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Company Participants

Soren Tulstrup - President and CEO

Matthew Shaulis - CCO

Donato Spota - SVP and CFO

Conference Call Participants

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Christopher Uhde - SEB

Douglas Tsao - HC Wainwright

Bo Zhang - Intron Health

Ingrid Gafanhao - Bryan Garnier

Matt Phipps - William Blair

Johan Unnerus - Redeye

Operator

Good afternoon, and welcome to the Hansa Biopharma Quarter 2 2023 Conference Call. My name is Carla, and I will be the operator for today's call. [Operator Instructions].

I would now like to pass the conference over to our host, Soren Tulstrup to begin. Please go ahead when you're ready.

Soren Tulstrup

Thank you, operator. Good morning, good afternoon, and welcome to the Hansa Biopharma conference call to review second quarter 2023 results. I'm Soren Tulstrup, CEO of Hansa Biopharma. Joining me today is our Chief Commercial Officer and newest President, Matt Shaulis, and our CFO, Donato Spota; our Head of Investor Relations, Klaus Sindahl, is also with us. Today, we'll discuss the highlights and progress we made during the second quarter of 2023 and review our near-term milestones.

The presentation should take roughly 20 minutes, after which there will be an opportunity to ask questions during the Q&A session. 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. Please turn to Slide 3 and an overview of Q2 highlights. I'm pleased with the solid performance in the second quarter.

The launch of Idefirix in Europe continues to track well against the key launch metrics, and we've also seen good progress in our efforts to advance a valuable pipeline of broad candidates in all our 4 priority therapy areas. We delivered our best quarter yet when it comes to product sales as we continue to scale Idefirix in established markets with pricing and reimbursement secured. Our progress was further underscored by encouraging pages in the transplantation clinical community, including implementation of medical guidelines on a national level, in key markets and a UT sensitization program by Eurotransplant targeting Idefirix-eligible patients.

Importantly, during the last year, we have secured positive reimbursement decisions in many key markets. Most recently, in June, Idefirix was branded reimbursement in Belgium, where more than 1,100 patients are waiting for a kidney transplant, and approximately one in 10 are classified as highly sensitized with limited or no access to suitable donor organs.

We're also pleased with the recent decision by the Australian Therapeutic Goods Administration to grant provisional approval for Idefirix in Australia as desensitization treatment in highly sensitized patients prior to kidney transplantation. This regulatory milestone marks the first time that Idefirix has been approved in kidney transplantation from both living and diseased donors.

Matt will cover our commercial progress in more detail later during this presentation. On the clinical development side, we have continued to drive progress across our early and late stage programs and franchises. In the U.S. during the second quarter, we exceeded our initial enrollment target in the pivotal ConfIdeS trial in kidney transplantation. As previously communicated, we will continue to involve patients and add more centers to accelerate randomization.

In the autoimmune disease space, we are excited about the launch of the new investigator-initiated Phase 2 trial in ANCA-associated vasculitis. This new trial is an important step in developing Imlifidase as a drug candidate in a new indication with very few treatment options available today. The trial will target 10 patients with pulmonary hemorrhage due to severe ANCA-associated vasculitis and will be led and sponsored by Charite Universitatsmedizin hospital in Berlin.

Additionally, within autoimmune disease indications, our pivotal global Phase 3 study in anti-GBM disease saw the first patient treated in May, as previously reported, and further patients have been enrolled since. The target is to get 50 patients enrolled at 30 to 40 sites across the U.S. and Europe. In April, we announced a new gene therapy collaboration with Genethon to imlifidase as pretreatment to gene therapy in Crigler-Najjar syndrome patients with anti-AAV antibodies. Genethon is a pioneer in research and development of gene therapies for rare diseases.

Through this collaboration, patients with Crigler-Najjar syndrome and preformed labs will be enrolled in a study where imlifidase is evaluated as a pretreatment prior to the administration of GNT-0003 Genethon's gene therapy candidate, which is currently

being evaluated in a pivotal clinical study in France, Italy, and the Netherlands and has received prime status from EMA. This research and development collaboration is further testimony to our commitment in gene therapy and to bring in valuable therapeutic options to patients with unmet medical needs.

With this overview, I will now hand over the call to Matt Shaulis, who will walk us through our commercial progress in more detail. Matt, please.

Matthew Shaulis

Please turn to Slide 4. Thank you, Soren. Slide 4 illustrates where we are in our commercial journey as we scale Idefirix as a new way of allowing transplantation, while transforming the desensitization landscape. As Soren stated in the beginning of the presentation, we have recently seen solid performance and progress on our key launch metrics, including our best quarter yet of product sales. While we're pleased with this most recent quarter, based on unpredictability in organ allocation, we do anticipate seeing volatility in sales from month-to-month and quarter-to-quarter.

That being said, as discussed back in the first quarter, we expect an even better second half of the year as key markets such as the U.K. and Germany are expected to contribute, given the recent market access obtained, changes to the Eurotransplant allocation system, as well as Hansa's securing a number of clinic level agreements.

In Europe, we've now secured market access in 13 countries, including the five largest markets and the recent positive reimbursement decision in Belgium. Our progress is also underscored by encouraging changes in the transplantation clinical community, where we, in recent months, have seen medical guidelines and recommendations implemented on a national level in a number of key European markets, including the U.K., Finland, France, Belgium, and the Netherlands. These medical guidelines and recommendations are incorporated on the back of the ESOT guidelines published in transplant International last fall, which helped the transplant community in shaping the framework for management pathway for highly sensitized kidney transplantation patients.

Another example is the ESOT engaged Delphi consensus Working Group, which recently released findings and a poster presentation at ATC in San Diego. Not only does the working group include the role of imlifidase for desensitized patients, it also provides viewpoints on important elements of managing patient complexity in desensitization, such as antibody removal strategies, induction and maintenance of immunosuppression, and patient monitoring.

As mentioned, back in June, the group of Hansa representatives from R&D, medical and commercial attended the American Transplant Congress 2023 in San Diego. The ATC is the joint Annual Meeting of the American Society of Transplant Surgeons and the American Society of Transplantation, with more than 5,000 transplant professionals, including physicians, scientists, nurses, pharmacists, and allied health

professionals attending, representing more than 50 countries. This year, more than 500 role presentations and 1,200 poster sessions were scheduled in five days.

For Hansa, this was a key opportunity to interact with experts and stakeholders from the clinical research community, gather insights on clinical management of highly sensitized patients and further raise awareness of our U.S. ConfIdeS trial among KOLs, while at the same time, promoting Hansa's reputation and share of voice as a promising biotech company driving innovation in the field of kidney transplantation.

Lastly, our post-approval study continues to enroll according to plan. The post-approval study will support full marketing authorization in Europe. The post-approval study will help generate invaluable patient experience among the up to 25 clinics as we build the foundation for Idefirix to become a new standard of care in desensitization treatment is highly sensitized kidney transplant patients.

Please turn to Slide 5 and a review of our ongoing clinical programs. The end of June, Eurotransplant initiated a new desensitization program for imlifidase-eligible patients as a pilot in the acceptable mismatch program. Eurotransplant is an international nonprofit organization that acts as a mediator between donor hospitals and transplant centers among its member states, which today includes countries in the Benelux zone, Germany, and select Eastern European countries such as Hungary and Croatia.

The Eurotransplant network has facilitated organ allocation in a diseased donor setting and cross-border exchanges for more than 50 years, and the network has one overarching ambition to ensure best possible match for patients. Today, patients with a high level of donor-specific antibodies are eligible for a special priority list within the acceptable mismatch program. However, the list still precludes HLA incompatible patients who are immunologically compromised because of their HLA profile to a deceased donor, leaving them with basically no hope to be transplanted.

With the new Eurotransplant desensitization program, the aim is to include 20 imlifidase-eligible patients who are incompatible to a diseased donor than a pilot program. Patients will be included based on certain criteria such as minimal waiting time of three years in the acceptable mismatch program, donor below 65 years of age, and preferable negative T cell cross match towards accessible antigens for the desensitization program. We're very excited about the prospects of the new Eurotransplant program, which will provide opportunities for important clinical experience and Idefirix to treat highly sensitive patients, potentially lead to improved outcomes for hundreds of Idefirix-eligible patients in the Eurotransplant zone.

Please turn to Slide 6. Last week, Idefirix received provisional approval in Australia as a desensitization treatment in highly sensitized patients prior to kidney transplantation. Importantly, the decision from the Australian Therapeutic Goods Administration represents the first regulatory body in the world to approve the use of Idefirix in transplants from both living and diseased donors, which helps ensure comprehensive access for highly sensitized patients in Australia to this important therapy. With nearly 21% of kidney transplant candidates in Australia considered

highly sensitized with a CPRA of 95% or higher, the approval of Idefirix represents an important innovation in kidney transplantation care for patients and clinicians.

In 2021, 875 kidney transplantations were performed in Australia with 24% coming from living donors and 76% from diseased donors. Full approval in Australia will require submission to the TGA of further safety and efficacy data from studies that are currently underway, like the U.S. Confida trial and the post-approval study in Europe, while a decision on market access is expected sometime in the second half of 2023.

Please turn to Slide 7. With regard to our pivotal U.S. ConfIdeS trial in kidney transplantation, we exceeded our initial enrollment target during the second quarter and we'll continue to enroll more patients as previously got accelerate randomization. As of today, we've enrolled 76 kidney transplant patients at 14 sites, and we'll continue to add centers with a goal of approximately 20 or more to accelerate our organization of 64 patients.

The increasing number of centers will also help build valuable clinical experience in desensitization of these highly sensitized patients among KOLs in preparation for our planned launch in the U.S. market. Completion of study enrollment is expected shortly, while randomization should be completed by the end of the second half of 2023, and as previously guided.

With this, I will hand it back to Soren for continuing the update on our clinical programs.

Soren Tulstrup

Thank you, Matt. Please turn to Slide 8. As we announced yesterday, a new investigator-initiated Phase 2 study in ANCA-associated vasculitis has been started. This is the first study evaluating imlifidase in this patient population and is an important step forward in broadening the development of technology platform and pipeline of drug candidates for rare neurologic diseases and conditions. In fact, ANCA-associated vasculitis will be the third program in the autoimmune disease space in clinical development for our lead antibody cleaning enzyme molecule imlifidase.

As you'll recall, we have existing clinical studies in both anti-GBM disease in Guillain-Barré syndrome. ANCA-associated vasculitis is a group of rare autoimmune conditions that affect approximately three patients in 100,000 people annually across Europe and the U.S. of which between 8% and 36% are estimated to have acute respiratory distress syndrome due to pulmonary hemorrhage.

The disease is characterized by the presence of ITG antineural cytoplasmatic antibodies directed against antigens expressed by the neutrophils, a type of white blood cells in the body system. The presence of ANCA antibodies against neutrophils causes blood vessels damage that can affect multiple organs, most frequently the lungs and kidneys where it leads to rapidly deteriorating organ function.

In 25% of patients, the damage done leads to end-stage renal disease and sometimes also causes pulmonary hemorrhage in the lungs and respiratory failure. The study, which is led by Dr. Adrian Schreiber and Dr. Philipp Enghard at Charite - Universitätsmedizin Berlin is single center, single-arm Phase 2 trial in 10 patients with severe ANCA-associated vasculitis and acute respiratory distress syndrome due to pulmonary hemorrhage.

Patients will be treated with imlifidase on top of standard of care, which consists of standard neuro suppression and intensive supported care with the primary objective to assess efficacy and safety in the treatment of patients for pulmonary hemorrhage due to severe ANCA-associated vasculitis.

We look forward to the results from this study in yet another autoimmune disease and are excited about the potential for imlifidase to help even more patients suffering from serious autoimmune diseases and conditions. Please turn to Slide 9 and a review of our ongoing clinical programs. At the end of May, we announced that the first patient was dosed with imlifidase in a global pivotal Phase 3 trial in anti-GBM disease. The Phase 3 program, which targets 50 patients at 30 to 40 centers is the first and currently the only pivotal randomized trial in anti-GBM disease, a condition with significant unmet medical need. The primary objective of the study is to assess the superior effect of imlifidase in combination with standard of care versus standard of care alone consisting of the combination of immunosuppressants, steroids, and plasma exchange.

The performance of the treatment will be assessed through the evaluation of the function at six months as measured by filtration rate and need of dialysis. In addition, the safety profile and efficacy on pulmonary symptoms and health-related quality of live aspects will be explored. As of today, four patients have been enrolled, and we have 12 active sites up and running across the U.S., U.K. and EU. Earlier this year, we announced completion of enrollment in our GBS Phase 2 program. GBS is an acute autoimmune attack on the peripheral nervous system, which affects approximately one to two patients per 100,000 people annually.

Top line data on safety, tolerability and potentially the early effect imlifidase treated GBS patients is expected to be announced in the second half of this year. The full data from the GBS Phase 2 study is expected in 2024 following a comparative efficacy analysis treating imlifidase-treated group of patients in the trial and the matched cohort from the IGOS database at the Erasmus Medical Center in Rotterdam in the Netherlands. Lastly, we plan to publish the full data set from the AMR study in the second half of this year, as previously announced, following the positive top line data announced in November of last year. Now please turn to Slide 10 and a summary overview of our pipeline.

As you can see on this slide, we have successfully developed a broad and exciting pipeline currently with eight ongoing clinical programs across transplantation in autoimmune diseases. As we indicated back in April, we have initiated the clinical program with HNSA-5487, the lead molecule from our second-generation IgG antibody cleaning enzyme program NiceR. HNSA-5487 is an opportunity to substantially expand the number of potential indications for our antibody-cleaning

enzyme platform, including in areas where more than one dose of an IgG modulating enzyme is beneficial. The program is progressing according to plan and enrollment in the Phase 1 study in healthy volunteers was recently completed. The data analysis is now underway to value relevant indications to pursue in clinical development.

In gene therapy, our partner, Sarepta, presented data during this year's American Society of Gene and Cell Therapy Conference, which was hosted mid-May in Los Angeles. The data presented in nonhuman primates confirms the ability of imlifidase to remove antibodies towards AAVrh74, which supports the upcoming clinical study combining imlifidase with Sarepta's product Elevidys, previously known as SRP-9001. Elevidys received U.S. FDA approval in June as a onetime treatment in ambulatory pediatric patients aged four to five years suffering from Duchenne Muscular Dystrophy. In combination with imlifidase additional treatment may potentially be enabled in up to 14% of patients who are currently suffering from two high titers of neutralizing antibodies against AAVRh74.

With this overview, I will now hand over the call to Donato, who will walk us through a review of the financials for the second quarter and first half of 2023. Donato?

Donato Spota

Thank you, Soren. Please turn to Slide 11. Total revenue for the second quarter of 2023 amounted to SEK36.7 million, including SEK29.6 million in product sales and SEK7.1 million in contract revenue, mainly from the agreement of Sarepta. For the first half of 2023, total revenue came in at SEK60.8 million, including approximately SEK44 million in product sales. The second quarter was our strongest product sales quarter so far, and we continue to expect sales to grow further in the second half of this year.

As indicated by Matt, but we still anticipate quarter-on-quarter volatility to remain. We do expect sales for the remainder of the year and going forward to increase on the back of repeat business, implementation of new guidelines, additional countries being launched, the new Eurotransplant desensitization program targeting imlifidase eligible patients.

Please turn to Slide 12. Total SG&A expenses for the second quarter of 2023 amounted to SEK129 million compared to SEK19 million for the second half -- for the second quarter of 2022. The increase reflects Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix in Europe and building our U.S. footprint. Further inflation and devaluation of the Swedish krona against the euro and the U.S. dollar are negatively impacting cost.

For the half year, SG&A expenses increased to SEK233 million versus SEK171 million for the same period last year. Investments into R&D amounted to SEK115 million for the second quarter of 2023, which is a step-up versus the recent quarter reflects an increase of SEK22 million compared to the second quarter of last year.

The increase is mainly driven by expanded pipeline activities such as the ongoing pivotal Phase 3 program in anti-GBM and the U.S. ConfIdeS trial as well as our

clinical Phase 1 trial and CMC development activities related to HNSA-5487, our lead molecule from the second-generation enzyme program. R&D costs are also impacted by price adjustments due to inflation and the devaluation of Swedish kroner.

Looking at the full year 2023, we expect the operating expenses in the first half year to be indicative for the expected expenses in the second half of this year. Net loss amounted to SEK251 million for the second quarter 2023 compared to SEK170 million in the same period of last year. For the half year period, net loss stood at SEK457 million versus SEK309 million for the same period last year. In addition to the increased investments in our operations, the increase in net loss versus last year period is also driven by the amortized interest expenses related to our long-term loan. Notably, these interest expenses are noncash expenses.

Please turn to Slide 13. Cash flow from operating activities amounted to minus SEK182 million for the second quarter of 2023 compared to minus SEK136 million for the second quarter a year ago. For the first half of 2023, operating cash flow was minus SEK389 million versus minus SEK266 million in the first half year of 2022. The increase over last year is mainly driven by the increase in operating expenses and the upfront payment of SEK50 million we received early 2022 under the Aspire agreement.

Our cash position at the end of June was approximately SEK1.1 billion, which is expected to provide a cash runway into 2025, as previously guided.

I will now hand back the call to Soren for his final remarks.

Soren Tulstrup

Thank you, Donato. Please turn to Slide 14. We're encouraged by the solid performance in the second quarter and a very eventual first half of 2023 with good progress in our pipeline across all our four franchises. Looking ahead, there are several milestones we must deliver on for the remainder of 2023 and the years to come. As highlighted earlier, we continue to see healthy interest among clinics to participate in our pivotal U.S. ConfIdeS trial and will continue enrollment to accelerate randomization by adding new centers up to a total of 20 or more. Randomization is expected to complete in the second half of this year as previously guided.

In the second half of this year, we plan to announce the first high-level data readout in GBS following the completion of enrollment at the end of March. As discussed earlier, top line data is expected later this year with a full data set, including the outcome of the comparative efficacy analysis to an externally matched cohort for the IQOS database expected to be available in 2024. Additionally, we also expect to announce 5-year data from the long-term follow-up study in keeping transplantation.

Data is expected to be announced in the second half of 2023, which is also the time we expect to publish the full data readout from the AMR Phase 2 trial. Finally, we're encouraged by the recent progress with Sarepta and gene therapy following

promising preclinical data with imlifidase in their Duchenne Muscular Dystrophy program. Together with our partner of Sarepta, we plan to commence a clinical study after the summer in a small group of DMD patients with pre-existing IgG antibodies to Sarepta's newly approved gene therapy providers. Now please turn to Slide 15.

So, this concludes our presentation, and we would now like to open the call for questions. Operator, please begin.

Question-and-Answer Session

Operator

[Operator Instructions] Our first question comes from Gonzalo Attali from ABG Sundal Collier. Please go ahead.

Gonzalo Attali

Hi, thank you for taking my questions. First one on the ConfIdeS study in the U.S. Now you have enrolled 74 patients -- 76 patients, sorry. But from the way you describe it, it's difficult to know how fast this business will be randomized. So, my question is, how sure are you that you will achieve the goal of full desensitization by the end of the year? And if it's a matter of number of patients being enrolled, how many patients would you like to have enrolled in the trial, let's say, by the end of Q3 to be sure that you will make it before the year-end? Thank you.

Soren Tulstrup

Well, thank you for this very relevant question, Gonzalo. So, you're right, we've currently enrolled 76 patients. And the reason why we've continued to enroll patients, even though we are above the target of 64 randomized patients is because there is this delay between enrolling a patient and that patient actually getting an organ offer and being randomized. That delay is -- it varies from patient to patient, sometimes it's a month. Sometimes it's a couple of months. Some patients may actually not receive an organ offer within the period.

So that's why we've decided to continue to enroll patients. A subsidiary recently also that we really want to make sure that the centers have the opportunity to develop relevant expertise and experience in this field. How sure are we that we'll meet the target by the end of the year? Well, the randomization is increasing and given what we see right now, we are continuing to guide that we will have all 64 patients randomized by the end of the year. But obviously, just like with the uptake in Europe, it is a little bit difficult to predict the exact rate of organ offer to the patients. But that is what we're guiding at this point in time.

Gonzalo Attali

Okay. Great. Thank you, very much. Second one, if I can, and it's regarding the new transplant allocation here. Could you give us some color on how this tier will be -- will speed up transplantations? I mean your transplant accessible mismatch program

has around 330 patients had, this amount of patients at the end of 2022 with 83 patients were transplanted in the same year.

So how much will this leader as part of the accessible mismatch program speed up transplantation using imlifidase for the population that will not have an organ offer after three years, which should be around 25%, if I'm not wrong? Thank you.

Soren Tulstrup

Thanks again for the second question, Gonzalo and I'll hand over to Matt in just a minute or so. But overall, I mean, the Eurotransplant program has the great benefit that in a systematic way now, patients are identified, put on a list as part of a formal evaluation of the use of imlifidase. So certainly, it's very, very helpful, not just looking at individual patients that will be identified and transplant is hopefully, but also the fact that there is this focus on this from the Eurotransplant organization. Also, we definitely think that this is something that will help speed up the penetration of Eurotransplant markets, which, as you know, includes Germany, Benelux, certain Eastern European countries. So -- but with this, I'll hand over, maybe Matt will have an additional comment or two on this.

Matthew Shaulis

Thank you, Soren. I think you covered the main principles here. And I think the acceptable mismatch program, obviously, will continue on. I think that there will be a high level of awareness around it. It's really the desensitization program where we -- as we indicated in the call, we'll see 20 patients initially. But our understanding with Eurotransplant is that there's a substantially larger number of patients beyond that initial group of 20. So, our understanding is that as organs become available, there will be a process by which committee reaches out to centers that are known to have these patients. And for this cohort that qualify for the desensitization program, we see that there will be a relatively quick identification of those patients and treatment.

Operator

We have our next question from Christopher Uhde from SEB. Please go ahead.

Christopher Uhde

Thanks for taking my question. So, I guess I have a few that are sort of clinical and then a couple of others. So, starting with the clinical. We're getting close to the readout in GBS, as you've highlighted. What can you say about what the bar for success is at this point? Do you have any more clarity you can offer there? Then you got a label in Australia for living donor transplantation. So, congratulations. But are you planning a living donor transplantation trial for registration at this point? And if so, can you offer any details? And if not, what more do you need to see happen in order to do it? And I guess, yes, I'll come to my third one next.

Soren Tulstrup

Okay. Well, thanks, Christopher, for those questions. So first, on the GBS study. So, I don't know this is going to be kind of a two-step readout process where we'll have data relating to safety-tolerability coming out in half of this year. And then we're going to have the efficacy comparison to the IGOS match cohort next year. And obviously, what we expect and hope for looking at the first data readout is that this is a well-tolerated, again molecule in these patients. And hopefully, there are some high-level conclusions on the efficacy.

But we haven't set any specific kind of success bars for the first readout other than what I just said in broad parameters. And clearly, for the second batch or second readout next year, we would expect -- we would hope to see that there is a superior efficacy of imlifidase in the -- in relevant treated patients versus the IGOS-match cohort. I can't give you specifics there.

It's the overall aim to demonstrate superior efficacy.

Then on the second question, yes, we're very excited about the fact that we now have officially in the label kind of donor source agnostic transplantation using imlifidase as desensitization therapy. This is the first time we've seen that. And that obviously is an opportunity to expand the market. We get out of the rate limiting factor caused by the availability of organs from diseased donors.

In the first instance, it's good to have it in the label in Australia. And certainly, we expect that, that will lead to actual usage. There may be usage outside of Australia as well at some point in time to get it officially into the label. We may have to run a trial. There are no specific plans at this point in time. But certainly, it is something that we aim at ensuring that there will be usage in the living donor population as well.

Christopher Uhde

Okay. Thanks. I mean, I guess the thing I would wonder about that further is, I mean, there's obviously a trade-off between cash burn, which is I'm sure why you're waiting. But at a certain point, it starts to become a drag on what you actually earn versus what the potential is. And so, yes. I mean, I guess, if you could give a little bit more color around your thoughts on that.

And then my last question would be, obviously, you've done a lot of small trials, including IIS [ph] in the past, and you've experienced both the advantages and the advantages of them. Now you got an anti-GBM trial with almost as many sites as patients targeted, which brings challenges of different patient management strategies between centers into play.

And then, of course, you also have now another IIS in ANCA-associated vasculitis. So what learnings from past experiences you apply here to facilitate a more rapid recruitment of patients and also more homogeneous patient management to maximize the trial success? Thanks, so much.

Soren Tulstrup

Yes. So, the anti-GBM pivotal study is one that we're running ourselves, right? And obviously, this is -- so it's important to have enough trial sites up and running quickly. And there, we are progressing quite nicely. And as we just discussed, we have already four patients in here. So, we're quite pleased with the performance so far. As far as anti-GBM is concerned, the ANCA-associated vasculitis trial is a single-center study. Again, it's off to a good start. We have not only the patient and we have several patients, and we believe that working with this one clinic is quite helpful, and they're very engaged in this. So, let me then also follow up on your first comments there on living donor registrational trial plans.

And you're right. I mean, obviously, there is a need to prioritize those things that are critically important in the short run, which is what we are doing. And we do think that there is a path forward in living donor transplant situations. And that may not be a path that requires a substantial trial. But certainly, it's something that we're evaluating and have in our minds, getting that into the label and certainly getting that usage is important for the uptake of imlifidase.

Matthew Shaulis

Soren, if I could just make a quick comment on living donor. I think it's really encouraging, and we're very pleased that TGA provided both living donor and deceased donor in the label. And that's a view, I think, that reflects that from a scientific and a clinical perspective, the living donor setting is actually very similar to the deceased or when it comes to our data and the overall safety and efficacy associated with the treatment. But also, I think it's noteworthy that in general, some parameters, including obvious things like cold ischemic time that the living donor is actually a lower risk cohort. So, we'll continue to do things like, in particular, an observational study that includes both deceased and living donors in Australia, and that will be a source of data, which will allow us to continue to evaluate the opportunity.

Operator

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

Douglas Tsao

Congrats on all the progress on both commercially as well as work on the pipeline. I'm just curious, in terms of the commercial performance, it sounds like, you are starting to get a number of reorders. Just can you provide a balance to some perspective on how meaningful that ultimately was this quarter, and we're still talking about relatively numbers?

Soren Tulstrup

Yes, I'm not sure I got all of your question there. But overall, you're right. I mean it's obviously important for us to now see kind of repeat business, which is not at the patient level, as we've discussed previously. It's really at the clinic level. We're seeing

this in a growing number of clinics and that's very encouraging. Matt, I don't know if you want to add to this, but clearly, it's an encouraging development.

Matthew Shaulis

Yes, yes. Absolutely. We're seeing a number of centers across Europe, get to that point where they have repeat ordering. And the other thing, of course, that we look at too is when centers have repeat utilization of patients across trial activity as well. So, when we look at repeated use in patients, we get to the point where it's double-digit numbers of centers that have had multiple patients. And we'll continue to evaluate this on a quarter-by-quarter basis as we look across Europe on our launch activities.

Douglas Tsao

I guess to put it more simply, I mean, I guess, what percentage of this quarter's sales were repeat business with investors?

Soren Tulstrup

I don't know that, Douglas, we can give you a specific percentage at this point in time. I mean, clearly, what you are seeing is that there are more centers having their first patient than centers having number 2 or number 3 patients. So that's the overall picture. But it's really encouraging to see the growth in the number of centers having repeat business, and that's obviously based off of positive experiences in the first patient or patients treated.

Douglas Tsao

Asking a different subject. So, finish up.

Soren Tulstrup

Yes. I would just say that we're going to see volatility on a quarter-by-quarter basis given that overall in the earlier stages of the launch, which we sort of remain in overall patient numbers are going to be low. So, if we come back one quarter from now, there could be a change in this or it could be similar. It's more on the semester-by-semester basis we probably would continue to see more meaningful patterns.

Douglas Tsao

Okay. Great. And obviously, you're adding a lot of new in quite significant markets from a number of plans taking place base. just, do you expect to see a factor learning for them. I know it took some time for some of the early adopters to sort of work in this way into the protocol. And then just also as a follow-up on GBM. I think you said Soren that there were 12 sites now enrolling. We have just 30 to 40 targeted. How quickly do you think you can get to the target number of sense sites up and run in that setting?

Soren Tulstrup

So, on your first question, obviously, I mean, there's always learnings that we're applying from market to market. I think overall, the launch so far has really played out almost exactly as expected, which is great. It does take a little while from having secured pricing and reimbursement to getting the specific protocols in place on a national level and within specific clinics. And clearly, we're doing whatever we can to assist and speed up this process also in new geographies.

And what is really important, I think, we've learned is to make sure that there are appropriate kind of groupings so that the centers can learn from each other and they can align and so on. I was recently in France, we hosted a very, very successful meeting with 30, 40 key opinion leaders and staff from the leading clinics across France, discussing patient experiences using imlifidase. And that kind of to really very helpful because they also learn as they go, right.

And so, we can facilitate a steeper learning curve that is really very beneficial. Then on your second question, anti-GBM. I cannot give you a specific kind of expected timing here. We're encouraged by the good start we're off to, right? But we do expect that we'll have to set up a very significant number of sites to make sure that we can recruit the 50 patients within a reasonable time frame.

Operator

We have our next question from Bo Zhang from Intron Health. Please go ahead.

Bo Zhang

Thank you for taking my question. Congratulations on a successful quarter. Just a few from me. First on the Eurotransplant. We understand the long-term end of putting more focus in this patient setting. But just on the near term, what is the time frame you sort of expect the pilot program of enrolling 20 patients to wrap up?

And then number two, on PAS, on the post-approval study, is there any numbers you can give on the number of patients that have been enrolled or even as a percentage, so it would be helpful. And the last one is on Australia. So, on time line, what can we -- what is the expected time line of, I guess, commercial readiness or when we can start seeing revenues coming in from the region? Or is it more looking for a commercial local partner for Australia? Thank you.

Soren Tulstrup

Sure. Let me hand over to you, Matt, to talk about the Eurotransplant program, right? Obviously, we have 20 patients and different cohorts. And then we can take the post-approval efficacy study afterwards. So maybe let me just address that because I can't give you the specific number, but we do have a very material number of patients enrolled at this point. And as you know, the aim is 50, and we need to have the study concluded by the end of '25, which is then what we're aiming at. And the third question was around the time line for Australia, which again, I think I'll let you answer, Matt. So over to you, Matt.

Matthew Shaulis

Sure. Yes, happy to talk about both the Eurotransplant desensitization program and Australia timing. Yes, just to close the loop on the post-approval study, we don't have specific data available to answer that question. Now I do know that post-approval study, again, is a situation where we have multiple centers treating multiple patients. That much I can say.

As for the Eurotransplant desensitization program and timing there, our understanding is that patients are already identified that would be appropriate and fit within that cohort. It's difficult for us to provide more guidance on exact timing. Again, as organs become available and are in the protocol associated with that program, there's a central committee that then reviews the match between the organ that's been allocated for the program and the patients from across the centers in Eurotransplant that have been identified.

And so, there's an alignment that happens between the local center that's going to do the complex immunologic procedure and the central committee. And so, between the process of the organ, the allocation going into the program, and then that match happening, it's difficult for us to say exactly how long it's going to take for that first group of 20. We have been told that there's a substantially larger number than the 20, but the actual speed is difficult for us to provide guidance on. Again, on a timing question, related to Australia, again, there, we're really encouraged by TGA and their decision on labeling. We have conversations ongoing with MSAC [ph] related to reimbursement coverage and the pricing point. We think it's going to be a little bit later in the year when those conversations are resolved. We're very encouraged with the initial steps in that process.

But again, we think it's going to be until sometime in the second half of the year that we have reimbursement and the price secured. Needless to say, though, there was very good support within Australia for our labeling. We anticipate the patient identification is going to happen pretty quickly in Australia. So, when we get that price and reimbursement secured, then we do anticipate seeing some patient treatment fairly quickly in that country.

Bo Zhang

Thank you. Just a quick follow-up for Australia. Is it more of thinking building commercial teams, field forces in house? Or is it more of a partnership opportunity?

Soren Tulstrup

Matt, I think you can...

Matthew Shaulis

Yes, happy to go, Soren. We're going to finalize those decisions when we work through the pricing and the reimbursement coverage. So right now, we've got a couple of avenues that we've looked at very, very thoroughly. And when we have sort of a final disposition on pricing and reimbursement and we can combine that with what we already know about the label, then we'll make a final call on it. I would also

say that regardless of what direction we go, we've outlined a number of what we consider to be very strong options for the commercialization.

And as I'm sure you know dialogue with management here at the company and your understanding of the space, it's really a commercial and medical process that's really critical, managing the complex protocols associated with these patients. So, we believe that the avenues that we have to pursue are going to rise to that level of complexity.

Operator

We have our next question from Ingrid Gafanhao from Bryan Garnier. Please go ahead.

Ingrid Gafanhao

I'll be really quick. I have some questions on the Australian approval. So actually, I wanted to confirm with you that you are not required to do any country-specific additional studies in a post approved setting? And the second question would be, I know you're still having some discussions in the second half of this year, but what are you thinking in terms of pricing, is it going to be at least in line with what you have now for Europe? Thanks.

Soren Tulstrup

Well, thanks. So essentially, I mean, we obviously need to submit additional data. And as we said, we can get that from other sources. So that's the overall situation. As far as pricing is concerned, clearly, we will use the same value proposition approach that we've taken in Europe successfully and apply that also in Australia. But Matt, I don't know if you have any additional comments on Australia?

Matthew Shaulis

Yes. I guess I would just say that we've seen some fairly positive opinions in Europe and the same data and analysis from health economics and an outcome standpoint that we've used in Europe will be the same information that we're using with MSAC in Australia. So, we can't provide very specific guidance on the Australian price recommendation. But I think what we can say is that we don't anticipate that it's going to be substantially out of line with what we've seen in some other markets.

Ingrid Gafanhao

And if I may have just a quick follow-up on this. So, I think Australia is sort of the first territory that was a little bit different than the ones that you had got an approval before. Are you pursuing a similar approach in any other territory at the moment? Or are you still more for the long term? That was my last question.

Soren Tulstrup

So obviously, we're -- we plan to use the data we have and the approval in Europe to get additional approvals. If your question is around whether we want to secure a different type of label, that really depends on the specific dialogues we're having, obviously, with the relevant regulatory authorities. Please go ahead. Go ahead, Matt.

Matthew Shaulis

Yes. I was just going to say, not necessarily that we have a specific plan related to expanded labeling in existing markets. But I think one thing that we do plan to do is gather some data in Australia related to both the deceased and living donors that are treated with the product. And as we get that data, that can be useful in the future, and we'll evaluate our options as we gather that data to use it with regulatory authorities in other markets. But again, I think that's a situation where we want to gather the data first, see how things look and then evaluate our options in other markets.

But no question, I think this is some of the nature of the question. It's an opportunity to have living donor patients in Australia and in some ways to gather the data on it. And we're still pulling together our plans on how exactly we'll do that in a way that suits our future strategic interest.

Operator

We have our next question from Matt Phipps from William Blair. Please go ahead.

Matt Phipps

Hi, guys. Thanks for taking my question. Congrats on a nice quarter of sales. I was wondering if you could give us any more info on 5487 and just what you'd be able to disclose after you analyze the data? And then any sense of timing for when you will disclose indications? Is that something we can get later this year?

Soren Tulstrup

Yes. Thanks, Matt, for that question. Yes, we're certainly very excited about the potential that 5487 offers the ability to use a more hopefully, a more flexible dosing regimen. Amy had more longer extended IgG-free windows and repeat dosing and so on and so forth. So, through the study in healthy volunteers, obviously, we'll be able to get data that we can compare to the very extensive data set we have from our preclinical and clinical trials with imlifidase.

And based on what we know so far, we're very optimistic that we can develop and we have a molecule here that we can develop further that is superior to imlifidase in terms of the immunogenicity. So, we expect to complete this Phase 1 trial in the second half of this year. And based off of this, we would then make a decision as to the specific next indication that we pursue with this molecule, and we expect them to initiate a trial next year. There is a range of options available.

We really see tremendous potential certainly in the autoimmune disease space, where there's a number of DC driven more chronic diseases, where the patients

would benefit from induction therapy and add-on to their maintenance therapy when they have flares. It's quite a range of diseases there that will be relevant. We clearly see a tremendous opportunity in the gene therapy space, where right now with imlifidase focused on preexisting neutralizing antibodies against the vector used, but there is, I think, an even larger opportunity for, let's say, ameliorating the performance of the gene therapy and certainly also allowing repeat dosing of the gene therapy, which given the issues with your dose of response is likely to be required for a number of the gene therapies currently in development.

So that's another broad opportunity. And then clearly, we talked about allogenic stem cell transplantation in the broader oncology space previously. That's another product area. And then finally, even in transplantation where we have a fantastic molecule in imlifidase, given the opportunity to treat not just patients that are prohibited from actually accessing quickly transplant and making equipment transplant, these patients and some other patients certainly will have issues with AMR following the transplantation and that's another opportunity in the transplant space for 5487 potentially.

So, there's a very broad range of indications that could be relevant. And we will get back, of course, as quick as we can when we make that decision to talk about the path forward.

Operator

Our next question comes from Johan Unnerus from Redeye. Please go ahead.

Johan Unnerus

Thank you for taking my questions. A few questions. The first, just a follow-up on the U.S. study. You are not targeting at least or possibly more than 20%. It's just a clarification then, will these centers also participate in sort of long-term follow-up studies and post-approval study possibly with aim to secure unconditional approval in the future?

Soren Tulstrup

Yes, that's correct. We are targeting at least 20 centers to be involved here, a, because obviously, we want to speed of the randomization; and b, because it is critically important to get experience with imlifidase prior to the launch. We've seen that in Europe. And so, we're very encouraged by the strong interest from a broad range of leading transplant centers in the U.S. to participate in the ConfIdeS trial. We do expect these centers to also continue to assist us with the clinical trial activity also looking at post-approval commitments. So yes, please.

Johan Unnerus

Thanks for that clarification. And also, the ANCA at this stage in the independent study, it seems to be an interesting acute setting then. And if I got it correctly, it's already started to recruit patients. Could you clarify when it's reasonable to expect results? And also, if possible, to get a feel for what is to be expected normally with

the present standard of care for this troublesome patient group, I guess, their own immune suppressing therapies now.

Soren Tulstrup

Yes, that's correct. If I start looking back part of your questions. Clearly, this is a very, very severe disease with a high degree of unmet medical need. And the mortality rate overall is close to 20%, if I'm correct. And you see organ damage, hit the organ damage, lung damage, and so on.

So, this is the outcome of the existing standard of care. So clearly, as I said, there is a high degree of unmet medical need. It is not just kind of a hyperacute monophasic disease. I mean some patients will be treated well and will respond well and will not necessarily have kind of a chronic situation. But some patients will be affected for a long period, and we'll have, again, various levels of disease and symptoms.

So, that's the disease per se. I can't give you a specific kind of expected timing for completion of enrollment of this trial. It is aiming to enroll 10 patients. And as I said, we have more than one patient involved at this point. But it is dangerous at this point, so early on to make any specific predictions. But we -- it's not a huge trial. So hopefully, we'll get this completed and analyzed sooner rather than later.

Johan Unnerus

And in a reasonably successful scenario, you have sort of onboarded independent studies earlier and another clarification is possible. Could this move on to Phase 3 straightaway?

Soren Tulstrup

I didn't get the first part of your question. Can you repeat that?

Johan Unnerus

Just a reflection that we see in Hansa sort of -- that you have experienced independent trials earlier and then made them your own at the next following stage. I guess this is as a scenario for this initiative as well.

Soren Tulstrup

Yes. Yes, sure. So that's what we have seen in anti-GBM, right, where it was an investigator-initiated trial with 15 patients and now five pivotal trial run by us in 50 patients. So that certainly is a possible path forward for the ANCA-associated vasculitis indication as well.

Johan Unnerus

Yes. And then to the financial side, it's clearly a few moving parts. FX is one. Cost inflation is another. And of course, activity is the third, and that goes for both SG&A and R&D. Is it possible to give any more insight into these moving parts?

Soren Tulstrup

I will hand it over to Donato to talk a little bit about this.

Donato Spota

Sure. Yes, happy to give you a little bit of more insight Jonas. So obviously, the biggest drivers are certainly our expansion in our operational activities, right, on the commercial side in Europe, but also then starting to build up our footprint in the U.S. and, obviously, also the expanded activities related to our clinical pipeline. So that's certainly the biggest impact that on the inflation side and on the FX side, you've seen inflation, average inflation rates in Europe hitting up to 10%, and the devaluation of the Swedish kroner now versus U.S. dollar and euro is also about 10% against each of these currencies. If you look back first half of 2023 versus first half of 2022. So, I hope this gives you a little bit of a flavor of what drives the increase in the cost versus periods of last year.

Johan Unnerus

Just to round it off then, you said something along the line that the first half or possibly Q2 is sort of an indication for the second half of the year. Should we read that as R&D and SG&A.? SG&A activity that Q2 levels is a good indication for the second half.

Donato Spota

I would say the first half is also isn't the indication of what we expect for the second half.

Johan Unnerus

So, could that mean that we actually could see quarters with less OpEx than Q2.

Donato Spota

That could mean that we see quarters with last year. So, we don't expect to continue to grow on a quarter-on-quarter basis, right? But yes, but overall, I think first half is indicative of what we would expect for the second half.

Operator

We have no further questions registered at this time. So, I will now hand back to the management team for final remarks.

Soren Tulstrup

Well, thank you, operator, and thank you, everyone, for your interest in Hansa Biopharma. As you've heard, we've had a good and exciting quarter, and we look very much forward to keeping you updated on further progress for the remainder of the year. Thank you so much.

Operator

This concludes today's call. Thank you all for joining. You may now disconnect your lines. Have a great day.