gut, we know that that is essential to human health. We know that's the case, and we have actually proven it as a company. And what we'll talk about today is why we're so excited about our path forward. Our foundation starts with Vowst, which is a solution for patients which is highly effective, well-tolerated in oral formulation, a solution for patients where innovation in the last decade in this disease area has been lacking, in our opinion.

Eric Shaff: We are a very short time away from our next data readout for our placebo-controlled SER-155 Phase 1b study. We had encouraging results from the first cohort of this study, and the next cohort is on the on-deck circle. And we certainly believe that the opportunity with SER-155 and where we go next if 155 is successful will be considerable to patients, to shareholders, and to other series stakeholders.

Eric Shaff: So, let's start with a discussion around Vowst, which is our first successfully developed therapeutic. Vowst was approved in April 2023 as a novel treatment for recurrent C.difficile infection. This is the first ever oral approved microbiome therapy. Vowst is the best evidence that these therapeutics are not an aspiration or a hope to help patients in the future, they are transforming lives now. And Vowst supports the idea of why we can see the power of our science and our platform to change patients' lives. Vowst showed a remarkably clean safety profile and a robust clinical activity, with 88% of patients showing sustained clinical responses in our pivotal phase 3 study.

Eric Shaff: Mechanistically, Vowst was designed to reduce C.difficile pathogen abundance, crowding out harmful bacteria and repopulating the gut with a healthy and diverse set of bacteria. Now, Vowst provides an excellent example of medically vulnerable patient population, which can be addressed with our platform technology, and we think that C.diff is just the tip of the iceberg with respect to the therapeutic potential of our medicines. We spent the last decade building know-how and capabilities to discover, develop, and manufacture therapeutics, and that experience is unique and relevant to the success of SER-155, SER-147, as we will talk about, and what comes after those programs.

Eric Shaff: Now last week, we announced the sale of Vowst to our partner, Nestlé Health Science, who will continue to lead Vowst's commercialization. The asset purchase agreement provides series with meaningful short-term infusion of capital to continue development of our therapeutic pipeline, including $175 million in a cash upfront payment, a prepaid sales-based milestone, and an equity investment due upon closing of the deal, reduced by a net 18% settlement of operating obligations due to Nestlé.

Eric Shaff: We expect the transaction to close within 90 days of our August 6th deal signing. Now I really believe that this transaction is the best of two worlds and puts Seres in the best position to be successful going forward. We continue our commitment to C.diff patients by ensuring Nestlé takes full ownership of Vowst. Nestlé has the commitment, the resources, and the capabilities we believe to drive Vowst's sales forward. We also put Seres in the best position to be successful going forward including supporting our pipeline. We expect to emerge from this transaction with a clear line of sight to support SER-155 and what comes after it following our imminent SER-155 phase 1b readout expected in September.

Eric Shaff: So, let's talk a little bit more about science and opportunity. We are developing products that could transform the care of medically vulnerable patient populations who are at high risk of serious GI and bloodstream infections. Now these include patients with a significant number of complex medical needs. For vulnerable patients at high risk of infection, we believe that current standards of care are not meeting their needs. Recent publications such as the findings that infections cause more than half of non-relapse mortality in CAR T recipients highlight that infections are causing substantial mortality in these patients despite current treatment and prevention options, and we talked about this a little bit more this morning at our Q2 earnings announcement.

Eric Shaff: Based on disease characteristics and the mechanism of our drugs, we believe that there are a range of potential indications that we could target. Now our current pipeline is primarily focused on populations with high risk of infections, but we also believe that our approach could benefit patients with a range of diseases, including inflammatory bowel disease. Now, we know that the microbiome is essential to human health, and disruptions to a healthy microbiome, or what we call in the company a "dysbiosis," has direct connections to serious disease. Disruptions to a healthy microbiome can cause bacterial pathogens to dominate the GI microbiome and some of these bacteria can translocate across the epithelial layer. The result of this can be serious bloodstream infections and inflammation. There has been a question historically as to whether this microbiome disruption can be drugged or not. We believe definitively that we have answered that question with Vowst, and we intend to do it again with other disease indications.

Eric Shaff: Now how do our products work? Our therapeutics are designed to modify the disrupted GI microbiome and restore critical functionality. Specifically, Seres Therapeutics are consortia of bacterial strains that are cultivated and grown in our lab. We use commensal bacterial strains commonly found in the healthy human gut, and we select strains from our bacterial strain library based on their functional properties to provide specific biological activity relevant to disease. We deliver them in an oral capsule to the GI tract, where they populate into the GI microbiome. Once present, they carry on biological activities, for instance, reducing pathogen abundance, improving gut barrier integrity, enhancing mucosal layers. These are all functions required to improve clinical outcomes, we believe, and help to reduce or eliminate translocation of pathogens from the gut into the bloodstream.

Eric Shaff: Now I want to highlight a few important points related to safety where we believe too often, new drug modalities run into complexity before even having a chance to establish efficacy. And as a reminder, our products are based on bacteria that are naturally found in the gastrointestinal tract of healthy humans. We believe that this approach of using healthy human-derived bacteria provides important safety dimensions. And based on data from Vowst and from several other clinical programs, the safety profile of our products has been strong, has been well tolerated. This includes patients in the current SER-155 study who are fragile. And given that safety is a primary reason for drug development failures, we believe that our approach provides an important advantage that should meaningfully reduce risk and support probability of success.

Eric Shaff: Now, our pipeline focuses on several medically vulnerable patient groups who are at risk of developing life-threatening infections and related complications. We believe that clinical success that we saw in Vowst provides important validation based on the demonstrated activity and safety of that product and of our approach. Our lead program, as you can see, is SER-155, which is currently being evaluated in cancer patients who have received allo stem cell transplants. Now in addition to allo-HSCT, we believe that there are numerous additional opportunities for future development, which I'll talk about in the next few slides.

Eric Shaff: We're also developing a second bacterial composition, SER-147, that has been formulated for certain metabolic disease, specifically chronic liver disease, also a population at high risk of infection. And we expect this program to be ready to enter the clinic next year.

Eric Shaff: Just a little bit more time on the design and intent of SER-155. So just for background, allo-HSCT patients undergo a really difficult treatment regimen of chemotherapy, conditioning therapies and treatments, and antibiotics during their transplant. Now, as a result of this, these patients can be highly vulnerable to infections and other complications post-transplant, and these are incredibly sick patients. We know that these patients also have substantially disrupted GI microbiomes, making them susceptible to GI infections and other consequences.

Eric Shaff: It's really one of the reasons that we selected this indication as our next step after recurrent C.diff infection. Our collaborators at Memorial Sloan Kettering had data showing that these patients with reduced GI microbiome diversity are more likely to die due to infection or GvHD. And we designed SER-155 rationally based on the understanding of the changes in the microbiome in allo-HSCT patients, as well as our understanding of which bacteria we think could replace the functions that they are missing.

Eric Shaff: Now if we dig a little bit deeper into the literature, the understanding or the underlying biology that leads to high infection risk in allo-HSCT patients has been studied pretty extensively. And it's known that many of these patients have highly disrupted microbiomes that are often dominated by known bacterial pathogens, such as enterococcus, as seen on the left panel here. Enterococcus domination, as one example in allo patients, has been associated with increased mortality, as seen in the right panel of this slide. And the hypothesis is that by reducing this underlying pathogen domination, we should be able to dramatically reduce the risk of infections and poor outcomes.

Eric Shaff: So, the SER-155 consortia was selected or rationally designed to address several microbiome-related functions linked to GI infection and GvHD in allo-HSCT recipients. Pre-clinical data show reduction in pathogen bacterial colonization, oral SER-155 administration led to a 2 to 3 log reduction in VRE and CRE titers compared to untreated bacterial colonization in mouse models. We also saw improvements in the epithelial barrier integrity, which we believe is important to prevent pathogens from entering the bloodstream. In addition, we saw favorable changes in immune function. I would also note that these model systems are useful in optimizing our other programs going forward. So, there's value to the platform in general.

Eric Shaff: Now, a little bit more on SER-155, we are currently evaluating SER-155 in a Phase 1b study in post-HSCT settings. The study is designed to evaluate safety, SER-155 bacterial engraftment, and signals of clinical efficacy. The study has two cohorts.

Eric Shaff: We reported supportive data from the open-label Cohort 1 last year. I would also note that we received fast-track designation from the FDA, and we were pleased to gain experience with this first patient population, which is far more complex than past patient populations that we have studied. And we finished enrollment in a placebo-controlled second cohort with results expected in this September.

Eric Shaff: So just to quickly review the Cohort 1 data that we reported on last year. The data were highly encouraging. The safety profile was well tolerated, which is important in this highly medically vulnerable patient population. We also saw evidence showing efficient engraftment of SER-155 organisms and importantly, a reduction in GI pathogen dominance. In our study, the rate of pathogen domination was far lower than a historical reference cohort that we had been working on to establish with Memorial Sloan Kettering. One of nine subjects had a pathogen overgrowth versus what we would have expected to be significantly greater, greater than 60% in the MSK cohort, and importantly that one pathogen event was transient. Now this data, while early, increases our confidence of seeing a clinical outcome of reduced infection rates, and that will be one of the things that we'll be looking for in this next upcoming data readout.

Eric Shaff: So, speaking of that readout, we are eagerly looking forward to the Cohort 2 data from the placebo-controlled portion of the study in September. In this data set, we will be evaluating safety. We'll be looking at bacterial engraftment and impact on biomarkers and host functions and importantly, we'll be looking at infection rates and the severity of infection. We believe that mechanistically, SER-155 could also reduce the rates of the most severe forms of GvHD. However, our expectation is that the background rates are lower and that this study is not likely sufficiently sized to evaluate these endpoints.

Eric Shaff: So why is this important? And why beyond the clear medical need do we think that there's an opportunity to create value with SER-155? The use of viral prophylaxis in allo patients shows that reducing infections in this patient population can result in meaningful commercial opportunity. As just one example or one data point, Prevymis is a Merck product that's intended to prevent CMV reinfection. It achieved $600 plus million in 2023 worldwide revenues, predominantly from use in allo-HSCT patients with an approval to extend to prevention in specific kidney transplants.

Eric Shaff: Allo is an expensive procedure with many potential complications. And as we've talked about, infections cause these patients to utilize the ICU more, stay longer in the hospital. Critically important, delay other treatments. In some cases, there certainly is mortality. So, our belief is that agents that can prevent these consequences are useful and we believe that they will be used by physicians to keep patients in their primary treatment regimens, and we think that that supports a strong pharmacoeconomic case going forward.

Eric Shaff: So, for these reasons, we think that there's a meaningful opportunity for SER-155 and allo-HSCT. There are a significant number of procedures each year in the US and top European pharma markets. Serious bacterial infections are frequent and the standard of care to prevent them is we believe inadequate, creating a strong medical need for better prevention. Infections are also expensive due to the increased ICU utilization, additional medical treatments, and increased duration of hospital stays.

Eric Shaff: So, if the clinical outcomes from our SER-155 Phase 1b study are positive, we plan to engage regulators to confirm an accelerated path to approval. We're already planning for what's next in this case, in the case of a positive outcome, and it's not unfamiliar to us. So, we believe that the path forward for SER-155 could potentially resemble our experience with Vowst. This includes moving forward potentially with a single pivotal study utilizing a modest study size. We will work with the agency as we did with Vowst to obtain the necessary designations to accelerate our path forward, and ensure alignment in the study design and safety requirements. We also plan to engage with EMA and European countries to assess the path forward and enable a global study. And these conversations should also set the foundation for rapid indication expansion studies in adjacent populations.

Eric Shaff: So, what are those beyond allo? We think that there's a number of opportunities for further development. For example, the similarity between allo and autologous stem cell transplants creates one adjacency. AML is a leading malignancy requiring allo-HSCT, so it makes sense to explore use in that population. And all of these populations have the same basic characteristics as allo: High risk of life-threatening infections, infections derived from GI pathogens, and a favorable or maybe an established clinical and regulatory path. So, with favorable results, we have the potential to indicate multiple clinical studies within the next 12 to 18 months.

Eric Shaff: Now as I mentioned earlier, oops. We're also developing SER-147, which is a new consortia with an initial focus on patients with chronic liver disease. We're looking at patients with decompensated cirrhosis. This is a highly prevalent condition, two and a half million patients across the EU and the US. These patients also suffer the same functional losses as allo patients.

Eric Shaff: They have substantial GI microbiome disruption, which is associated with mortality. They lose gut barrier integrity. The current standards of care offer little prevention. And we've designed 147 to learn, to build on what we've learned with 155. We also have designed 147 to ensure flexibility in formulation to maximize access for patients who might benefit from it.

Eric Shaff: I think our capabilities as a company have been established, so I'm going to roll through this quickly. We have capabilities to identify disease targets from clinical data sets, identify and optimize candidates with our platforms, and move to clinical studies quickly.

Eric Shaff: I'd also just quickly like to comment on our manufacturing capabilities. I think in a new field, manufacturing now has chronically misunderstood or underappreciated as a strategic facet of moving forward.

Eric Shaff: So, we start with Vowst. We transform thousands of patients' lives with Vowst. SER-155 is next with our 1b study readout expected in just a matter of weeks, SER-147 after 155, and then we think that there are significant adjacencies for us indicated here in blue as well as AMR more generally.

Eric Shaff: So just to close again, thanks to Canaccord for having us at the conference this year to speak. Vowst, we believe, is just the start of our journey to impact patients' lives. Our expected transaction with Nestlé will support our ability to move forward with our pipeline starting with SER-155, and we look forward to talking about that data set and potentially what comes after it very soon with you. So, with that, I'll conclude. And John, I don't know if we have time for questions, but would be happy to take them.

John Newman: Great. Thank you very much, Eric. We've got a couple minutes here. So, a question that I have for you, Eric, is with the SER-155 study, one of the things that the Sloan Kettering data suggests is that you are able to prevent the emergence at high levels of serious pathogens or basically to keep levels low for bad bacteria. Based on the results that you previously showed in the C.diff indication, how do you think those results sort of read over potentially for 155? What I'm getting at here is, if you already have evidence that your technology can keep levels of bad bacteria low, how does that potentially translate to the 155 study?

Eric Shaff: Yeah. So great question and maybe I'll start and Matt's here, so I'll ask Matt to comment on some of the science. But you know, one of the reasons that we are, John, so excited about this upcoming readout is that we've got two significant dimensions that we will be studying as part of this clinical experiment. Obviously, the clinical data, the safety, or potential signals of efficacy that we've talked about, but then we've got the whole pharmacology side of it. And what will be really interesting, particularly given the fact that it's a placebo-controlled phase 1, is to see if those signals line up. So, if we see a reduction in infection, as an example, how does that correlate or how does that connect with what we're seeing on the microbiome analysis side, the decolonization of pathogens? Obviously, the first cohort was small, so we have an opportunity to potentially see those connections between a much larger data set. Maybe Matt can comment further.

Matt Henn: Yeah. And John, I think anchoring on pathogen abundance and that reduction of pathogen abundance as Eric said we saw in the first cohort, there is a deep literature including numerous publications the New England Journal and Nature Medicine, that have shown in large cohorts how increases in pathogen abundance and overgrowth in the gastrointestinal tract is linked to significant negative clinical outcomes, which include increases in bloodstream infections, which includes increases in severe forms and acute forms of graft-versus-host disease, as well as other complications.

Matt Henn: And the underlying biology of those complications is linked to the metabolic function of the microbiome and the gastrointestinal tract. And so, what SER-155 is doing is going after those specific mechanisms that are tied to how you actually prevent those pathogens from taking up residence in the GI that actually prevent damage and actually even repair potentially the damaged epithelial barrier due to chemotherapy, radiation treatments, and other factors, which helps prevent the bacteria moving from the gut into the bloodstream, and then obviously there's immune pieces to that. So, in the end what we're doing is the rise of those bad bacteria is very problematic not just for the infections, but other complications that come along with that so we think we have an opportunity to address multiple dimensions of this disease.

John Newman: Super. Maybe we can sneak one additional question in here. The question I have is, and Matt, I think you alluded to this a bit, but I'd like to hear from both Eric and Matt. One of the things that you're also looking at in this study is GvHD. And as many people know, graft-versus-host-disease is a big problem with transplant. It's very bad, not something that we want to happen. What is understood about the potential mechanism for SER-155 when it comes to GvHD?

Eric Shaff: So maybe I might ask Matt to comment, then maybe Lisa can comment on how we think about GvHD relative to the study design.

Matt Henn: So biologically, part of what's happening in the context of graft-versus-host-disease is that you have an inflammatory state in the gastrointestinal tract. So, chemo, radiation, leads to all kinds of compounds that can have inflammatory responses. And what happens with those inflammatory responses, they create an immune response when the person has the new graft of stem cells. And that is all primarily a T-cell-driven response. And what we know is that basically there are specific set of microbes in the gastrointestinal tract that modulate and drive CD4 T cell differentiation into either T regulatory or particularly, Th1 or Th17 cells. And there are bacteria in SER-155 that produce a set of specific compounds that we have identified at Seres that actually drive that differentiation towards T regulatory cells. So, we are looking to induce immune tolerance.

Lisa Von Moltke: Yeah. And as you said, GvHD is still a big problem for transplant patients, but the good news is, is in the last year, there's been a big development, which is the advent and more ubiquitous use of post-transplant cyclophosphamide, which is leading to pretty precipitous drops in the rates of GvHD. Unfortunately, severe GvHD is still happening, but it's happening at a much lower rate. So, we would not be surprised to see that the incidence in the trial overall is going to reflect that what's happening in the medical community right now, which is lower rates everywhere.

John Newman: Great. Excellent. Well, thank you, Eric and team. And thank you to Seres for being with us today. Thank you to everyone in the audience as well.

Eric Shaff: Thank you.

Forward-Looking Statements

This communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this communication that do not relate to matters of historical fact should be considered forward-looking statements, including statements about the financial terms, timing and completion of the sale of VOWST assets to SPN; the receipt of future payments and the use of proceeds of the transaction,; the timing and results of our clinical studies and data readouts; future product candidates, development plans and commercial opportunities; operating plans and our future cash runway; our ability to generate additional capital; our planned strategic focus; anticipated timing of any of the foregoing and other statements which are not historical fact.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: (1) we have incurred significant losses, are not currently profitable and may never become profitable; (2) our need for additional funding; (3) our history of operating losses; (4) the restrictions in our debt agreement; (5) our novel approach to therapeutic intervention; (6) our reliance on third parties to conduct our clinical trials and manufacture our product candidates; (7) the competition we will face; our ability to protect our intellectual property; (8) our ability to retain key personnel and to manage our growth; (9) the occurrence of any event, change or other circumstance that could give rise to the termination of the Purchase Agreement; (10) our failure to obtain stockholder approval for the proposed transaction or to satisfy any of the other conditions to the completion of the proposed transaction; (11) the effect of the announcement of the proposed transaction on our ability to retain and hire key personnel and maintain relationships with our customers, suppliers, advertisers, partners and others with whom we do business, or on our operating results and businesses generally; (12) the risks associated with the disruption of management's attention from ongoing business operations due to the proposed transaction and the obligation to provide transition services; (13) our failure to receive the installment payments or the milestone payments in the future; (14) the significant costs, fees and expenses related to the proposed transaction; (15) the uncertainty of impact of the 50/50 profit and loss sharing arrangement on our reported results and liquidity; (16) the risk that the proposed transaction will not be completed within the expected time period or at all and (17) we may not be able to realize the anticipated benefits of the proposed transaction. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the SEC, on August 13, 2024, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this communication. Any such forward-looking statements represent management's estimates as of the date of this communication. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this communication.