Hansa Biopharma

Interim Results and Q1 Earnings

April 24, 2025, 08:00 a.m. Eastern

CORPORATE PARTICIPANTS

Peter Nicklin - *Chairperson*

Evan Ballantyne - *CFO & Senior VP*

Hitto Kaufmann - *Senior VP, Chief R&D Officer*

Renee Aguiar-Lucander - *CEO*

PRESENTATION

Operator
Good day, and welcome to the Hansa Biopharma Interim Results and Q1 Earnings Conference Call. All participants will be in listen-only mode. Should you need assistance, please signal a conference specialist by pressing the star key, followed by zero. After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press star, then 1, on your telephone keypad. To withdraw your question, please press star, then 2. Please note this event is being recorded.

I would now like to turn the conference over to Peter Nicklin, Chairman of the Board, Hansa Biopharma. Please go ahead.

Peter Nicklin
Good afternoon, and good morning, everybody. Welcome to the Hansa Biopharma conference call to review our Q1 results for 2025. I'm Peter Nicklin, Chairman of the Board of Hansa Biopharma. You'll recollect, in June this year, I actually reached my 30-year anniversary as Chairman of the Board. Joining me today is Evan Ballantyne, Chief Financial Officer; Hitto Kaufmann, our Chief R&D Officer; and Renee Lucander, our newly appointed CEO.

Before we turn to the Q1 results, you are most likely aware that earlier today, we announced the departure of Soren Tulstrup, CEO of Hansa Biopharma, effective immediately. Over the course of his tenure, whilst with the organization, Soren successfully navigated the company through several key milestones and financial rounds. The Board and I certainly appreciate his leadership and commitment to the company and wish him well for any future endeavors.

Later in the call, we will hear from Renee, who has been appointed as CEO effective immediately. Today is her first day at Hansa and while she is in the room with me here, I trust that you will agree that it would be unfair to ask her to host this call with you today.

So, with that, please turn to Slide 2. Please allow me to draw your attention to the fact that we will be making forward-looking statements during this presentation, and you should therefore apply appropriate caution. Please turn to Page 3. Today, we will discuss the progress we have made during Q1 and review the quarterly performance. The presentation will take roughly 15 to 20 minutes, after which there will be an appropriate -- an opportunity to ask questions during a Q&A session.

Please turn to Slide 4. In Q1 2025, total revenue reached SEK 66.3 million, including IDEFIRIX sales totaling SEK 65.7 million. This represents a 39% product sales increase over the prior quarter. Please remember, Q1 2025 represents the final negotiated lower pricing in certain markets in comparison to the Q1 2024. We are encouraged by the continued growing European market uptake seen in Q1, reflecting the increased number of transplant clinics with initial and repeat usage of IDEFIRIX and growing clinical consensus on the appropriate use of IDEFIRIX as desensitization treatment for highly sensitized patients as demonstrated by consensus and clinical guidelines being published at both the international and local market level.

Please turn to Slide 5. Thank you. We continue to make good progress with the pipeline and are working towards several key catalysts in the second half of 2025. In the quarter, we announced the completion of enrollment of patients in the post-authorization efficacy and safety or PAES study -- Phase III study in Europe. As a reminder, the trial is part of our obligation to EMA based on conditional approval of IDEFIRIX in Europe. We'll talk more about the study in a moment.

During the quarter, we also had positive regulatory agency interaction with BfArM, the Federal Institute for Drugs and Medical Devices in Germany and gained alignment on a proposal -- on a proposed clinical trial in myasthenia gravis for HNSA-5487, our next-generation molecule with redosing potential. There is high unmet need for better options to treat acute phases of this disease, and we believe that HNSA-5487 has the potential to address this. Hitto will share more on this later on in the presentation.

As we look ahead in 2025, we turn our focus to delivering several key catalysts, including data from the Phase III GOOD-IDES-02 study in anti-GBM, and the U.S. Phase III ConfIdeS study in kidney transplantation, as well as data from the Phase II IDES trial with our partner, Genethon in Crigler-Najjar syndrome and presentation of the data from the Phase II 09 trial in Guillain-Barre syndrome, as we call it, GBS. We also expect data from the Phase Ib Sarepta study with our partner, Sarepta in Duchenne muscular dystrophy, which has enrolled the first few patients. Currently, several IDEdeS trials are temporary halted due to the IDEdeS safety update in March, including the Sarepta-9001-104 study that we are involved in.

An independent review committee occurred that -- concurred that overall ELEVIDYS benefit risk profile remains favorable and importantly, no material impacts are anticipated on the timelines of these studies.

Before moving to the next slide, I'd like to highlight our ongoing efforts to publish and present our science to the scientific and clinical community. Importantly, there have been several new international and market-specific clinical consensus guidelines recently published on the appropriate use of imlifidase as a desensitization strategy in highly sensitized kidney transplant patients. This underscores the increasing awareness and belief by the clinical community in the benefits of imlifidase in desensitization.

I'll ask you to turn to Slide 6, please, the next slide. Thank you. In Q1 of 2025, we completed enrollment of patients into the PAES study in Europe. The study is part of the company's obligation under the European conditional marketing authorization following conditional approval of IDEFIRIX in 2020 by EMA. The study remains on track to read out in the second half of 2026 and is intended to support full marketing authorization in Europe at that time. Twenty-two transplant centers were part of the trial with 14 centers having treated a total of 50 transplant patients. This is important because it means that participating centers now have both the clinical experience and protocols in place to treat highly sensitized kidney transplant patients in future.

We believe these key participating centers will continue to utilize IDEFIRIX to desensitize appropriate patients now converting to commercial product and thus, contributing significantly to continued product sales growth and most importantly, ensuring even more patients will have access to this innovative desensitization therapy and a potential life-saving kidney transplant. Just this week, a center in Italy that participated in the PAES study transferred its first patient to commercial IDEFIRIX. As indicated on the slide, the next step is to complete the 12-month follow-up in 2026, followed by submission to EMA to enable full approval.

I'd ask you to turn to the next slide, please. As stated previously, we continue to make solid progress with the commercialization of IDEFIRIX in Europe. In the quarter, we saw four additional transplant clinics gaining an initial experience with IDEFIRIX and the number of clinics with repeat usage following a successful first experience continues to grow. Our engagement with European key opinion leaders and medical societies is underscored by the continued publication of new

consensus and clinical guidelines on the appropriate use of imlifidase in desensitization of highly sensitized kidney transplant patients.

Just this quarter, we saw new international consensus guidelines published in the Journal Transplantation Direct and also new national guidelines issued in Spain. Finally, during the quarter, we secured access in 3 additional European markets, and IDEFIRIX is now reimbursed in a total of 18 countries, including the first -- the five largest European markets. Yesterday, we also learned that we now have reimbursement in Switzerland, underscoring continued advancement of reimbursement in markets throughout Europe.

I would now like to turn to Hitto for an update on the progress that we've made with our pipeline projects. Hitto, over to you.

Hitto Kaufmann
Thank you, Peter. Please turn to Slide 9 for an update on the pipeline and clinical development highlights to date. As you can see, we continued to make good progress across the pipeline in all three therapeutic areas. And in the fourth quarter, we shared several updates in both the autoimmune and gene therapy areas. I'll now walk you through some of the specific files and studies we have been going and the clinical development plans we have in place.

Please turn to Slide 10. I'm pleased to share that we continue to make good progress across all eight active clinical trials. And as you can see on the right and as Peter has mentioned previously, we have several key catalysts in the second half of the year. In 2025, there have been six peer-reviewed journal articles on imlifidase, including two on the 17-HMedIdeS-14 study, which is the five-year data we have shared previously. Of note, we had a positive regulatory agency meeting with BfArM on the development path for HNSA-5487, our next-generation molecule with redosing potential.

The meeting confirmed the suggested clinical trial design in myasthenia gravis, an indication with a new immunology. We aligned on investigating the safety and efficacy of HNSA-5487 in myasthenia gravis patients, utilizing short and long interval redosing at two dose levels. This approach will facilitate reliable and fast recruiting. Furthermore, we received confirmation on meaningful efficacy endpoints, including patient-reported outcomes such as the MG-specific Activity of Daily Living Scale, MG-ADL, and physician-reported outcomes like the quantitative MG scale, QMG. I'm incredibly pleased with the team's work to get us to this point and look forward to sharing more in due course.

We announced positive results in October '24 regarding NICE-01, the first-in-human trial and findings from a 12-month analysis of that data for HNSA-5487. The analysis demonstrated that HNSA-5487 can robustly and very rapidly reduce IgG levels, has redosing potential and a favorable safety and tolerability profile in the study subjects. We continue to believe HNSA-5487 has a highly differentiated profile compared to published data from studies with other IgG-targeted therapies.

Additionally, I'm pleased to share that data from the 15-HMedIdeS-09 Phase II study of imlifidase in Guillain-Barre syndrome, also known as GBS, has been accepted for presentation at upcoming medical congress. We look forward to sharing this data with the clinical community. It's worth mentioning that we are hosting a virtual science deep dive discussion on June 16 at 2:00 p.m. Central European Time -- at 8 a.m. Eastern Time on GBS. This is part of a larger series of deep dives we plan to hold throughout the year. The intention is to discuss the current diagnosis and treatment of GBS, as well as the existing unmet need that exists for patients and clinicians.

I'm thrilled to be joining my colleague, Elisabeth Sonesson, Global Franchise Lead, Autoimmune at Hunter, as well as two key opinion leaders, Dr. David R. Cornblath, MD with Johns Hopkins University, and Simon Rinaldi, MRCP, PhD with the University of Oxford. Registration is required for this event and can be found on our website. We hope you can join us.

We anticipate that we will also have data from the GOOD-IDES-02 Phase III trial in anti-GBM. As a reminder, the GOOD-IDES-02 trial is a Phase III open-label controlled, randomized multicenter trial across Europe and the U.S. and is evaluating renal function and the need for dialysis at six months in patients with severe anti-GBM disease.

Encouraged by our Phase II data, we believe imlifidase has significant potential in improving the outcome of these patients and address the unmet medical need. Imlifidase has been granted orphan drug designation for the treatment of anti-GBM disease by both the U.S. Food and Drug Administration and the European Medicines Agency. Later this year, we anticipate that from GNT-018-IDES, a Phase II trial in patients with Crigler-Najjar syndrome with the pre-existing antibodies against adeno-associated virus vectors or AAV. The trial will evaluate the efficacy and safety of a single intravenous administration of Genethon's gene therapy, GNT-0003 following pretreatment with imlifidase. GNT-0003 is currently being evaluated in a pivotal clinical study in France, Italy and the Netherlands and has received prime status from the European Medicines Agency.

As Peter mentioned, several ELEVIDYS studies have been temporarily halted due to the safety update provided in March. We look forward to continuing our collaboration with Sarepta on SRP-9001-104. Importantly, Sarepta does not expect a material impact on the timelines for these studies. And based on the findings from an independent data review committee, the benefit risk profile remains favorable to continue dosing in the PAES trials without changes to study protocols.

Finally, the confided U.S. pivotal Phase III trial was fully randomized in May '24, and we plan to deliver data in the second half of '25, followed by a BLA submission to the U.S. FDA. Please turn to Slide 11 for a summary of long-term data and various publications.

The 17-HMedIdes-14 study is a prospective observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration. Importantly, trial data was pooled with data from four Phase II trials and showed sustained positive outcomes out to five years in most highly sensitized patients who received an imlifidase-enabled kidney transplant.

The five-year extended pooled analysis is a continuation of the analysis at three years of cross-match positive only patients. The pooled analysis showed sustainable positive outcomes out to five years in most highly sensitized patients who received an imlifidase-enabled kidney transplant. After five years, patient survival rate was 90% and graft survival was 82%, in line with outcomes seen at three years post-transplant. At five years, mean estimated glomuleral filtration rate, eGFR, was 50 mL per minute per square meter. EGFR is a measure of how well the kidneys are working in the body. The extended pooled analysis has been published in several key journals and presented at key medical congress.

We continue to look for ways to share this important long-term data with the community. I will now turn the presentation over to Evan to cover financial performance.

Evan Ballantyne

Thanks very much, Hitto. Let's walk through the company's financial performance for Q1 2025. If we go to the next slide. Total revenue for Q1 2025 was SEK 66.3 million, representing an 18% increase compared to Q1 2024 of SEK 56 million. Product sales for Q1 2025 were SEK 65.7 million, representing a 39% increase as compared to Q1 2024. Additionally, this represents a significant increase over the previous quarter. As Peter mentioned, we continue to see fluctuation in our performance quarter-over-quarter. However, it should be noted that year-over-year performance continues to increase.

Quarterly volatility reflects the unpredictability of the organ allocation market. We expect this fluctuation to diminish over time, having completed the post-approval efficacy study and as Hansa continues to enter new markets. Could we go to the next slide? For Q1 2025, SG&A expense totaled approximately SEK 76 million, which was 16% favorable to the prior period. Restructuring activities helped to reduce total year-over-year SG&A expense. R&D expense in Q1 2025 totaled approximately SEK 64 million and were 38% favorable compared to Q1 2024. The favorable decrease in R&D expense was primarily driven by restructuring actions.

In Q1, net financial income and expense represented income of approximately SEK 57 million in contrast to an expense of SEK 59 million in Q1 2024. Changes in financial income and expense are primarily driven by noncash expense related to the NovaQuest note and changes in the U.S. dollar exchange rate against the Swedish Krona. In Q1 2025, the operating loss of approximately SEK 93 million was 71% favorable compared to the Q1 loss of SEK 159 million. The improvement in Hansa's operating loss compared to the prior year was driven by increased sales and an overall reduction in expense, a very positive trend.

Please go to the next slide. Cash used in operations in Q1 2025 totaled SEK 152 million. In Q1 2025, cash and cash equivalents totaled SEK 250 million. As we mentioned in the Q1 earnings report, given the priorities and projects, the company anticipates a cash runway into Q4 2025. Further expense management would allow the company to extend its cash runway into early 2026.

And now I would like to turn the presentation back to Peter for closing remarks and for the Q&A portion of the call.

Peter Nicklin
Thank you, Evan. With this overview, our presentation is now concluded. I would like to mention that we are postponing the upcoming AGM that had previously been scheduled for June 4 to a later date in June. We will share the new date with you in due course. And if there's questions around that, obviously, the main reason for it is the newness of Renee to our team to give her a little bit more time before an AGM were to take place, which I trust you understand. I would like to take the opportunity to welcome Renee now to the company as the new CEO of Hansa Biopharma. Renee, would you like to say a few words?

Renee Aguiar-Lucander
Sure. Thank you, Peter. I'm very excited to join Hansa at this point of the company's journey. I hope to bring some relevant experience and insights to the table, and I really look forward to engaging with all stakeholders once I've had some time to review and assess the product pipeline and organization in some more detail. I look forward to bringing you all some updates, if not earlier, than certainly in the Q2 report. And with that, I turn it back over to you, Peter.

Peter Nicklin

Thank you, Renee. Let's now turn to questions. I'm sure many of the listeners may have by now. Operator, can you please begin?

QUESTION AND ANSWER

Operator
Yes, thank you. We will now begin the Question-and-Answer Session. To ask a question, you may press star, then 1 on your telephone keypad. If you're using a speakerphone, please pick up your handset before pressing the keys. Any time your question's been addressed, you would like to withdraw it, please press Star then 2. At this time, we will pause momentarily to assemble the roster.

And the first question comes from Suzanne van Voorthuizen with Kempen.

Suzanne van Voorthuizen
Hi, there. This is Suzanne from Kempen. Thank you for taking my question. Maybe first on the CEO change. Of course, a warm welcome to Renee. I'm looking forward to work with you again. But, if possible, from the Chairman, I would like to hear more on what were the drivers behind this change in leadership as it's effective immediately? Some color will be helpful. And then from Renee, I'm curious to hear what you see as the biggest opportunities and the biggest challenges around the -- that you wish to tackle better sooner than later. And then I have some questions on the programs as well. Thank you.

Peter Nicklin
Thank you, Suzanne, for the question. And I haven't realized you'd worked with Renee before, but that's good news. Okay. I'm sure there are others on the call, too. The reasons for the change, the drivers for the change, and obviously, I'm not going to go into specifics concerning individuals and various performance characteristics of the old and new. But I will talk in general terms. I mean, Soren was with the business for seven years. He led the business, as I said, successfully through a period of preapproval. He took it through approval here in Europe. He launched the product here in Europe, and he continued to advance the science of the business and we look back at those seven years of dedicated work and thank him for that period.

However, every business and certainly all the businesses I've been involved, that's the right time for leadership and for different styles of leadership. And I felt together with my Board and then discussion with some of our investors as well that it was time for a change of leadership of the company, maybe a somewhat different approach to the leadership, and this was the right thing to do. Obviously, we considered a number of candidates in the process. And when I met Renee and others of my Board met Renee as well, we were all convinced unilaterally that she would be the right person to take the company forward.

And it's never done lightly. And I can tell you, as many hours of good discussion on this topic, all considerations and so on. As I said, it's never a great time to change CEO. But I think at this time, this is very much the right thing to do, and I'm convinced Renee is the right leader for this business going forward.

Renee Aguiar-Lucander
Hi, Suzanne, I look forward to working with you, too. So, in terms of kind of the opportunities and challenges, so I think that there's nothing new under the sun. As you know, I think I have a strong affinity to rare diseases in general. Hansa obviously -- it's a late-stage opportunity, really having two Phase III readouts expected in the second half of this year. I think that there is an attractive

commercial potential in the U.S., both for kind of the existing commercial product in Europe, that type of -- but also for other kind of rare diseases, so kind of autoimmunity really in general.

And obviously, I think there is also a highly interesting potential in gene therapy that I think needs to kind of be explored further and with more depth. And then obviously, there's a maturing kind of European commercial footprint as well. So, I think that this really kind of has a significant number of opportunities and potentials to play with and really develop and grow. And I think that's kind of ultimately what attracted me to this particular opportunity.

In terms of challenges, I think that they are also kind of pretty obvious. I think every time we kind of open a newspaper or look at any screen in this kind of day and age, I think that there are obvious challenges in the kind of macro environment, whether that is rates or tariffs or FDA or resources. I mean I think there's just a generally very, very high level of uncertainty. And as we're all familiar with that, that kind of generates kind of unproductive capital market settings and so I think that's clearly, I think, a challenge for the company is really to kind of ensure that there is sufficient funding in place. But also, I think that the company has a sustainable kind of base operation going forward that's appropriate in terms of kind of cost base.

I also think that there are opportunities here to work with partners, whether that is out-licensing on a geographic basis or other kind of opportunities, but I think there are quite a lot of other opportunities as well to kind of draw upon in order to secure kind of that stable kind of sustainable operating environment.

Suzanne van Voorthuizen
Got it. Thank you. That's very helpful. And maybe on the programs, on the repeat dose program, 5487, there's a plan to start a study for the indication of MG crisis. I've broken up for a second, so apologies if this was already covered. But can you recap where you stand in the process in terms of regulatory feedback, study design thoughts and when you expect to start the study? And then my last question is on the Phase II kidney readout that would like over the summer. What level of data disclosure should we be expecting when the top line release will be there? Will this be only whether the primary endpoint was met or where -- will there be an actual eGFR effect in numerical terms also be shared? Thank you.

Peter Nicklin
Thank you, Suzanne. I will pass this to someone with far more expertise on the detail than I have to Hitto, who's on the call. So Hitto, could you please take that question?

Hitto Kaufmann
Sure, Peter. Hi. Thanks for this question. 5487, we are very happy that we have this very constructive and productive scientific advice exchange with BfArM. And that was in particular important for the design of the Phase Ib study in myasthenia gravis that we anticipate to start as a next step in our clinical development plan. Here, the important thing was that we got confirmation on the two dose levels we want to investigate. We got a confirmation on the patient population that we want to dose imlifidase 5487 with and the dosing regime because we want to look at short and long-term interval redosing.

And last but not least, we had a very productive confirming exchange on the endpoints that we suggested to BfArM. Next step, we'll be starting the trial. We are not yet guiding on the specific starting date, but that will probably follow very soon. Then I understood you asked also about the ConfIdeS trial. As there's no change in guidance, the trial is progressing as planned, and the last

randomization happened at the last day of May last year. This is a 1-year readout, and we expect late summer to have top line data available.

Now you commented on endpoints. What you can expect is a very, very strong focus on eGFR as the primary endpoint, especially since many of the secondary endpoints are highly linked to eGFR.

Suzanne van Voorthuizen
[Inaudible] Thank you.

Operator
Thank you.

Peter Nicklin
Thank you, Suzanne. Thank you, Suzanne for your questions. Next.

Operator
Thank you. And the next question comes from Douglas Tsao with H.C. Wainwright.

Douglas Tsao
Hi, good morning. Thanks for taking the questions. Peter, maybe just as a starting point in terms of the change in leadership. I'm just curious, was it a sort of change in terms of the direction of the company and sort of the strategic prioritization? Or did you see alignment on that, and it was just a question that the company wasn't achieving those objectives as quickly as you thought was needed, especially in light of the current environment?

Peter Nicklin
Yes. Thank you for your question. It's -- well, it's kind of a little bit of all of the above, okay? So that doesn't answer your question. So, I think the -- from a strategy point of view, let's start there at a high level, okay? What I would expect of Renee, and obviously, we have discussed several occasions is a, how would I say, a thorough thoughtful process of looking at existing strategy and where we place our emphasis in future or don't place our emphasis in future. You bring in a new CEO not to continue everything that you've done before, but you bring in a new CEO to reconsider and ensure either we are on the right path or we need to deviate from that path, either small or significantly.

And we don't know the answer to that, frankly, now. And to ask Renee after whatever it is, 6 hours in the office this morning, what that is would be very unfair. So -- and there is no pre-agreed plan with Renee to strategically completely change the direction of the company. So, on that hand, I would ask you all to just bear with Renee a little while. It is clearly a top priority for her to ensure that we are on the right path. And if not, then, of course, we will communicate otherwise.

Regarding other things, I mean, a seven-year tenure in a tough environment is -- everybody who's ever done it before here, and Renee, you did it seven years in your previous company, has done it in other places. There's wear and tear involved as well, right?

So, I think clearly, we've not seen the results that we were all hoping to, okay? And you can look at the outside markets and say, "Okay, the tide is out and tides low." So, when the tide is low, all boats come down. But that's one point. But at the same time, we clearly haven't been recognized for the work that was done for whatever reasons. And maybe bringing in a new CEO with a different experience, okay, by far, Renee comes from a very different background, as you guys

know. Maybe bring in someone with different experience and a different style is the right thing for the company. And after considering that, we felt that Renee does bring that different perspective that we would expect and different style to the company right now, okay? So, as the right leader for the right time, and we think that Renee is that person. So, I hope that answers.

So, strategy, at this point, too early, but leaving strategy aside just from an individual point of view, we think now Renee is suited to take the company forward.

Douglas Tsao
Peter, that's a very helpful answer and greatly appreciated. And then just a follow-up question to Hitto in terms of 5487. And when you think about sort of the development of that asset and sort of need for repeat dosing or sort of obviously, repeat dosing is the goal for the program. I'm just curious, when we think about, say, an indication like MG where you treat [Inaudible], it's likely that there may be a change in that patient's treatment. And so, is it practical to think that you would be able to have patients need multiple doses within a reasonable amount of time? And so, just sort of thinking conceptually like a patient who might be on sort of immunosuppressants mycophenolate, has an MG crisis, enrolls in the study, gets treated with 5487, but then they come out on the other side, there's a good likelihood that they're going to change their ongoing chronic treatment, perhaps go to an FcRn inhibitor where the likelihood of a crisis might be reduced. And so, I can see the treatment and demonstration of efficacy in that initial crisis. Do you need to treat multiple crisis? Or is there another way to get assurances around safety for repeat dosing?

Peter Nicklin
Yes. Thank you for that question. And given the science and nature of it, I'll pass that surely to Hitto.

Hitto Kaufmann
Thank you for that question. Starting statement is, obviously, we're at the beginning of the clinical development of 5487 in patients. So that's sort of the frame for my answer. What we hear very clearly from all KOLs we talk to and certainly from the ones that have been intimately involved in the design of our next studies is that despite progress on maintenance therapies, there is still a significant unmet medical need for reoccurring acute phases of myasthenia gravis. And when you talk to people in the clinical centers, the number of patients that come back to the clinics with these acute phases, some of them ending up in myasthenia crisis, that hasn't changed.

So that unmet medical need is there. And then, of course, that's why in our upcoming study, we want to investigate initially also the safety of this repeat dosing paradigm. The patient population we haven't discussed now with health authorities for the Phase Ib trial is a patient population that has symptoms under -- are stable but have symptoms under immunosuppressant treatment that allows us to also pick up, if possible, pick up some signals on efficacy as well.

Douglas Tsao
Okay, thank you so much.

Peter Nicklin
Thanks very much. Next question, please?

Operator
Thank you. That comes from Matt Phipps with William Blair.

Eric Yeung
This is Eric on for Matt Phipps. Just 2 questions. Maybe first one for Renee. So firstly, congrats, looking forward to your leadership here at Hansa. Just wondering what attracted you to the Hansa opportunity? And just initially, how do you prioritize IDEFIRIX expansion versus some of the opportunities for 5487? And just secondly, I was wondering on potential next steps for the GBS program.

Renee Aguiar-Lucander
Okay. So, I think what attracted me to the company is I do have a soft spot in my heart for rare disease. And I am really looking forward to kind of really engaging with patient organizations and really looking at kind of where there is really truly kind of significant unmet medical needs that Hansa can really address effectively. The fact that the company is late stage in terms of having the Phase III readouts kind of coming up in the second half of this year, that obviously leads to a situation where I think I have relevant insights and experience in terms of all of the kind of regulatory, the pre-commercial, the medical affairs, the kind of building of a commercial footprint, accessing the U.S. market, etcetera.

And obviously, also because the company really today has all rights for all regions across the portfolio, there is also obviously opportunities, I think, to kind of broaden the potential access to patients in other geographies in different ways. And then obviously, there's kind of the European commercial opportunity or footprint that's already kind of in existence. So, I think that all of these things really kind of, I think, is a great opportunity to create significant value on the basis of this platform, the science, the technology and I think that in terms of any kind of new, kind of what do you call it, life cycle management, you call it kind of new and other kind of related to kind of the imlifidase, I think that, that really is an area where like -- where I will spend some time, I'll spend some time in a lot of different areas, but I think that obviously is going to be part of kind of that in-depth review that the team and I will kind of go through in terms of really assessing what -- where -- what area or what indication or how does Hansa really kind of most effectively compete and really dominate in some of the kind of chosen areas.

And so, I think that's really kind of one of the exciting parts of kind of coming into a late-stage business like this is you get the opportunity to learn from the team that's here and to really kind of go through a very rigorous kind of process in terms of strategic options and opportunities. And I think that with all of these things that are going on, I think that there is a lot of areas for us to kind of pursue and look at and really clarify kind of where should Hansa really kind of spend its time, what should be the focus, how can we really kind of be as successful as possible in the areas that we choose to pursue. And I think in terms of the GBS, I think that probably goes to Hitto to answer.

Hitto Kaufmann
Sure. Thanks, Renee. GBS, just as a reminder, we have -- the last guidance we gave was on the contextualization of our Phase II data with the IGOS database and showing significant differences in the speed of recovery of these GBS patients when we compare to our arm, a single-arm study for Phase II with imlifidase followed by IVIg treatment. What we are currently disclosing about the Phase III design is that we intend to compare in the active arm in imlifidase followed by IVIg to an IVIg control arm because in both key geographies in Europe and in the U.S., this is what the feedback we get from KOLs from regulatory authorities. We're not guiding anything beyond that at this point.

Eric Yeung
Great. Thank you so much.

Peter Nicklin
Thanks very much, Eric.

Operator
Thank you. And the next question comes from Christopher Uhde with SEB.

Christopher Uhde
Hi, there. Thanks for taking my question. So first, I'd like to start by saying congratulations to Hansa on, I think, a very exciting and serendipitous appointment of Renee as CEO. And congratulations also to you, Renee.

Renee Aguiar-Lucander
Thank you.

Christopher Uhde
So, my question -- my first question is -- they're both about strategy. And I guess, Renee, you have experience of dual listing. We've heard in the past on multiple occasions that Hansa is looking to explore a dual listing or intends to do one. But of course, we've seen -- I think the evidence is quite clear that it's not necessarily the answer to -- or a way to actually increase share prices by having a secondary listing in the U.S. Can perhaps Peter and Renee comment on your thoughts around why that might be different for Hansa, if you are still planning to do that or what your thoughts are? So that's my first question. Thank you.

Peter Nicklin
Yes. Thanks very much for the question. And clearly, has been discussed between myself and Renee, but I'll let Renee answer the question.

Renee Aguiar-Lucander
So, I think that under the present circumstances, there's really -- the capital markets in the U.S. seem pretty shut in general for like U.S. companies doing any IPOs. And if that's the case, then obviously, there really is no ability for kind of a European-based company, in my view, to do an IPO in the U.S. market. So, for now, I don't think that, that's really on the drawing board in terms of doing that kind of right now because I just don't think that that market is available. I do think that at the end of the day, one hopes that at some point in time, the VIX [ph] will decline, things will become a little bit more stable, a little bit less uncertain.

And then I think it's really a matter of kind of looking at where is the capital for the company that makes most strategic sense. If that happens to be in the U.S., then I think that, that's obviously kind of a reasonable place to go. And if it's here, then that's perfectly fine, too. I do think in terms of having a dual listing, I would agree with you. I think that having a dual listing with a view of saying that you only do a dual listing to achieve kind of an increasing share price. I don't think that that's necessarily the case. I think there are operational reasons for doing some of these things. And -- but again, I think at the end of the day, it comes down to where do you have the demand and the understanding and the will to support some of the biotech companies in the sector.

And I think at this point in time, companies obviously are going to have to go to wherever that capital is available and live with whatever consequences that might come with at the present circumstance. But I think in principle, I would say that I think it would be extremely challenging for any European biotech company to kind of explore a U.S. IPO at this stage.

Christopher Uhde
Yes. Thank you for that thoughtful answer. And a second question then is around the 5487 NiceR program. So, I'm going to ask, I guess you, Peter, this because I haven't been so satisfied with the responses I've had in the past. When it comes to the choice of acute versus chronic, and I heard you talk about the -- your plans to reappraise the strategy in its various forms. But up until now, you've been talking about a focus on acute care settings, but the lion's share of the opportunity is obviously also straddling chronic. And we have a competitive space -- increasingly competitive space in IgG degraders. So, is this something that you're going to reevaluate? And if not, would you please clarify why you don't see that as a good avenue to go down given that we have a 2-week window where it's possible to before you have too high IgG to prevent that from happening? And secondly, because you might be able to induce tolerization. Thank you.

Peter Nicklin
A good question. I will ask Hitto to answer, and I hope your reference to not getting a good answer was not to Hitto. Otherwise, I'll take it back. But what I would say is just an overall comment, we should first learn to walk before we start to run. There's still work to be done in my mind before we can determine what that approach should be. But Hitto, I will pass to you, if I may.

Hitto Kaufmann
Sure. Thanks. Thanks, Peter. So, 5487 is in terms of efficacy, currently from what we've seen in the in vitro experiments, extremely comparable to imlifidase, meaning that within hours, it reduces IgG levels to less than 5%. Our initial step into neuro autoimmune diseases is a step into chronic indications to cover, hopefully, if the clinical data support this repeat acute phases. By doing this, we will establish a profile, including a safety profile for repeat dosing. And of course, our strategic long-term view includes chronic settings in chronic diseases, and we hope to learn. But it's also fair to say that at the moment, it's not really clear what the safety profile will look like if you would dose for a very long time with IgG cleaving enzymes that bring down IgG levels to less than 5%. Other IgG, I would say, reducing technologies, I wouldn't necessarily call it degrading technologies, bring IgG levels down to something like 30%, 40%, which is, of course, clinical at different stage. There's a huge space to explore. I think we have a key angle on it. And I would hope that the more clinical data we get, the more we can expand on that theme.

Christopher Uhde
Thank you very much. That's all for me.

Peter Nicklin
Okay. Thank you.

Operator
Thank you. And once again, please press star, then 1 if you would like to ask a question. And we have a follow-up question from Douglas Tsao with H.C. Wainwright.

Douglas Tsao
Hi, good morning. Thanks for taking the follow up. Just a quick one for me. Just thinking about commercial performance with the post-approval study completed in Europe, I'm just curious, would you expect to see similar commercial adoption as that study enrolled? Or do we think about the 177 consented patients perhaps as a better benchmark? Or was that simply a clinical trial and so that there were some sort of restraints on use of the technology and that now that it's -- those centers have access to it or can just use it on a commercial basis, do you think there might be an increase in use at those sites? Thank you.

Peter Nicklin
Thank you for the question. It's a good question, and the answer may be a little bit speculative because we -- but you're asking it right, what do we expect to see? Obviously, it will show. Hitto, do you want to have a go first and then maybe I can follow up?

Hitto Kaufmann
Sure. I think the way you worded it is entirely correct. We have to look at this, I would say, the acceleration of our launch through the PF sites, not only from the angle of how many patients have they treated, but also how many patients have they consented. There are a number of sites. There's 14 that have enrolled patients, but there is, in total, 22 sites. I think it's too early to really say, but I would also think it's fair to say we see early signs of these PAES [ph] centers, especially in countries like Italy and Spain to help accelerate our commercial readthrough.

Douglas Tsao
Okay, great. Thank you so much. That's helpful.

Renee Aguiar-Lucander
I mean I think I would add to that just a general comment, not specifically on this program because I don't have the knowledge to kind of comment on this specifically. But I think that in general, I don't think one should underestimate the very big value of kind of having access to additional data, long-term data, follow-up data, any kind of real-world data kind of out there or it's in a clinical trial, but still it's -- I do think that this -- I mean a lot of the kind of communities, physician communities in Europe are quite conservative. And I think having a full approval versus a conditional approval, I don't think one should underestimate that. And I also think that just having access to this type of data is hopefully obviously going to kind of further just support why this is a very, very important kind of alternative for these type of patients. So, I think irrespective, again, I don't think one should underestimate the potentially positive impact on the kind of community as a whole from publishing and sharing this type of data.

Douglas Tsao
Okay, great. Thank you very much for those added thoughts, Renee.

CONCLUSION

Operator
Thank you. And this concludes both the question-and-answer session as well as the event itself. Thank you so much for attending today's presentation, and you may now disconnect your lines.

Peter Nicklin
Thank you. Have a good day, everybody.