Hansa Biopharma Q3 2024 Conference Call Transcript

Company Participants

Søren Tulstrup - President and CEO
Evan Ballantyne - CFO
Hitto Kaufmann - Chief R&D Officer

Conference Call Participants

Laetitia Wehry - Van Lanschot Kempen
Alexander Kramer - ABGSC
Douglas Tsao - H.C. Wainwright
Matt Phipps - William Blair
Christopher Uhde - SEB
Johan Unnerus - Redeye
Natalya Davies - Intron Health

Operator

Good morning, and welcome to the Hansa Biopharma Interim Report for January to September 2024 Conference Call. All participants will be in listen-only mode. [Operator Instructions]. After today's presentation, there will be an opportunity to ask questions. [Operator Instructions]. Please note, this event is being recorded.

I would now like to turn the conference over to Søren Tulstrup, President and CEO of Hansa Biopharma. Please go ahead.

Søren Tulstrup

Thank you, operator. Good afternoon, good morning, and welcome to the Hansa Biopharma conference call to review the Q3 results for 2024. I'm Søren Tulstrup, President and CEO of Hansa Biopharma. Joining me today is Evan Ballantyne, Chief Financial Officer; and Hitto Kaufmann, Chief R&D Officer.

Please turn to Slide 2. Please allow me to draw your attention to the fact that we'll be making forward-looking statements during this presentation, and you should therefore apply appropriate caution.

Now please turn to Slide 3 and an overview of today's agenda. Today, we'll discuss the progress we made during the third quarter 2024 and review our near-term priorities. The presentation should take roughly 15 to 20 minutes after which there will be an opportunity to ask questions during a Q&A session.

Please turn to Slide 4 and an overview of our Q3 performance. The third quarter 2024 marks the company's highest ever quarterly in-market IDEFIRIX sales and fourth consecutive quarter of solid sales performance with total revenue of SEK78.4 million. Of this, SEK69.5 million can be attributed to IDEFIRIX sales.

Year-to-date sales for IDEFIRIX totaled SEK164.2 million. The continued strong IDEFIRIX sales performance can be attributed to an increase in clinical utilization in key EU markets, including Italy, Germany, France, Spain and the UK. Additionally, we're seeing more repeat utilization of IDEFIRIX in clinics across major European markets following cost of outcomes of first transplants.

Of note, the provision of SEK29.7 million was recorded in the third quarter. This reflects a revised estimate of the one-time retroactive adjustment of cumulative sales since launch in 2020 based on recent advancement of near-final pricing negotiations in one key market where IDEFIRIX has benefited from early access under a special program prior to the conclusion of pricing and reimbursement negotiations.

We expect to achieve a successful conversion of this program into full reimbursement in Q4. Of the provision, only SEK4.9 million relates to sales in the third quarter of 2024. Evan will cover this in more detail later in today's call. I'd also like to highlight the trailing 12-month product sales data that shows performance over the previous year. This underscores the continued launch progress and growing market uptake without quarterly volatility.

Please turn to Slide 5 for an overview of Q3 highlights. Throughout 2024, we made significant scientific advancement. In May of this year, we announced the completed randomization of all patients in the U.S. ConfIdeS Phase 3 trial in kidney transplantation. The trial is on track for data readout in second half 2025, followed by the expected submission of the BLA to the U.S. FDA under the accelerated approval pathway. As a reminder, a total of 23 sites were enrolled in the trial and consented over 140 patients. The sites in the trial represent about 20% of the total transplantation volumes in the U.S.

The third quarter also marked steady progress in additional studies, including the Post Authorization Efficacy and Safety study or PAES study in kidney transplantation and the GOOD-IDES-02 Phase 3 trial in the autoimmune disease anti-GBM. The PAES study in Europe is 78% enrolled, with 39 out of 50 patients in the trial. The study is progressing in parallel with the continued commercialization of IDEFIRIX and is part of our obligation to the European Medicines Agency. We believe that the data generated by this study will support the adoption of IDEFIRIX more broadly and allow even more clinics to gain clinical experience.

The GOOD-IDES-02 Phase 3 trial in anti-GBM disease also continues to progress with 86% of patients enrolled in the trial. Completion of enrollment and data readout is expected in 2025, as previously guided. Anti-GBM is a rare, severe autoimmune condition affecting around 1.6 people per million annually. Imlifidase has been granted orphan drug designation for the treatment of anti-GBM disease by both the U.S. FDA and the European Medicines Agency. We also continue to progress scientific exchange to data presentations at key medical congresses and publications in peer-reviewed journals. This underscores our commitment to advancing the science related to IDEFIRIX.

Of note, as mentioned last quarter, a real-world evidence study was initiated in France to evaluate outcomes in nine imlifidase-treated patients. The study was presented at the AST meeting in June and published in Kidney International reports in July. Through the follow-up period, there was no graft failure and no deaths. These real-life data demonstrate that the use of imlifidase to desensitize highly sensitized patients can have an acceptable short-term efficacy and safety profile in selected patients in a real-world setting. Hitto will provide a more comprehensive update on the pipeline and clinical development progress later in the presentation.

Now please turn to Slide 6 for an update on IDEFIRIX launch in Europe. We continue to make solid progress with the launch of IDEFIRIX in Europe. To date, this marks the fourth consecutive quarter of strong commercial sales. As of today, we have reimbursement in 15

European markets, including the top 5 markets, representing approximately 75% of the European transplant market.

In the third quarter, we saw a 10% increase in the number of clinics who have gained clinical experience with IDEFIRIX. This represents 32 clinics in 11 markets. Of these, 62% have used IDEFIRIX more than once. This reflects clinicians' growing confidence in IDEFIRIX and willingness to identify IDEFIRIX-appropriate patients.

We also saw an increase in utilization in markets within the Eurotransplant program. In total, 53 patients have been identified as IDEFIRIX-appropriate patients and markets in the Eurotransplant program. Eurotransplant is an international allocation system responsible for the allocation of donor organs across eight countries, including Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands and Slovenia. This reflects the adoption of IDEFIRIX in local and international organ allocation systems and underscores an increased demand for IDEFIRIX designated organs.

We recognize the innate volatility in the transplantation market as it relates to organ allocation. We're encouraged by the growing number of clinics that are IDEFIRIX ready to treat and the increase in new and repeat users as we continue to build out opportunities to ensure ongoing expansion of IDEFIRIX, including extensive engagements with KOLs and clinics in key markets.

I will now turn over the call to Hitto for an update on the pipeline of clinical development. Hitto, please?

Hitto Kaufmann

Please turn to Slide 7. Thank you, Søren. Please turn to Slide 8 for an update on the pipeline and clinical development highlights to date. We continue to make good progress across the pipeline inclusive of studies in various stages in autoimmune, gene therapy and transplant. We continue to believe that imlifidase and HNSA-5487 or next-generation IgG cleaving molecule have the potential to address significant unmet need across the spectrum of diseases where IgG plays a role in disease pathology. During the second quarter, we have made solid progress across our three key therapy areas and with all trials.

Please turn to Slide 9. As Søren mentioned, we have advanced several key clinical trials over the course of the third quarter and 2024. To date, Hansa has seven ongoing clinical trials: three Phase 3 trials, two Phase 2 trials and two Phase 1 trials. We are excited about the imminent commencement of a second Phase 1 trial in gene therapy, broadening our clinical program with regard to vector used and targeted tissue.

In transplantation, we continue to advance enrollment in the post authorization efficacy and safety study as part of our obligation to the European Medicines Agency. The ConfIdeS U.S. pivotal Phase 3 trial was fully randomized in May, as previously mentioned, and we plan to deliver data in the second half of 2025 followed by BLA submission to the U.S. FDA. As mentioned last quarter, pooled 5-year data, including data from the 17-HMedIdeS-14 and four Phase 2 trials have been submitted to a peer reviewed journal for publication.

17-HMedIdeS-14 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. Patients vital was 90%, death censored, and graft survival was 82% and in line with standard of care outcome seen at 3 years post-transplant. This data is an important part of the broader clinical

evidence supporting the use of imlifidase as desensitization therapy for highly sensitized kidney transplant patients.

In autoimmune, we have also made good progress across all trials. The GOOD-IDES-02 trial in anti-GBM continues to enroll. Currently, the trial is 86% enrolled, which means 43 out of 50 patients are in the study. We look forward to sharing data in 2025. As a reminder, GOOD-IDES-02 trial is a Phase 3 open-label controlled, randomized, multicenter trial across Europe and the U.S. and is evaluating renal function and the need for dialysis at 6 months in patients with severe anti-GBM disease. We believe imlifidase has significant potential in improving the outcome of these patients and address the unmet medical need.

Further, I'm pleased to share the 15-HMedIdes-09 Phase 2 trial in Guillain-Barre syndrome remains on track. We plan to share contextualized efficacy data this year based on the comparison between the data of the study and a matched cohort from the international Guillain-Barre syndrome outcome study called IGOS. IGOS is a large-scale global research initiative that collects extensive clinical and biological data from GBS patients to enhance understanding and treatment of this potentially life-threatening disease.

GBS is an acute rare paralyzing inflammatory disease of the peripheral nervous system. Usually preceded by an infection or other immune stimulation. Two thirds of patients have senior symptoms resulting in the inability to work unaided. Lastly, data from the 16-HMedIdeS-12 Phase 2 trial was published in clinical transplantation in July.

Moving on to gene therapy. Enrollment in the Sarepta 9001-104 Phase 1b trial continues. As a reminder, the trial is evaluating the use of imlifidase as a pretreatment to Sarepta Therapeutic's ELEVIDYS gene therapy in Duchenne muscle dystrophy. We expect to share preliminary data from the trial in 2025. With both AskBio and Genethon, we continue to progress preclinical efforts. As previously shared, we have plans to commence the study this year with Genethon evaluating imlifidase as pretreatment to its GNT-0003 for patients with Crigler-Najjar syndrome. 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.

And finally, just a week ago, we announced positive results for the NICE-01 trial and a 12-month follow-up analysis of HNSA-5487, the company's next-generation IgG cleaving molecule. This analysis demonstrates that HNSA-5487 can robustly and very rapidly reduce IgG levels, has redosing potential and a favorable safety and tolerability profile. HNSA-5487 has a highly differentiated profile compared to published data from studies with other IgG targeted therapies. HNSA-5487 has transformational potential to address significant unmet need across the spectrum of chronic autoimmune diseases where IgG plays a role in disease pathology, including autoimmune conditions and where the need for management of repeat acute immune system attack is crucial.

The company will focus initial clinical development on HNSA-5487 in neuro-autoimmune disease with well-characterized role of specific autoantibodies in disease pathology and acute phases. Initial clinical development of HNSA-5487 will focus on Neuromyelitis Optica, NMO; Myelin Oligodendrocyte Glycoprotein Antibody Disease, MOGAD; and Myasthenia Gravis. A significant number of patients with chronic neurological autoimmune diseases face exacerbations and even severe crisis leading to hospitalization, demonstrating the high unmet medical need. It's also important to note that we are advancing the science of imlifidase through medical congress presentations and publications in peer-reviewed

journals. To date, in 2024, we have published in seven peer-reviewed journals and there have been eight presentations of data at key medical congresses.

I will now turn it over to Evan to cover financial performance.

Evan Ballantyne

Thank you very much, Hitto. Next slide, please. Let's walk through the company's financial performance in Q3. Revenue for the third quarter of 2024 totaled SEK78.4 million, including SEK69.5 million of in-market IDEFIRIX product sales and SEK8.9 million in contract revenue, mainly from the agreement with Sarepta. Third quarter product sales represented a 321% increase compared to the same period a year ago. This represents the fourth consecutive quarter of strong IDEFIRIX product sales and underscores the continued solid sales launch and execution Søren referred to earlier and the ongoing clinical utilization of IDEFIRIX across major European markets.

Year-to-date revenue of IDEFIRIX totalled SEK164.1 million, representing a 171% increase over the prior year. Total year-to-date revenue, including contract revenue was SEK188.1 million. In the third quarter, the company recorded a provision of SEK29.7 million to reflect discounts and a onetime retroactive rebate on cumulative sales since the launch in one market where IDEFIRIX has benefited from a special early access program.

Of the total Q3 provision, only SEK4.9 million relates to IDEFIRIX sales in Q3 2024. Net of the provision, Q3 2024 IDEFIRIX sales were SEK39.8 million. And total year-to-date IDEFIRIX sales were SEK114.5 million. In Q2, the company recorded a SEK19.9 million provision, of which only SEK2 million related to sales in Q2 2024. Of the total provision amount taken during the last two quarters, SEK42.7 million related to product sales prior to Q2 2024 and since its launch in 2020.

The Q3 provision is based on an updated best estimate of the onetime effect of an expected imminent successful conversion of a special early access program into full reimbursement in markets where IDEFIRIX has been made available through that same special early access program since its launch in 2020. We are currently finalizing negotiations and as mentioned earlier, expect to successfully convert the early access program to full reimbursement in the very near future.

Please turn to Slide 12. SG&A expense totalled SEK76 million in the third quarter of 2024 and SEK255 million year-to-date. As previously mentioned, SG&A expense has been affected by a restructuring reserve of approximately SEK3.5 million. Restructuring activities have reduced total SG&A expense compared to prior quarters. Noncash expense for the company's long-term incentive program was included in SG&A costs and totalled SEK24 million for the first 9 months of 2024. Additionally, R&D expense for the third quarter of 2024 totalled SEK79.6 million and SEK274.3 million year-to-date in 2024.

Year-to-date, R&D expense also included a restructuring reserve of SEK6.6 million. Compared to the same period in 2023, the decrease in expense was primarily driven by restructuring activities. Noncash expenses for the company's LTIP program were included in R&D expense and totalled approximately SEK7.9 million for the first 9 months of 2024. Other operating income and expense consists primarily of gains and losses on foreign exchange rates in the company's operations. Other operating income for the third quarter 2024 was SEK1.2 million compared to an expense in Q3 of SEK1 million.

Q3 2024 other expense was SEK565,000 as compared to income of SEK386,000 for the same period in 2023. This change in other expense was primarily driven by the U.S. dollar exchange rate changes against the Swedish krona associated with deferred revenue, accounts payable and accounts receivable balances.

Next slide, please. Cash used in operations for the third quarter 2024 totaled SEK149 million and SEK527 million for the nine months ended September 30, 2024. The decrease in Hansa's operating loss compared to the same period in 2023, which is driven by increased sales as well as an overall reduction in expense. As a reminder, the company completed direct sales issue of approximately SEK372 million or $34.6 million in the second quarter. At September 30, 2024, cash and cash equivalents totalled SEK554 million compared to SEK908 million in the same period in 2023.

And now, I'd like to return the presentation back to Søren.

Søren Tulstrup

Thank you, Evan. Please turn to Slide 14. With this overview, our presentation is now concluded. I would like to open the call for questions. Operator, please begin.

Question-and-Answer Session

Operator

We will now begin the question-and-answer session. [Operator Instructions]. The first question comes from Laetitia Wehry with Van Lanschot Kempen. Please go ahead.

Laetitia Wehry

Yes, thank you so much for the call. It seems like the GBS Phase 2 data for the matched cohort got delayed a bit. Previously, this update was guided for the middle of the year. What is behind that? And can you elaborate what you would like to see in a readout at year-end to move the program towards a registrational Phase 3? Thank you.

Søren Tulstrup

So we have guided for readout of the second part in the second half of this year. And so this is in accordance with the guidance given. What we hope to see, obviously, is that there is going to be speedy recovery looking at key functional parameters. The overall endpoint is a functional score and there are sub parameters here, versus those patients that have been treated with IVIG only. Hitto, I don't know if you want to add to this?

Hitto Kaufmann

That's absolutely correct, Søren. Nothing to add.

Operator

Did you have a follow-up, Ms. Wehry?

Laetitia Wehry

Thank you. Just a bit more on maybe a different question where GBM Phase 3 recruitment is progressing well with the primary endpoint being EGFR at 6 months. It seems like we could expect the study to read out in the second half of '25. How should we think about the next steps, assuming you can file for approval thereafter? And considering this timeline lines up with the U.S. trial in kidney transplantation, are you comfortable with readout -- comfortable with the company's bandwidth to do two filings and commercial launches at the same time?

Søren Tulstrup

Well, we're certainly excited that there is a possibility that we can submit a BLA for this indication. So clearly we're moving forward at speed with the enrollment, aiming to fully enroll it as quickly as possible. And as you said, it's a 6-month study. So the timeline is not too dissimilar to the kidney transplant indication. And obviously, we will make sure that we have the resources to move forward with prioritized indications.

Laetitia Wehry

Okay. Thank you.

Operator

The next question comes from Alexander Kramer with ABGSC. Please go ahead.

Alexander Kramer

Yes. Good afternoon. Alexander Kramer on the line. I have two questions. One question related to finance. Could you comment on your R&D OpEx or your R&D spend going forward into '25-'26, looking at the high clinical activity which you have at the moment and also potential future plans with the 5487 program like do you expect this to rise again after it goes down this year? And then I have a second question.

Søren Tulstrup

Yes. Thanks, Alex, for this question. I think I'll hand over to you, Hitto, for this one.

Hitto Kaufmann

Yes, it is true. I mean, obviously, we want to initiate the next clinical trial with 5487. At the same time, what we will also see next year, we will conclude to Phase 3 trials that we're currently running and operating the ConfIdeS kidney transplantation and the Phase 3 trial in anti-GBM. So that has to sort of be fleshed out a bit more in terms of planning, but there will be new clinical activities, but there will also be clinical activities that will be concluded?

Søren Tulstrup

Yes. And Evan, do you want to add to this?

Evan Ballantyne

No, I was going to just agree with what Hitto said. Look, we're wrapping up trials now and we'd like to start 5487 trial. So I'm going to tell you, if we start that 5487 trial in the near term, I view that increase in R&D expense is a good thing.

Alexander Kramer

Okay. Thanks. And my second question is about a potential competitor. So actually there was a poster from a company called Seismic Therapeutic. They have a candidate which I would say, I mean, it has some similarities with 5487 NiceR in terms of the design and the efficacy profile. And additionally which is interesting to note here is, I mean, NiceR is focusing on the acute setting while Seismic Therapeutic mentioned that it might be worthwhile investigating both in the acute and chronic treatment settings in autoimmune disease and they're also targeting myasthenia gravis. And what's your view on that and could you sort that in somehow with what you are doing?

Søren Tulstrup

Thanks, Alex, for this second question. So what is good to see is that there are additional players stepping into this space, right? I mean, obviously, we're well ahead and it's great to see that others see that there are opportunities here. As far as the acute versus chronic use or let's say maintenance use [ph], I think that there are opportunities in both spaces. And so this is certainly something that could be pursued. We're initially focusing on the acute phases, but certainly there is potential outside of that as well.

Alexander Kramer

Thank you.

Operator

The next question comes from Douglas Tsao with H.C. Wainwright. Please go ahead.

Douglas Tsao

Hi, thanks for taking my question. Just first question on the provision that was taken for IDEFIRIX. I guess, I know that was for sort of past periods. We saw a second quarter. So what does that necessarily mean? I mean, does that imply that the negotiations sort of have necessitated larger discounts? And does that sort of have an impact on the pricing going forward and I believe this is largely -- this is confirmed to just one market? Thank you.

Søren Tulstrup

Yes. Thanks for that question, Doug. So as we discussed and as you mentioned here this is related primarily to this conversion of an early access program into full reimbursement which obviously is a positive outcome. Overall, we're in line with the expectations around pricing going forward. But then there is this element of repayment of certain charges since the launch in 2020. So that's a onetime event essentially, but overall, certainly very, very positive outcome that we expect in the very near future that will lead to a full reimbursement at a price point that we think fully reflects the value proposition that we're bringing to the table.

Douglas Tsao

Okay. Great. And then just on anti-GBM, the recruitment has gone, I mean, certainly I think faster than our expectations. Do you have a sense, is it that there's greater enthusiasm for imlifidase and therefore, investigators are sort of putting a higher proportion of their patients on to therapy or is it that while it continues to be a very rare condition that perhaps there are more -- there's greater incidence than was previously expected? Thank you.

Søren Tulstrup

Thanks for this follow-up question, Doug. So clearly we're encouraged by the fact that we've been able to relatively rapidly enroll the patients in this trial. I think that reflects a couple of things. Certainly, it could be that the prevalence incidence is higher than expected. But we're also really seeing this as something that kind of mirrors the fact that it's a very severe condition and there is a high desire from the centers to participate and enroll patients. Remember two out of three patients in this disease lose their kidney function and end up in dialysis. So it's a very, very serious disease with very bad outcomes overall. So clearly, we're very encouraged by the progress here and we look very much forward to the readout next year which again, as I said, can lead to full approval.

Douglas Tsao

Okay. Great. Thank you so much.

Søren Tulstrup

Thanks Doug.

Operator

The next question comes from Matt Phipps with William Blair. Please go ahead.

Matt Phipps

Hi, thanks for taking my question. Congrats on continued commercial success in Europe here. Does the setting of a final reimbursement price in this market have read through to reference pricing in other countries that might cause other provisions to be needed or is that also taken into account? And then, Evan, I guess, when do you think you need to start building the U.S. commercialization ahead of expansion there? When should we expect kind of some growth in SG&A from that?

Søren Tulstrup

Thanks, Matt. So as far as the implications on other markets is concerned, we're essentially fully within the range that we have expected and want to put in, and this is a very stable range. Also in the wake of the preceding pricing and reimbursement approvals in other countries. So we're very pleased with not only the extent of coverage that we have now throughout Europe, but also the level that we've been able to negotiate with payers. So that's your first question. As far as the U.S. launch is concerned. Clearly, we will want to and are planning to build up additional infrastructure, launch infrastructure ahead of the expected launch in the U.S. We do believe it's a very, very significant opportunity. Again, recall, we have north of 20 clinics, representing a very large proportion of kidney transplant patients in the U.S. active in our U.S. ConfIdeS trial. And so there's going to be a high level of experience at the time of launch. So obviously, we want to be fully ready for that launch and that entails also investing another reasonable level. Evan, do you want to comment further on this?

Evan Ballantyne

No, I think you nailed it, Søren.

Operator

The next question comes from Christopher Uhde with SEB. Please go ahead.

Christopher Uhde

Yes. Thanks for taking my questions. I wanted to circle back to a subject that I raised on the NiceR call, not to say anything bad about this call. But -- so in terms of chronic versus acute, feedback we're getting from the investors we've spoken to is that there is a lot of enthusiasm for adding a chronic angle to the program along the lines of tolerization. And so I wondered if you could talk about what would it make -- what would it take for you to consider expanding to add that angle to what you've already talked about doing. And let's say, if you were to consider adding it, how quickly could you move ahead on that. And perhaps you could kind of talk about a little bit in more detail about what's -- why you don't -- why you haven't decided to go with that right out of the gate or if you were perhaps just not prepared to speak about it at that first call.

And then maybe if I could just try to pull a little bit on the thread there with the earlier question on SG&A. Would the timing of the ramp-up be reasonable to be expected to be around mid-2025, given you'd probably be launching in H1 '26? Thank you.

Søren Tulstrup

Thanks, Christopher, for those two questions. So first on the chronic versus acute opportunity. So clearly, as we communicated at the NiceR our 5487 call, we want to initially prioritize moving into these chronic neuro autoimmune diseases where you have recurrent attacks. And we will focus on the attacks to the acute setting because we think that there is a very, very high level of unmet medical need as also validated by our extensive consultations with KOLs and clinics. And we have a very, very unique profile that same people essentially are extremely excited about and feel that we have an opportunity to move in relatively fast to demonstrate a benefit in these situations. Now that does not mean that we don't see that there is also potentially an opportunity for more participation, let's say, in the maintenance part of managing these diseases. And as you will recall, we have also looked at how 5487 and imlifidase potentially could be part of that management program. So clearly, there is an opportunity, we think, in both spaces. But initially, we're focusing on the acute attack themselves. And we will provide further updates as we complete interactions with the regulatory authorities on the path forward here. On the second question, Christopher, SG&A on the ramp-up and so on ahead of the U.S. launch. So already, we have boots on the ground in the U.S., as you know, not just global boots, but also local U.S. boots. And so it's a question of building out that gradually as we get closer to the potential launch in the U.S. Evan, I don't know if you want to add some comments to this?

Evan Ballantyne

Look, we have, as Søren mentioned, we started building up a presence in the U.S. in advance of the submission of the BLA, but we'd like to be completely ready to the launch in the U.S. with a full sales force and MSLs as well.

Christopher Uhde

Yes. Thanks.

Operator

Thank you. The next question comes from Johan Unnerus with Redeye. Please go ahead.

Johan Unnerus

Excellent. Thanks for the question. Can you hear me?

Søren Tulstrup

Yes.

Johan Unnerus

Excellent. Yes. A follow-up and a clarification to begin with on the provisions and discounts and rebates. It's reassuring, of course, that it seems to be a modest part of this referring to both Q3 and the previous Q2 SEK2 million -- SEK3 million and a bit or something like that. And it also seems to be a result of negotiations and reviews of the specific market done in Q3. What should we think of the risk of having other sort of reviews referring to other markets historically? Is this sort of the end of the main historic provisions or reviews? Or is there a concern that we could see some more historic reviews?

Søren Tulstrup

Yes. Thanks, Johan, for that question. So clearly, this is related to a very unique situation where a special early access program that has been extremely successful is converted, we hope very soon to full reimbursement. And so this is a unique kind of retroactive application of the consequences of that. And we certainly don't expect that given where we stand right now, where we have, like I said earlier on the call, access to the vast majority of kidney transplant patients in Europe at a price point that we think, fully reflects the value that we bring to the table.

So it's certainly not something that is expected. But I'll hand over to you, Evan, to potentially add some comments to this.

Evan Ballantyne

Yes. I mean, look, negotiations for pricing as you're certainly aware, across Europe and the rest of the world have become more difficult for pharmaceutical companies, large and small. I think we've done a very good job of negotiating prices. And I think we are, as Søren mentioned, at the end of negotiations really, I'm going to say, across Europe. Obviously, I think you noticed we're selling in Germany, France, Italy, Spain, Belgium, just right across Europe. And so these negotiations have been going on for years, for the better part of two years, and we're seeing the end of them right now.

Søren Tulstrup

There are still a few outstanding good progress like Portugal; Switzerland, for instance; Hungary, just to mention a few. So -- and then there are, of course, also efforts outside of Europe like in Australia, where we're quite excited that we got approval recently. There is a very material opportunity in Australia, and we're currently in the process of negotiating with the Australian payer authority. So that's just one example of where we have additional negotiations ongoing.

Johan Unnerus

So in terms of sort of the reference for future sort of normal pricing. Of course, you stated that you're well within the boundaries of what you hope or expected to establish. But is it fair view to take that there could be some changes still, but those should be minor compared to what we've seen earlier.

Søren Tulstrup

Well, as you know, when you negotiate on a payer-by-payer basis, there may be volume discounts and so on that apply, and then there might be some other parameters. But those are to be more or less known within the existing quarter. So this is a very unique situation where there is a negotiation that has taken place over several years, reflecting what it normally takes. And then there are special parameters where there will be some retroactive effects, which may not be and certainly are expected to be the case going forward. So this is a unique situation.

Johan Unnerus

Excellent. And shortly, those refund liabilities of SEK132 million, is that something that should go through fairly soon? And what should we think about that line going forward?

Søren Tulstrup

Evan, do you want to take this?

Evan Ballantyne

Yes. Sure. Look, we've got the provision on our financial statements and as far as making the retroactive rebates or payments that will come in future years.

Johan Unnerus

So this position will stay a bit higher? Or is this something we should expect to come through in the working capital for the next quarter.

Evan Ballantyne

I don't think we're going to be establishing the provisions of this size anymore. And in fact, as I said earlier, I believe that we're substantially done with pricing negotiations.

Johan Unnerus

Good. And finally, you also secured sort of financial situation into '26, but it's probably fair to take the view that you will sort of need some additional firepower to support the growth and opportunities. The way you're advancing, you're also increasing your opportunities. Is there something to decide about potential partnerships and that might be even targets for NiceR that you could consider sort of partnering with? And yes, can you add some flavor into that?

Søren Tulstrup

Well, thanks for that additional question, Johan. So clearly, partnering is part of our strategy, right? And you've seen that play out within the gene therapy space where currently we have 3 partnerships with the leading players in that space, and they're quite successful. Going forward, there certainly are other opportunities to partner, not just within the gene therapy space where we continue to have a number of dialogues, but also around other assets and areas. So clearly, that's something that we're also pursuing. I think a successful biotech company like ours that has a versatile, flexible technology platform and multiple programs only benefits from partnering and partnering in a smart way as we've done in the past.

Operator

The next question comes from Natalya Davies from Intron Health.

Natalya Davies

Thank you for taking my questions. Just a couple from me. The first one, what are the next steps with the AMR program following the Phase 2 data? Are you actively searching for partnerships to fund a Phase 3 trial? So a bit more color on that would be great. And the second is just on the ramp-up of the IDEFIRIX sales. Is that primarily attributable to retreatment of existing patients or are there new clinics coming on board? And if there are any specific regions where you see more scope for growth? It'd be great if you could answer those.

Søren Tulstrup

So as far as the AMR program is concerned, we're obviously very thrilled that we saw this statistically significant benefits in the imlifidase-treated patients compared to standard of care in terms of the ability to rapidly and very robustly knock down donor-specific antibodies in these very critical situations where a kidney transplant patient has an acute episode of antibody-mediated rejection. And the data set has been published now and certainly is something that is being discussed broadly. We have not yet determined the specific next steps here for this indication. But certainly, this is something that is being looked at. We do not anticipate to start a Phase 3 trial in the very near future, but there's certainly a very encouraging data set as far as the primary endpoint is concerned. Even though if you look at the secondary endpoints where you look at more hard endpoints as we've seen in other AMR trials, given the fact that the patients are so heterogeneous, it is difficult and relatively small trials to get very clear outcomes. So running a Phase 3 trial would entail a relatively large trial, but that should be said. Then as far as IDEFIRIX uptake is concerned. So, it is really a mixture of new utilization in new patients and then reuse by the clinic in other new patients, right? So, remember, there's not going to be repeat usage in the same patient. A center will typically, for the first time, try it in a patient, wait 6 to 10, maybe even more, months before determining whether the center feels that it's comfortable moving into using it more broadly in second and third and succeeding patients. And so what is very, very encouraging to see is that not only are we seeing an increase in the number of clinics that are using it in the first patient, we're also seeing an increase in the number of clinics that are happy with the outcome in the first patient and have decided to move ahead and do it in second and third patients and so on. So that's on the clinic and patient side. As far as regions is concerned, what we've seen recently is that we have gained market access, reimbursement in key countries like Italy and Spain. And especially Spain, probably has one of the, if not the best, organ allocation system in Europe, potentially in the world. We have lots of support from key clinics in Spain. It will take a little while before they materially contribute so they haven't done this so far, because even though we have reimbursement at the national level, that reimbursement needs to be pushed down to the regions. But we're getting, again reimbursement at the regional level. Very recently, we got it in Catalonia, a key region representing one-third of all transplants in Spain. And so we're seeing very good progress that then also needs to be reflected in hospital budgets and so on. So we expect Spain to contribute materially next year. The same goes for Italy, where we now have access to, I think 90% of patients via the regions as well. And so that's looking very encouraging. We have strong support from key clinics and patient associations and so on so also a promising country there. And then, of course, the Eurotransplant program, where currently 53 patients have been identified. There is ample opportunity for expansion in those countries that are part of the Eurotransplant program as well. The UK is typically, as we see across many indications and therapies, relatively conservative country as far as early uptake is

concerned. But clearly, looking at the volume of kidney transplants in UK there's also significant potential there. And then France, which has been our leading country so far, and where we've seen great uptake. We definitely think that this will continue. Again, based on very, very positive outcome in the first treated patients and we're talking about the paper on the 9 imlifidase patients. So very, very positive around opportunities for further growth in France as well. And then we hope to see a mirroring of what we've seen in France in some of the other large countries in Europe. In addition, I should mention that we -- as I said earlier, we are looking at Australia, for instance, and there are significant other opportunities across the globe. There are certain in the Middle East, for instance, as well and South America over time. So clearly, lots of opportunities for continued growth there.

Operator

And we have a follow-up from Laetitia Wehry with Van Lanschot Kempen. Please go ahead.

Laetitia Wehry

Yes, thank you for making time for a second question. Regarding the repeat dose candidates, no call took place recently, but any update on when we could expect to hear more on the next development plans in autoimmune indications?

Søren Tulstrup

So the next step here is to complete interactions with regulatory authorities. And once that has happened, we expect to provide an update there. Obviously, we're doing what we can to complete this as quickly as possible. Also continuing dialogues with some leading players in this space. So I can't give you a specific time point. But certainly, this is a key priority for us. So we expect that to come in the near feature.

Laetitia Wehry

Okay, perfect. Thank you so much.

Operator

And we have a follow-up from Douglas Tsao with H.C. Wainwright. Please go ahead. Mr. Tsao, did you have a follow-up?

Douglas Tsao

Just in terms of current use, Søren, and I apologize if I missed it. I'm just curious between this quarter's sales, what percent were in new centers versus repeat use at centers of that previous experience?

Søren Tulstrup

Well, I can't give you top of mind an exact distribution there, Doug. But like I said, I mean, the growth is coming and the sales overall is coming from a mixture of repeat use and new clinics. And essentially, we're encouraged by both, right? We want to see increasing repeat usage, reflecting positive early experiences and also new centers coming online, right? So as I mentioned, we have now 113 centers in Europe that are ready to use imlifidase. That is a significant increase from the last quarter, again reflecting the positive, almost snowball effect of the early experiences of being then kind of given to additional centers as well.

Douglas Tsao

And another -- just one final quick follow-up. I mean do you have any centers that are now using it regularly, meaning that you're recording sales in pretty much every quarter?

Søren Tulstrup

We have certainly centers that are regular users, right? So once it becomes repeat users and again, that's based on positive early experiences. Typically, they have positive experiences going forward, and they will even increase their ability to manage these patients. So I can't give you a specific number on a quarter-by-quarter basis, but we're encouraged by the overall progress.

Douglas Tsao

Okay, great. Thank you, and congrats on the progress.

Søren Tulstrup

Thanks, Doug.

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Søren Tulstrup for any closing remarks.

Søren Tulstrup

Thank you, operator, and thank you everyone, for calling in here. We're very excited about the progress in the preceding quarter, and we look forward to updating you on continued programs as we move forward. Thank you very much.

Operator

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.