Hansa Biopharma Q2 2024 Conference Call Transcript

Company Participants

Søren Tulstrup - Chief Executive Officer

Matt Shaulis - Chief Commercial Officer and U.S. President

Hitto Kaufmann - Chief Scientific Officer

Evan Ballantyne - Chief Financial Officer

Conference Call Participants

Alexander Kramer – ABG

Matt Phipps - William Blair

Douglas Tsao - H.C. Wainwright

Erik Hultgård – Carnegie

Johan Unnerus – Redeye

Operator

Hello everyone, and welcome to the Hansa Biopharma Q2 2024 Conference Call. Today's call is being recorded. For the first part of this call, all participants will be in a listen only mode. Afterwards, there'll be a question-and-answer session. [Operator Instructions].

I will hand the call over to CEO Søren Tulstrup. Please begin.

Søren Tulstrup

Thank you, operator. Good afternoon. Good morning, and welcome to the Hansa Biopharma conference call to review the first half in Q2 results for 2024. I'm Søren Tulstrup, President and CEO of Hansa Biopharma. Joining me today is Evan Ballantyne, Chief Financial Officer; Matt Shaulis, Chief Commercial Officer and U.S. President; and Hitto Kaufmann, Chief R&D Officer.

Please turn to slide two. 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 three, an overview of today's agenda. They will discuss the progress we made during the first half of 2024 and review our near-term authorities. The presentation should take roughly 15 minutes to 20 minutes after which there will be an opportunity to ask questions during a Q&A session. Please turn to slide four and an overview of our Q2 highlights.

I'm pleased to announce we have delivered our third and second quarter of solid sales with total revenue of SEK54.2 million of this SEK47.1 million can be attributed to Idefirix sales. The strong sales performance we saw in the second quarter is a result of the team successful efforts to expand access to Idefirix for highly sensitized ticket patients across

Europe. During the quarter, we secured our first commercial sales in Italy following of reimbursement status in key regions.

To date, we have had commercial sales of Idefirix in all of the top five European markets. We are also seeing strong momentum in our pipeline and clinical development efforts. In May, we announced that ConfIdeS of pivotal Phase 3 U.S. trial and kidney transplantation has been fully randomized. This marks an important milestone for Hansa and following data readout in the second half of 2025, we expect to submit a biologics license application to the U.S. FDA seeking accelerated approval.

Matt will cover the status in next steps for the trial in more detail during his section of the call. Our post authorization efficacy study in Europe is progressing at a good pace in parallel with the continued commercialization of Idefirix and as part of our obligation to EMA. Non-generating data that could further support the adoption of Idefirix as desensitization therapy to enable incompatible kidney transplants, this study offers additional opportunities for important transplant centers to gain experience with Idefirix. Data readout is expected in 2025.

Looking beyond kidney transplantation, we have advanced several trials in autoimmune diseases. Our Phase 3 Anti-GBM disease trials continues with more than 70% of patients enrolled in the trial. Completion of enrollment expected in 2025, as previously guided and based on the strong momentum in enrolling patients, we now also expect data from the study in 2025. Our Phase 2 trial in Guillain-Barré syndrome also remains on track and we expect to share additional efficacy data later this year following promising high-level data communicated in 2023. Our efforts to advance HNSA-5487, the deep candidate from our next generation enzyme program continue as planned and we'll look forward to sharing further analysis on endpoint in the Phase 1 trial and the development path forward during the second half of this year.

Finally, I'd like to congratulate our partner Sarepta on the recent achievement of FDA full approval and expanded label imlifidase in Duchenne muscular dystrophy. While this approval enables more patients the opportunity to benefit from the therapy, some patients remain ineligible due to anti-AAV antibodies, and we're excited to continue our collaboration with Sarepta to determine the potential for imlifidase to enable gene therapy in these patients.

With this, I'll hand it over to Matt for a business and operational update.

Please turn to slide five.

Matt Shaulis

Thank you, Søren. Please turn to slide six for an update on Idefirix launch in Europe. As mentioned, this marks the third quarter of strong commercial sales for Idefirix. We attribute the continued commercial utilization of Idefirix to several things. The first is that we have seen additional centers come on board throughout Europe and continue to progress reimbursement in key European markets. As Søren mentioned, we secured our first commercial sale in Italy in Q2.

As of today, we have reimbursement in 14 European markets, including the top five markets, and we have access to approximately 75% of the European transplant market. By Q2, 28

centers gained clinical experience with Idefirix. This is an increase from last quarter with three additional centers gaining experience with Idefirix. Importantly, 60% of those centers have used Idefirix more than once, and there are over 50 transplant centers in Europe that have the capability to perform kidney transplants in highly sensitized patients.

Repeat utilization underscores the growing clinical confidence in Idefirix and clinician's ability and willingness to identify Idefirix appropriate patients. Given that we see increased uptake in new clinics in new markets, we believe that repeat utilization could happen at several clinics in the remainder of 2024. While we have full confidence that our strategy is the right one, we recognize the volatility of the transplantation market, particularly with respect to organ allocation, and therefore, we'll continue to broaden our base of opportunity, including the progression of health technology assessment processes in several countries to ensure ongoing expansion of Idefirix availability and reimbursement to even more markets and patients.

The second reason we believe we are seeing good progress in Europe is that desensitization strategies within the clinical community continue to advance. In fact, the European Society of Transplantation, ESOT, published a consensus paper in April, entitled European Consensus on the Management of Sensitized Kidney transplant recipient, Idefirix study. The paper recommends Imlifidase as a desensitization strategy for disease kidney transplantation in selected patients for whom no other treatment options are available. This follows the organization's publication of the first Ever Guidelines on desensitization in 2022 and which resulted in Idefirix-specific guideline implementation at the national level in key European markets.

And finally, Eurotransplant's desensitization program is helping identify patients eligible for Idefirix today. To date, the program has identified and treated five patients with Idefirix, including in Germany, the largest market in Euro transplant footprint. This validates that participating transplant centers are now receiving Idefirix designated kidneys. 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. Please turn the slide seven.

Advancing the science of Imlifidase in kidney transplantation is also important. To that end, there are two key studies we continue to progress including a long-term follow-up study. The 17-HMedIdeS-14 study and the post-authorization efficacy study, PAES. As we have communicated previously, the long-term study has demonstrated that for important endpoints such as graft survival and overall survival Imlifidase treated, highly sensitized patients achieve similar outcomes as non-sensitized patients. Both studies are on track and Hitto will share more about them in just a moment.

Additionally, a real-world evidence study has been initiated in France to evaluate out outcomes in nine Imlifidase treated patients. Through the initial follow-up period, there has been no graft failure and no death in these real-life data demonstrate that the use of Imlifidase to desensitize highly sensitized patients and have an acceptable short-term efficacy and safety profile in selected patients.

Please turn to slide eight. Finally, we are happy to announce that ConfIdeS the pivotal U.S. Phase 3 trial is now fully randomized. As a reminder, the ConfIdeS study is evaluating Imlifidase as a potential desensitization therapy compared to treatment according to standard of care to enable kidney transplantation in highly sensitized patients waiting for a

deceased donor kidney, a total of 64 highly sensitized patients on the wait list for kidney transplantation or randomized on a one-to-one basis to either desensitization with Imlifidase or standard of care.

What's important to know about the study is the total of 23 sites were enrolled in the trial and consent over 140 patients. Approximately half of these sites about 11 were responsible for randomizing two or more patients. The sites in the trial represent about 20% of the total transplantation volumes in the U.S. Currently, 13 sites have treated patients with Imlifidase thus far, which is very encouraging and we believe further validates that clinicians are recognizing the clinical value and patient benefit and Imlifidase in highly sensitized patients.

Following full randomization, all patients will be followed for 12 months per the study protocol and we expect data readout in second half 2025 and followed by submission of a BLA to the U.S. FDA to seek accelerated approval.

I will now turn to Hitto for an update on the pipeline.

Please turn to slide nine.

Hitto Kaufmann

Thank you, Matt. Please turn to slide 10. During the second quarter, we have made progress across our three key therapeutic areas with all trials. Let me orient to the slide and talk through the progress as well, what's come in the second half of 2024 and beyond. Importantly, Matt mentioned that randomization Phase 3 U.S. trial ConfIdeS. We now look to follow all patients who make 12 months for study protocol and begin to prepare for BLA submission to the U.S. FDA in second of ‘25.

In parallel, we're also advancing to additional trials in kidney transplantation. The long-term follow-up study 15-HMedIdeS-09 is a prospective observational long-term follow-up study of patients treated with Idefirix prior to kidney transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after Idefirix administration. The data shows sustained outcomes, out of five years in the majority of highly sensitized patients, who received imlifidase in kidney transplant. Data were presented at the American Transplant Congress in June and we expect it to be published in the peer review journal later this year.

And the Post Authorization Efficacy Study, PAES continues to progress as part of our obligation under the European Conditionally Marketing Authorization. The study will support full marketing authorization and data is expected into ‘25. In autoimmune, we are progressing three trials. Earlier this year, we reported initial data for our Phase 2 study in GBS, the 15-HMedIdeS-09 study, an exploratory single-arm study with several efficacy endpoint. We plan to share contextualized efficacy data later this year based on a comparison between the data of study and matched cohort from the IGOS database.

The International Guillain-Barré Syndrome Outcome Study or IGOS is a large-scale global research initiative that collects extensive clinical and biological data from GBS patients to enhance understanding and treatment of the disease. GBS is an acute, rare, paralyzing and inflammatory disease with the peripheral nervous system usually preceded by an infection or other immune stimulation.

Two-thirds of patients have severe syndromes resulting in the inability to walk on aid. The Good-IdeS-12 Phase 2 trial in anti-GBM disease has enrolled over 70% of patients in the trial. 36 out total of 50. We anticipate full enrollment in 2025 and data readout later the same year. The trial is an open-label, controlled, randomized, multi-central trial across Europe in the U.S. and as evaluating renal function and need for dialysis at six months in patients with severe anti-GBM disease. We believe imlifidase can have to significant potential in improving the outcomes these patients and address the unmet medical need.

Anti-GBM disease is a serious and ultra-rare acute monophasic autoimmune disease affecting approximately 1.6 people in a million. In anti-GBM disease, antibodies are directed against the patient's own organs causing acute injury to kidney and or lung function, and in worst case, organ failure. Rounding out in autoimmune, the Phase 2 trial AMR has been admitted to a peer-reviewed journal and we anticipate medications same time in 2024.

Moving now to gene therapy, I'm pleased to share that we continue to progress out collaboration with all three partners AskBio, Genethon and Sarepta. These collaborations will help determine the potential for Imlifidase as a pretreatment to gene therapy in those patients with anti AAV antibodies with both Hansa and Genethon, we continue to progress preclinical efforts in May at the American Society of Gene and Cell Therapy ASGCT annual meeting, AskBio delivered in oral presentations on preclinical data as part of the Hansa as bio partnership. The data evaluated the potential use of imlifidase pretreatment to gene therapy and demonstrated that imlifidase can keep AAV circulation for a longer time period, thus allowing a longer window for gene therapy transduction.

Together, with Genethon, we're finalizing our preclinical work and have plans to commence the clinical study later this year, evaluating imlifidase pretreatment to 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 EMA. I'm also pleased to share that we continue to collaborate with Sarepta DMD. A Phase 1b trial was initiated last December, and we anticipate data from the trial will be available in 2025. This is a slight change in the timeline to allow for protocol amendment.

In June, the Sarepta indicated that it putting a strategic focus on making their AAV based therapies available for antibody positive patients. Finally, we are making good progress with next generation molecules as part of the NiceR program. Previously, we announced high level results related to safety and tolerability from the NICE-01 trial with HNSA-5487 the company lead candidate from the NiceR program.

The trial included a total of 36 healthy male and female adult participants, further analysis of other endpoint will be completed in 2024, including a decision on the clinical development pathway. Hansa’s developing novel IgG-degrading enzymes with the objective on enabling redosing in autoimmune conditions, oncology, gene therapy and transplantations where patients may benefit from more than one dose of an IgG modulating enzyme.

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

Evan Ballantyne

Thank you very much, Hitto. Let's walk through the company's financial performance in Q2 and for the first half of 2024. Revenue for the second quarter of 2024 was SEK54.2 million, including SEK47.1 million in product sales before a SEK19.9 million provision. Revenue

included approximately SEK4.6 million in contract revenue, mainly from the agreement with Sarepta, including the provision product sales for the quarter total SEK27.2 million. The provision is associated with cumulative sales since the launch of Idefirix in Europe. What's important to remember is, as the new market entrant, establishing the provision reflects ongoing price and volume discounts, and this is not unique to Hansa, nor is it unique to the transplantation market.

Excluding the provision, we've delivered our third consecutive quarter of strong Idefirix sales. As we continue to expand our commercial footprint in Europe and other key markets, we expect this to increase. SG&A expense, please go to the next slide, slide 13.

SG&A expense totaled SEK88 million in Q2, 2024, and SEK179 million in the first half of the year. SG&A expense have been affected by restructuring reserve of approximately SEK3.5 million. Restructuring activities have reduced total SG&A expense compared to prior quarters.

Non-cash expense for the company's long-term incentive program, the LTIP program were included in SG&A costs and totaled SEK16 million for the first six months of 2024. Additionally, R&D expense for the second quarter of 2024 totaled of SEK92 million and SEK195 million for the first half of 2024. R&D expense included our restructuring reserve totaling SEK6.6 million. Compared to the same period a year ago in 2023, the decrease in expenses was primarily driven by restructuring activities.

As Hitto mentioned, R&D expense, including costs associated with the US confided study, EMEA post authorization commitments and anti-GBM Phase 3 studies, as well as the CMC development for HNSA-5487. Non-cash expenses for the company's LTIP program were included in the R&D expenses and totaled SEK6.5 million for the half 2024.

The operating loss for the quarter was SEK187 million and was driven by lower SG&A expenses and lower R&D expenses offset by higher cost of goods sold. The operating loss for the first half of 2024 totaled SEK347 million and was driven by lower SG&A expense and lower R&D expense.

Please go to the next slide for cash flow, on slide 14. In Q2, a company completed direct share offering of approximately SEK372 million or $34.6 million. This helped extend the company's cash runway into 2026.

Operating cash flow for the second quarter of 2024 totaled SEK189 million and SEK378 million for the first half of 2024. The decrease in Hansa's operating loss compared to the first half of 2023 was driven by increased sales and a reduction in overall expenses. At June 30th, 2024, cash and cash equivalents totaled SEK705 million compared to SEK732 million at the end of December, 2023.

I'd like to turn the discussion back to Søren for Q&A in this portion of the call.

Søren?

Søren Tulstrup

Thanks Evan. Please turn to slide 15. This overview, our presentation is now concluded and we'd like to open the call for questions.

Operator, please begin.

Question-and-Answer Session

Operator

[Operator Instructions]. The first question will be from the line of Alexander Krämer from ABG. Please go ahead. Your line will now be unmuted.

Alexander Krämer

Good afternoon. I have two questions. One, about the sales development in Q2 in light of the additional markets that you have gained in the quarter and also in relation to the post-approval study. Could you comment, the post-approval study did not recruit much, many additional, many additional patients. Could you comment on how you see the patient numbers like evolving based on like, also in the context of post-approval study? That's the first question. And the second question is about HNSA-5487 program, which maybe I will ask later.

Søren Tulstrup

Thanks for those questions or the first question, Alexander. The post-approval efficacy study continues right. In the last quarter, we had a few additional patients added, some centers are reaching caps and so on, so that plays into that. But we're on track to have that study completed by the end of 2025 per the commitment we have to the EMA. And obviously as these post-approval efficacy study centers reach the caps, they will convert into commercial use of Idefirix, and so that's going to benefit our sales going forward, as to patient numbers, and so on expected, I can be more precise. You had a second question as well around 5487.

Alexander Krämer

Yes. HNSA-5487 question, I guess, Evan to you so and to Hitto, 5487 so we'll see data soon, so I'm looking forward to that. And my question here would be when it comes to the announcement of the first indication, if this will come together with the data announcement or if it'll come later and also like yes, that's the question basically.

Søren Tulstrup

Once we get the data in the second half of this year from the healthy volunteer study, when we have the full data set including the 12 months follow-up, we will of course make an assessment and then we will chart out the path forward including selection of indications and so on. We are currently looking at a number of different indications that we find attractive and potentially feasible. And so that decision will be taken also in the second half of this year, whether we will communicate the past forward together with the data or we'll first communicate the data and then subsequently the past. I can't say at this point in time, I don’t know Hitto you have additional comments to this.

Hitto Kaufmann

No additional comments, Soren. As you outlined, there's a certain likelihood that we'll initially talk about the data and then digesting the data further will inform later about the clinical development part.

Søren Tulstrup

Great, thanks, Alexander.

Alexander Krämer

Thank you.

Operator

The next question will be from the line of Matt Phipps from William Blair. Please go ahead. Your line will now be unmuted.

Matt Phipps

Thanks for taking my questions and congrats on continue the execution quarter. Can you guys give us a little detail on why the Sarepta trial results moved into 2025? I think previously you said there have been some update later this year, and then on 5487, why do you feel the need to have 12 months of follow-up? If I recall from early Imlifidase data, the immunogenicity response is fairly soon and short half-life of the molecule. Just curious, what do you hope to see by 12 months that maybe you wouldn't see by six months?

Søren Tulstrup

Good morning, Matt, and thanks for those two questions. First on the Sarepta trial, as said, the reason why data will be forthcoming in 2025 is because Sarepta has guided that data will be available in 2025, and that follows the implementation of a protocol amendment. Right, obviously, you can have a full data set, you can have a slice of the dataset, you can have date of the first patients, and so on. We will let Sarepta continue to communicate around the timeline here and also the granular aspects of the trial. But we've certainly noted with satisfaction that Sarepta is clearly concluding that this is a priority for them and it's more for we'll get paid in 2025.

On the second question, Matt, 5487, why are we waiting to get a 12-month data? I'll let Hitto expand on this, but essentially, what we want to see is the ability to short interval re-dosing, essentially extending the IgG free window upfront, and then also redose later typically when you have these flares and crisis and, in a range, or autoimmune diseases and they can appear several months after mutation of the disease or year after or two years after. So, we want to see over the 12-month period, the development of ADAS and also the development of IgG. But maybe you have some additional comments here.

Hitto Kaufmann

Sure, Søren. Thanks, Matt, for this question. Søren you outlined it. Matt, what we are trying to do here in this study as an exploratory endpoint, we were taking samples of patients at the different time points, and then we subject them to in vitro cleavage experiments, which will help us guide to the right indication. And typically, in indications where you get reoccurring acute phases that doesn't happen very, very shortly after the third acute phase. It happens sometimes six months, 12 months, 18 months later. So, what we're trying to do is to cover the relevant endpoint for the diseases that we currently have in mind. And at the same time, we want to get a nice complete out of profile to test the hypothesis that we have that overall other levels will be lower compared to [Indiscernible]. I hope that helps.

Matt Phipps

Can I ask one quick follow-up? As you see some of the additional clinical data readout from both the FcRn class positive and negative trials, and then also non-FcRn degraders such as for Biohaven, do those play a role as you're thinking about indications or do you feel you're in just a different class compared to those anyways, as far as diseases that you're looking at?

Søren Tulstrup

Thanks for that question as well, Matt. So, clearly, we think that FcRn inhibitors and also bio degraders are more complementary than to our enzyme we feel we have a pretty unique profile in the ability to knock down IgG completely and immediately. And we don't see any data suggesting that FcRn inhibitors or Biodegraded should be able to do the same. So, we're essentially playing in a different field. Our enzymes potentially could be ideal at the onset of also chronic autoimmune disease or when you have these crisis and flares. Do you have additional comments?

Hitto Kaufmann

No, just to specify maybe the comparison with FcRn. So, if you look at pathogenic IgG level, if you treat with an IgG cleaning enzyme, you bring them down to something below 5% within hours. For FcRn type of treatment, you'll only ever bring levels down to something like 30% or 40% within weeks after treatment. And that's why we think of it as complementary.

Operator

The next question will be from the line of Douglas Tsao. Please go ahead. Your line will now be unmuted.

Douglas Tsao

Just in terms of 5487, I'm just curious that I understand the rationale for waiting over the 12 months to see potential formation of anti-drug antibodies, but I'm just curious, I mean, given

the relatively short half-life, I mean, would we expect most of the ADAs to have been formed within the first few weeks of dosing?

Søren Tulstrup

Hitto, so will you take this one?

Hitto Kaufmann

Sure, of course. Yes. That's true. However, as I said, that's probably not the most relevant data point for what we have in mind, quickly speaking. We wanted to make sure we cover the data points that are probably most relevant for the indications that we currently have in mind.

Douglas Tsao

I mean, can you, I mean you don't want to give too much because you don't want to sort of disclose the indication quite yet, but maybe just give us some examples of types of things that might be occurring in these latter months from after dosing.

Søren Tulstrup

Yes, again, so I will pass it over to you.

Hitto Kaufmann

Yes, as we said, we will talk more about it at a later point in time. But I just wanted to point out that there are a number of diseases, for example, autoimmune diseases with severe effects on the central nervous system where unfortunately 90% of the patients have reoccurring acute phases within the first five years after the first occurrence. That is one group of indications that we are currently having in mind, but there's certainly others as well.

Douglas Tsao

No, I get the recurrence and the concept of the flares. I'm just curious in terms of the trial results or the data that you're analyzing, what is, there any sort of biomarkers right now that you're particularly focused on. That would be forming or sort of developing in the later stages after several months after dosing with 5487?

Søren Tulstrup

[Indiscernible] I don't know if you have additional…

Hitto Kaufmann

No, just as a reminder, we're talking about a study in healthy volunteers at the moment. The markets that we are looking at are ADA levels and the cleavage experiments that I have alluded to before, where you basically take serum example, of patients that have dose one with 5487 at the relevant dose for our Phase 1 study, and then you subject them in the laboratory to a cleavage essay that we have established now.

Douglas Tsao

Then just in terms of -- a question for Evan. The adjustment to product sales that was done today, that's a onetime event to account for rebate levels, or is that something that will happen on a somewhat regular basis? Thank you. Just to clarify that.

Evan Ballantyne

Yes, go ahead, Søren.

Søren Tulstrup

No, I will hand it over to you, Evan, just to say that, as Doug in Europe getting market access is a complex is a multi-year effort. We have a stellar team that has been able to achieve access now in Europe for the majority of kidney transplant patients at a price point that we think reflects the value we're bringing to the table. And they've actually been able to do that ahead of the typical kind of timeline for this. Each country applies its own standards and models and so on. And in some countries, you benefit from special early access programs where you can actually charge a price upfront that will not be the final price because you're negotiating in parallel.

And then once you have achieved full reimbursement, it is with the obligation to then pay the delta between what you charge upfront and then what you have agreed to that applies in certain situations and in certain other situations. You have volume-based discounts and so on and so forth. And so, we have been making provisions also in past periods, but now we have better and fuller insight as to what the outcome will be in certain specific situations. And that's why there is this material provision in this in this period. But Evan, I don’t know if you have additional info here.

Evan Ballantyne

Søren that was a great explanation, and we look at the provision every single quarter and as negotiations with various European authorities get closely to a final price. We will adjust the provision. So, we didn't see anything unique in Q1, but in Q2, we felt we had to adjust it. And then volume discounts, we typically pay those at the end of the year. So, if we pass a volume discount hurdle rate and we realize that we're going to have to refund an European authority money, we will increase the provision and reflect that in the quarter. And that's what's happened here.

Operator

[Operator Instructions]. And the next question will be from Peter from Carnegie. Please go ahead. Your line will now be unmuted.

Erik Hultgård

This is Erik Hultgård from Carnegie. Thanks for taking my questions. If I may, first, if you could comment on, it's obviously very nice to see that you have sort of reached a new level for Idefirix sales in Europe. But I was wondering, what your confidence level is in terms of ramping sales in the second half? And what would be the main driver of that? Will it be re-treatment or will it be new clinics coming on board? That's my first question. And what disability has on that progress.

And then secondly, if you could comment on the gross margin in the quarter, and what the level will be the common quarters that would be very helpful? Thank you.

Søren Tulstrup

Well, thanks Eric for those questions. So yes, you're right. Obviously, it's nice to see that there is some level of stabilization of sales. We certainly do expect volatility to continue given the specifics of the sales situation here. But we are seeing growing repeat usage across Europe and that kind of will stabilize and increase the growth. So, that's very reassuring.

Looking forward, clearly, we expect countries like Italy and Spain that have come online recently to start to contribute more meaningfully. We are happy that we've seen good progress in Germany and the Euro transplant area. And France continues to be a growth engine. Hopefully, the UK, typically is also a relatively conservative market will also start to contribute more meaningfully. It’s very, very difficult to predict, but we are certainly very pleased with the overall development and we expect growth to continue. But Matt may have additional comment here.

Matthew Shaulis

Happy to just provide some color commentary around that term. You have outlined the framework for growth quite well. The comments I would add are that in France, we certainly have a number of centers already, but we are actually seeing a additional centers. With each center we have the opportunity for numerous patients on the wait list, and then it just becomes a matter of organ allocation. We are pleased with France and believe that there are good prospects for the future there, and I would count that as a driver. Søren had mentioned and I had mentioned earlier in the call as well, Eurotransplant in Germany in particular. We're pleased to see some momentum there, and we believe that that will continue and that will very much be a source of growth, particularly given the size of Germany, but also other markets that fall within that Eurotransplant footprint.

Then Søren also mentioned that we are moving towards achieving regional reimbursement in both Spain and Italy. These will be opportunities both for additional centers, as well as further identification of patients on wait list. We absolutely see that as a catalyst, and then

finally, I would say that there are continued opportunities in the UK. We would previously got into some of our first sales there. When we continue to see patients get identified in that market, all of this bodes well knowing that you we've achieved some caps at some PAES centers, and we believe that in the future we will reach the completion of that study. That is another factor that across numerous markets is going to create an opportunity for further commercial sales.

Overall, I would say that we are quite confident that we have prospects for growth in the second half of this year and also into next year. What we can never account for is the volatility associated with organ allocation and how that might impact a particular month or even a particular quarter. But suffice it to say the base is getting broader more markets, more centers, more patients on wait list. Thanks for the question, Eric.

Søren Tulstrup

Thanks for the question for Matt. I'll hand over the question on gross margin to you, Evan.

Evan Ballantyne

Yes. Our Q2 gross margin was negatively impacted by our manufacturing. We manufactured three largest large batches of drug substance in Q2, specifically in June. And that had that increased the cost of goods sold had we not manufactured those batches, cost of goods sold would have improved by approximately SEK25 million, and we would have had a gross margin. If you used the SEK47.1 in sales, less the new gross margin after you back at that SEK25 million of close to 70%. I should point out that the batches of drug substance we manufactured will last us for the rest of the year. And as sales increase, we won't have to manufacture additional matches.

And although, we have excess manufacturing capacity, this will ultimately help us when we enter the US market. And I should point out, if we manufacture excess or excess drug substance and we don't think we're going to use it, we have to write it off in the quarter or the period that we did that. And that's why you see the increased cost of goods sold in Q2.

Erik Hultgård

There was some sort of rise off in Q2, if I understand it correctly, but also that we produced more than or sold basically, so we will have a positive impact on the gross margin in the second half. Is that correct?

Evan Ballantyne

That's correct. Our gross margin will improve in the next two quarters.

Erik Hultgård

So, can you say something about the sort of average gross margin that we should expect for the full year, assuming all these factors?

Evan Ballantyne

I'd rather not, but I can tell you this, that as we increase sales, as sales increase and we produce more Idefirix in the finished product, our gross margin will improve because we'll have sufficient inventories to cover the increased sales.

Operator

For the next question, please state your name and company. The line will now be unmuted.

Unidentified Company Representative

We can't hear you.

Operator

[Operator Instructions]. And the next question is from Johan from Red Eye. Please go ahead. Your line will now be unmuted.

Johan Unnerus

Thank you for taking our calls, and sorry, I was at this connection for a while there. Some follow-up. What to expect on the cost of goods going forward in terms of manufacturing for batches is are we going to expect some efficacy gains as volume increases into ’25 and ‘26?

Søren Tulstrup

Evan, will you take this again?

Evan Ballantyne

Our primary supplier for drug product or drug substance currently manufactures at minimum levels, but levels that we do not fully use or utilize at this stage. So as sales increase, we'll still continue to manufacture these minimum levels, but more of those will be used in sales. So, our gross margin will improve and then that'll be further impacted very positively by entering the U.S. market. When we enter the U.S. market, we'll still have sufficient manufacturing capacity to fulfill U.S. imlifidase drug substance and drug product sales and also increase sales in Europe. So, our expectation is that our gross margin will continue to improve.

Søren Tulstrup

And to some extent. I suppose it would be easier to manage and expect volume as well. Also, according to provisions and true ups, the core dynamics is you have explained earlier, but it would be interesting to get feel for presumably you have expected the need to do some ups and provision revision. Have you planned for be sort of sufficiently wide or have you expected a sort of a more substantial revision, if you see my point? I mean, ideally, I guess you would be in a position where you have sort of taken sufficiently hike for future revision and then have not substantial revision.

Matthew Shaulis

Yes, I mean, establishing a provision really is an exercise in estimation and judgment. We use the best available data at the time, including discussions with our pricing committee and discussions with the various European authorities that try to set price. We monitor that on a quarterly basis, and if we think we need to increase the provision, we will do that. Ultimately, though, once we get to final prices, we won't be making these provisions anymore. Look, we're a new market entrant into the European market and that this is a very common process as you get early access to various European markets.

Johan Unnerus

Yes, so this is mainly the result of sort of a tricky initial launch period where different regions market and you have early access and different dynamics in terms of volumes. As you get firm approval and sort of normal reimbursement, we should expect the well much less relative provision revision ahead them.

Matthew Shaulis

Absolutely. That's fair.

Johan Unnerus

Also, clarification then on Sarepta and the protocol in the Phase 1 study, is does that sort of, will you include patients from the revised label as well or will they include patients from the updated label?

Søren Tulstrup

This is not something that is, I'm not going to comment on the specifics again, of the trial. You have to talk through to Sarepta. But essentially, the patients that are being included in general are those that have too high of neutralizing antibodies against their rates. That's the trial design going forward. There's been this amendment and as soon as it's implemented, we will start getting the data.

Johan Unnerus

Also, what to expect from the U.S. once you sort of approach approval and once you are approved, will you expect the initial launch to be targeting the clinics that already are included in patients that have not been given active treatment?

Søren Tulstrup

Sorry, what indication talking about now in the U.S.?

Johan Unnerus

Now in the main indication in the U.S. you have the ConfIdeS study and it's fully randomized and you plan to submit in late '25. And of course, it's looks like you will be having an approval in '26. And a lot of half of the patients hasn't received active treatment. And some centers are included and some centers hasn't been sort of given the opportunity to participate, but they're being interested, if there's a natural sort of target for the initial launch.

Søren Tulstrup

Absolutely. I'll let Matt comment on this, but there's a huge difference between Europe and the U.S., and the fact that at the time of launch in the U.S., we hope, we'll have centers essentially representing, as Matt said, 20% of the kidney transplant volume in the U.S. already having experience and have worked on the basis of protocols and so on. So that's a very, very big difference from the Europeans, and where we just had a couple of clinics in a couple of countries at the time of launch and where the experience had to be developed over several years. So, there's a very, very big difference there.

But Matt you may want to comment on this.

Matt Shaulis

Happily, Søren and thanks for the question, Johan. It's an excellent one, particularly around targeting. And as Søren said, we'll absolutely have an initial focus on those 23 centers that have been involved in this study. And of course, those centers will have familiarity with how to identify the appropriate patients on their wait list. And by reviewing and being familiar with our protocols, we'll also be familiar with things like patient delisting that will help enable organ allocation as well as the incorporation of Idefirix into their treatment protocols. So that's a significant headstart when compared to Europe.

We also understand that there's a sizable number between 50 centers and perhaps 70 centers in total in the United States out of over 200 centers that do transplants in the U.S. wherein these 50 centers to 70 centers have all the necessary infrastructure to do complex immunologic transplantation procedures like treating the highly sensitized patients. And this is a group of centers that have the access to 24-hour immunology and pathology labs. They have access to t-cell and b-cell depletion. Importantly, they have the expert clinical staff in

place to take on these complex procedures. That group of 50 centers to 70 centers will be sort of the total number that we initially put our targeted effort on.

And the ‘23 that we've already worked with are a significant portion of that. But we think there's plenty of opportunities for further engagement here. We'll be doing some other things in the U.S. like working with the right stakeholders, for things like U.S. guidelines. And then one other notable advantage of the opportunity or the market conditions in the U.S. when compared to Europe is that whereas it takes quite some time to work through pricing reimbursement and access with European markets and often much of that work must be done post-launch through health technology assessments and other governmental payer reviews.

In the U.S., we have opportunities for pre-approval information exchange with the public and private payers. And that's going to allow us to review our data and of course, our health economic value proposition with those payers before and during the time of launch, which we think, again, will similarly be an opportunity to accelerate things in the U.S., when compared to Europe. So, thanks for the question and you hope that addresses your area of interest.

Johan Unnerus

Absolutely. I suspect we should expect your U.S. commercial launch team to sort of reflect this and approach already in ‘25.

Evan Ballantyne

I mean, we definitely will be working towards building out the team into ‘25 and into ‘26. We will be happy to provide further perspective on this as we get close to the launch.

Johan Unnerus

Great. And finally, not that you are in the business of guiding for milestone support, but have to provide some flavor as suspect in this situation. It's more realistic to expect some support on that side in ‘25, for example, relating to Sarepta?

Søren Tulstrup

No, we can't be specific around the milestones, if you know what the amount is, Johan?

Johan Unnerus

Yes. But less realistic to expect that in 24 level, I suspect.

Søren Tulstrup

Evan, do you want to add some comments here? We can't be specific on these milestones.

Evan Ballantyne

Yes. But yeah, I would rather not be specific on them.

Operator

The next question is a follow-up from Erik from Carnegie. Please go ahead. Your line will now be unmuted.

Erik Hultgård

I have two follow-ups. First, on your cash position. You said that, the cash would take you to 2026, so given operational has been more or less current span over the past two quarters. If your cash would take you into ‘26, that would imply a quite significant reduction in the quarterly burn in the six quarters that remain. So, my question is basically how much of this will come from cost savings and how much will come from top line growth, more or less? No sort of exact numbers, but just sort of ballpark where you see this reduced burn will come from.

And then secondly, in medical question, obviously your ConfIdeS study will hopefully get you an accelerated approval. I was wondering what if you know what the FDA will require in order to get the full approval in the U.S.? Will there be another study, or will it be just more collecting more data from the same study? Thank you.

Søren Tulstrup

Thanks for those two additional questions, Erik. As far as the reduction in the burn rate is concerned, I mean, you're absolutely right. Of course, there are two contributing factors. One is, see the growing top line, the other is cost savings. I don’t know, Evan, if you can provide any guidance there, but I think, this essentially what we can say, but over to you, Evan, on this.

Evan Ballantyne

Yes, I mean, you can see that SG&A expenses have come down quarter-over-quarter for the last four or five quarters. That's generally the same for R&D, a little more mixed, but we should recognize or realize the full impact of the restructuring activities we took earlier in the year, in the third and fourth quarter and then into 2025. Then as Søren mentioned, obviously we expect sales to increase in ‘25 compared to ‘24. So, it's going to be a combination of both those activities or actions.

Søren Tulstrup

And on your second question there, Eric. The fact that if as we hope we get accelerated approval, we will need to run a confirmatory trial to get full approval. So that's part of the negotiations and the discussions with the FDA prior to initiating a trial that could lead to accelerated approval. There is this high-level discussion, but the final outcome of this is something that is subject to, again, alignment with the FDA. So, we can't be more specific at this point in time, but we'll have run confirmatory trial. That's clear.

Operator

There are no more questions left in the queue, I'll hand it back to the speakers for any closing remarks.

Søren Tulstrup

Thanks operator, and thank you everyone for your time and interest in Hansa Biopharma today. We look forward to continuing to update you on conference going forward. thank you.