Hansa Biopharma

Second Quarter Earnings Conference Call

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CORPORATE PARTICIPANTS

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PRESENTATION

Operator
Good day, and welcome to the Hansa Biopharma Second Quarter Earnings Conference Call. [Operator Instructions]. I would now like to turn the conference over to Renee Aguiar-Lucander, Chief Executive Officer. Please go ahead.

Renee Aguiar-Lucander
Thank you. Good afternoon, and good morning, everyone, and welcome to the Hansa Biopharma Conference Call to review Q2 and half year results for 2025. I am Renee Aguiar-Lucander, CEO of Hansa Biopharma. And joining me today is Evan Ballantyne, Chief Financial Officer; Hitto Kaufmann, Chief Scientific and Technology Officer; and Maria Tornsen, Chief Operating Officer and President of the U.S.

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

Please turn to Slide 3. So, this -- today, we'll discuss the progress we've made in the first half of 2025 and review the quarterly performance. I'll also share my reflections and insights based on my first few months in the role. The presentation should take roughly 50, 20 minutes -- 15 to 20 minutes, after which there will be an opportunity to ask questions during a Q&A session.

If you can please turn to Slide 4 for the significant achievements in the first half. In the first half of 2025, the company achieved several notable achievements. Of note, in Q2, we stabilized the business through a directed share issue and the restructuring of existing debt held by NovaQuest. Together, these actions ensure a cash runway into Q2 2026 and the opportunity to read out the two Phase 3 trials the ConfIdeS U.S. trial in kidney transplantation, and the GOOD-IDES--09 trial in anti-GBM, both scheduled for readout later this year.

Additionally, we further bolstered the executive leadership team with the addition of Maria Tornsen, CEO and President of the U.S. and Dr. Richard Philipson, Chief Medical Officer, who just joined us this week.

In Q2, the company significantly increased sales revenues as compared to previous year. We continue to see an increase in transplant clinics with initial and repeat usage of IDEFIRIX, and we're encouraged about the number of regional and local clinical consensus on the appropriate use of IDEFIRIX’s desensitization treatment for highly sensitized patients.

Additionally, in the first half of the year, we completed enrolment of the Phase 3 Post Authorization Efficacy and Safety or PAES study in kidney transplantation. We expect the data readout for that trial to occur in the middle of 2026. The 15-HMedIdeS-09 Phase 2 study in Guillain-Barre syndrome, delivered positive results for imlifidase. This study was presented at leading medical congress in Q2, and we look forward to following up with publishing the data during 2026.

Please turn to Page 5. So as mentioned, the company posted solid financial performance in the first half of the year. IDEFIRIX sales revenues for Q2 were SEK47.9 million representing a 76% increase when compared to Q2 2024. IDEFIRIX sales revenue for the first half of 2025 amounted to SEK113.5 million, representing a 52% increase in IDEFIRIX sales revenues as compared to the same period last year and around 80% of full year product sales in 2024.

As a consequence, the company's total revenue in the first half of 2025 represents a 27% increase as compared to the first half of 2024. So, it is important to note that full year 2024 IDEFIRIX product sales were SEK140 million, and we believe despite continued market volatility and quarterly variability that we are well positioned to significantly exceed this in 2025.

Please turn to 2026 -- to Slide 6. So as mentioned, there were two key financial catalysts for the company in Q2. The first was a successful capital raise of SEK232 million to support key data readouts in the second half of 2025 and including ConfIdeS in kidney transplantation and GOOD-IDES-02 in anti-GBM. Additionally, the company restructured the existing debt agreement with NovaQuest. The original agreement, which was set in July of 2022, has been amended to offset $14.8 million of outstanding debt to new shares or equity for NovaQuest. The remaining debt will be paid in fixed cash payments in June 2027, 2028, and in 2029. A true-up payment of $14.9 million is also due either in cash or in equity at the discretion of Hansa in January 2026.

Please turn to Slide 7 for a brief overview of operational and strategic progress. So today, it's been almost three months since I joined Hansa. And during this time, I focused on reducing the annual burn rate to ensure a sustainable operating base for the company and also worked to simplify and clarify reporting lines to enhance transparency, accountability, and speed of decision-making. I can now report that the restructuring process has been completed, and we expect that annual savings will exceed the previous estimates to amount approximately SEK60 million on an annual basis.

We're obviously sad to see many extremely experienced colleagues leave us at this juncture, but the challenging and extremely volatile macro environment has, as you know, resulted in biotech companies taking a hard look at their cost bases, and we've taken that responsibility very seriously as reflected by the rapid action.

In conjunction with these actions, however, we will invest in systems and processes, market research and analytics to support activity and efficacy across operational activities as well as select key U.S. market-related competencies and expertise to support our pre-commercial activities in the U.S.

At this stage, I'm very happy with where the organization stands with regards to complementary expertise we've been able to attract and add to the highly experienced staff which Hansa already has in place. I believe that we will, at the end of the year, have an extremely strong, experienced, and aligned team to execute on our strategic goals.

On this basis, we look forward to the upcoming catalysts in the second half 2025, which I believe will put the organization in a position to truly leverage these strategic initiatives. I'd now like to turn it over to Maria Tornsen, who joined the company in Q2 as Chief Operating Officer and President of the U.S.

Maria Tornsen
Thank you very much, Renee. I am very excited to join Hansa at an important time for the company. I've spent the last several weeks assessing our priorities and current preparation for several key milestones in the second half of the year. In a few minutes, I'll talk about the opportunities we have in the market. But first, I'd like to provide an update on the current European commercialization of IDEFIRIX.

Please turn to Slide 9. In Q2 2025, we saw an increase in the overall number of centers using IDEFIRIX. You may recall that last quarter, the PAES trial completed enrollment. And following

this, 65% of these participating trial centers have now transitioned to commercial utilization. This affirms the fact that having both clinical experience and protocols in place to treat these highly sensitized kidney transplant patients is key to IDEFIRIX utilization.

We also continue to see an increase in the total number of centers with repeat utilization. 60% of centers have had more than one positive clinical experience with IDEFIRIX. This is good news, as it ensures that even more highly sensitized kidney transplant patients are gaining access to IDEFIRIX and receiving a life-changing organ transplant. As mentioned in previous quarterly reports, the access to organs continue to fluctuate based on country and regional organ allocation system.

Earlier in the year, Germany decided to post the Euro transplant prioritization program for highly sensitized kidney transplant patients. This is a program which is active in seven other European countries. And while German physicians can use IDEFIRIX through the standard allocation system, this lack of this prioritized program impacted Q2 revenues from Germany. We expect this to continue to have a negative impact over the near term. However, we are working with clinical, patient, and public health communities to understand the potential impact on commercialization in Germany over the longer term.

Earlier in the quarter, additional consensus guidelines were published in the journal Transplant. This consensus from Belgium marks the ninth country with guidelines supporting the use of IDEFIRIX as a desensitization strategy. And reinforcing its potential to be the standard of care in kidney transplantation for highly sensitized patients. Finally, in Q2, we secured access in two additional markets. Australia and Switzerland. IDEFIRIX is now reimbursed in a total of 20 countries, including the five largest European markets.

Please turn to Slide 10. I thought it was worth sharing the learnings from the European market and how the progress we have made here is helping us prioritize activities as we plan for entry into the U.S. market. As you may recall, there are 170,000 people on the kidney transplant waitlist in Europe and in the U.S. Of that, approximately 25,000 have a CPRA above 98%, and are considered highly sensitized. And more than 5,000 have a CPRA over 99.9%.

Without national prioritization programs and access to desensitizing treatment, these highly sensitized patients have a very low chance to receive a kidney transplant. IDEFIRIX therefore represents significant opportunity to transform kidney transplantation.

Through commercialization of IDEFIRIX in Europe, we have gained several important learnings, which will help us as we prepare to enter the U.S. market. Organ allocation systems can be complex and vary between countries. And having local guidelines and centers that are clinically ready to use IDEFIRIX is critical for success. However, we need to remember that we will enter the U.S. market with access to significantly more clinical data and experience compared to when we launched in Europe a few years ago.

In addition to engaging with clinicians, we also need to establish an account approach to commercialization to ensure that the multidisciplinary team is educated on desensitization and treatment guidelines. We will also focus on establishing a strong market access team to build relationships with the payer community and secure access for patients.

Additionally, we are engaging with patient advocacy groups and policymakers to elevate the discussion of the unmet needs and changing the standard of care for highly sensitized patients. We are very excited and positive with regards to potential launch into the U.S. market, assuming

approval. As we will have substantial multicenter clinical data from the Phase 3 study in the U.S., several high-volume, high-quality transplant centers, as well as the readout of the PAES study from Europe in mid-2026, involving 50 patients. In addition to these substantial data sets, there is also significant real-world data from Europe which we believe will be supported for adoption of this groundbreaking and innovative approach.

I will now turn it over to Hitto to cover off on the progress we have made with the pipeline.

Hitto Kaufmann
Thank you, Maria. Please turn to Slide 12, for an overview of the pipeline. As you can see, we have eight programs in various phases in both desensitization and autoimmune disease. In desensitization, I'll start with gene therapy. In collaboration with Genethon we continue to enroll patients in the GNT-018-IDES Phase 2 program evaluating imlifidase as a pretreatment to Genethon gene therapy, GNT-0003 in Crigler-Najjar.

GNT-0003 is currently being evaluated in the pivotal clinical study in France, Italy and the Netherlands and have received prime status from the European Medicines Agency. We look forward to reporting out on top line data later this year.

Additionally, we continue to progress with Sarepta Phase 1b trial in Duchenne Muscular Dystrophy, evaluating the effectiveness of imlifidase as a pretreatment to ELEVIDYS Sarepta's gene therapy. Again, we look forward to sharing initial data later this year.

In May data from the 15-HMedIdeS-09 Phase 2 study of imlifidase in Guillain-Barré Syndrome, also known as GBS, were presented at the Peripheral Nerve Society Annual Meeting in Glasgow. This was followed by a deep dive discussion we hosted with key opinion leaders, Dr. David Cornblath, John Hopkins University and Simon Rinaldi, MRCP PhD University of Oxford and we look forward to publishing the data later this year.

Please turn to Slide 13 for a summary of the ConfIdeS Phase 3 pivotal trial in kidney transplantation. As Maria mentioned, there is significant unmet medical need when it comes to highly sensitized kidney transplant patients. The ConfIdeS U.S. pivotal Phase 3 trial was fully randomized in May 2024. There are 23 participating centers in the trial, which is an open label controlled randomized trial evaluating kidney function in 64 highly sensitized CPRA 99.9 and above kidney transplant patients with positive crossmatch against the disease donor comparing desensitization using imlifidase with standard of care.

The primary endpoint of the trial is kidney graft function at 12 months, measured by Estimated Glomerular Filtration Rate called eGFR. The total trial duration is 5 years, including a long-term follow-up as agreed with the U.S. FDA as part of the accelerated approval pathway. We look forward to sharing top line data from ConfIdeS trial later this year, followed by a BLA submission to the U.S. FDA.

Please turn to Slide 14 for a look at the GOOD-IDES-02 study in anti-GBM. We anticipate that we will have data from the GOOD-IDES-02 Phase 3 in anti-GBM later this year. As a reminder, the GOOD-IDES-02 trial is a Phase 3 open-label controlled randomized multicenter trial across Europe and the U.S. and is evaluating renal function and the need for dialysis at six months in patients with severe anti-GBM disease.

Encouraged by our Phase 2 data, which showed that 10 out of 15 patients were dialysis independent after 6 months versus the historic cohort where only 18% were dialysis independent

at this point in time. These results were published in JASN in 2022, and we believe imlifidase has significant potential in improving the outcome of these patients and address the unmet medical need.

Imlifidase has been granted orphan drug designation for the treatment of anti-GBM disease by both U.S. Food and Drug Administration and the European Medicines Agency. I'd like to now turn over to Evan to cover financial performance.

Evan Ballantyne
Thank you very much, Hitto. Total revenues for Q2 2025 were SEK49.1 million, representing a 43% increase compared to Q2 2024 and of SEK34.3 million. IDEFIRIX product sales for Q2 2025 were SEK48 million, representing a 76% increase compared to Q2 2024. Product sales for the first half of 2025 totalled SEK113.5 million, representing a 52% increase compared to the same period a year ago.

As Renee mentioned, we continue to see fluctuation in our performance quarter-over-quarter. However, it should be noted that year-over-year performance continues to increase. Quarterly volatility represents the unpredictability of the organ allocation market. We expect this fluctuation to diminish over time having recently completed the post-approval efficacy study and as Hansa continues to enter new markets.

For Q2 2025, SG&A expense totalled approximately SEK90.5 million, which was 2.6% unfavorable compared to Q2 2024. SG&A expenses in Q2 2025 included a SEK21 million reserve to reflect restructuring actions taken by the company in late Q2 to reduce costs and improve operating efficiency. Excluding the impact of the restructuring charge, Hansa's SG&A expenses would have been 20% favorable compared to the same period a year ago.

R&D expenses in Q2 2025 totalled approximately SEK95.8 million and were 4.4% unfavorable compared to Q2 2024 expense of SEK91.7 million. R&D expenses in Q2 2025 also included a restructuring charge. Excluding the impact of the restructuring charge, R&D expenses in Q2 2025 were essentially flat compared to the same period a year ago.

In Q2 2025, financial income and expense net represents a charge of approximately SEK23.3 million compared to a SEK20.5 million charge in Q2 2024. Changes in financial income and expense compared to the same period a year ago were primarily driven by favorable changes in the U.S. dollar exchange rate against the Swedish krona, noncash interest expense related to the NovaQuest note and a SEK59.4 million charge taken by the company to reflect the NovaQuest loan restructuring modification.

In Q2 2025, the company's operating loss was SEK154.8 million or 17% favorable compared to Q2 2024 of a SEK187.4 million. For the first half of 2025, Hansa's operating loss was 28% favorable compared to the same period a year ago.

On a year-to-date basis, Hansa's cost of sales was approximately SEK20 million favorable compared to the first half of 2024. The company's gross margin in the first half of 2025 was 66% compared to 35% in 2024.

The improvement in Hansa's Q2 and year-to-date operating loss was driven by increased sales, a substantial improvement in the company's gross margin associated with the lower cost of goods sold and a reduction in expenses across all departments, a very positive trend.

Next Slide, 18. Cash used in operations in Q2 2025 totaled SEK111.7 million, an improvement of SEK77.5 million compared to the same period a year ago. For the period ended June 30, 2025, cash and cash equivalents totaled SEK354.4 million, with the recent capital raise and debt restructuring, the company has extended its cash runway into early Q2 2026.

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

Renee Aguiar-Lucander
Thank you, Evan. So, with this overview, our presentation is now concluded, and we'd be happy to open it up for any questions. Operator?

QUESTION AND ANSWER

Operator
[Operator Instructions]. Today's first question comes from Sushila Hernandez with Van Lanschot Kempen. Please go ahead.

Sushila Hernandez
Yes, thank you for taking our questions. Two from our side. So, on the Euro transcend desensitization program that was closed in Germany, are you expecting an update from the other European countries where it's still active, do you anticipate a closing in these countries?

And then a second question on your Sarepta partnership. So yesterday Sarepta announced restructuring and strategic changes. With this current sequence of events, how does Sarepta look at your partnership? And what kind of data can we expect this half of the year? Thank you.

Renee Aguiar-Lucander
So, thank you. No, so we're not expecting this to kind of be the case in other countries or regions. We have had no information data or kind of any signs of that being the case. I do think that historically, as well, I think Germany has had a quite a kind of conservative approach generally to transplantation, but we have no kind of reason to believe that this is going to be the case.

So, with regards to Sarepta, yes, you are correct, indeed. There was a very interesting release, obviously from them yesterday. I guess, in terms of any potential impact on our program with them, I guess my point of view is that obviously, if anything, this would probably mean that Sarepta is going to be even more interested, I think, and really kind of want to try to reach all patients on label with their kind of commercial drug.

So, I don't see that the kind of restructuring or any other -- the other kind of actions that Sarepta is taking would have any negative impact on our -- kind of on our program at all. Quite the opposite.

I think obviously, there is the outstanding question of limb-girdle, which also is covered by our contract with Sarepta. And with that, I don't have any kind of particular updates on that from Sarepta as of yet. But I think that, obviously, with regards to the vast majority, obviously, here is with regards to the DMD program. And I think that, as I said, from our perspective, I think that this it really should make it more -- even more interesting and exciting, I think, for both of us to continue with that program. I don't know Hitto if you have any additional comments on that?

Hitto Kaufmann

Thanks, Renee. I would just add because you also asked about the sort of what type of data are we generating in the study that's currently ongoing. What Sarepta and Hansa would like to demonstrate is that through a conditioning treatment with imlifidase, we can bring down the anti-AAV antibody levels and enable virus transduction. And that's how the study is designed. Ultimately, demonstrate that the transcript is expressed in the relevant tissue, and that's the type of data we expect to have this year.

Operator
And our next question today comes from Matt Phipps at William Blair. Please go ahead.

Matthew Phipps
Hi. Thanks for taking my call, a question on the call. Do you guys have a sense of what you will be able to disclose in the top line release from the ConfIdeS trial? Just wondering if it will be purely qualitative or maybe get some of the numerical eGFR data? And then it seems like there has not been any comments on 5487. Just wondering if any of the plans for that program have changed. Thank you.

Renee Aguiar-Lucander
Sure. So, I'll briefly cover the 5487. And then Hitto, I will hand over to you for the ConfIdeS top line. So, in terms of the 5487, so yes, that is something where you can squarely blame me for that not being an update.

So actually, what we are doing since I've been here for a fairly short period of time, I do want to kind of go through in some detail in terms of what the best kind of positioning and indication, et cetera. So, 5487. So, we are in the midst of an internal review of that, really involving all aspects kind of the market aspect as well as kind of the profile of the drug.

So, we are going -- making a fairly kind of significant as kind of internal assessment and review to make sure that whatever kind of clinical plans we then present with regards to 5487 are well anchored and aligned within the entire organization. And so, we will be sharing that probably, my guess is that we'll probably share that publicly in Q4 would be my best guess at this point in time. Hitto?

Hitto Kaufmann
Thanks, Renee. We have not yet shared in detail what we will disclose as part of the top line results. But the clear focus is, a, on the primary endpoint, which is eGFR measured 12 months post-transplant. So that will, of course, be something that we will have done some statistical analysis to see whether we have reached that primary endpoint with a statistical significance.

The other thing we obviously will be looking at very early on is any safety signals. And so that's roughly what you could expect for a top line results, Matt.

Operator
All right. Thank you. [Operator Instructions]. Our next question today comes from Douglas Tsao with H.C. Wainwright. Please go ahead.

Douglas Tsao
Hi. Good morning. Thanks for taking the questions. So just Renee to confirm on 5487, it sounds like the prior guidance in terms of positioning for a pursuit of indications is kind of on pause and that you're going to just reconsider whether things like MG are necessarily the right indication for the sort of initial clinical work? And then as a follow-up, I'm just curious, in terms of Germany and

Europe transplant, do you have a sense of what the catalyst was for them to stop the program? Thank you.

Renee Aguiar-Lucander
Thanks. So, I will hand over to Maria for the background on the kind of German decision. And so yes, you are correct. I do think that it is particularly in these kind of time -- times that we live in. I do want to make absolutely sure that when we make a decision to spend significant dollars in any kind of clinical research program that we have an extremely clear view on how we can possibly accelerate that as much as possible and how we can target that market and truly kind of be a dominant player in that market.

And so, I think we really need to make sure that we've done the homework in order to ensure that the indications that we will choose are the right ones. And I think, obviously, in this case, it's a good problem to have, but I think this enzyme could actually be used in quite a variety of ways and indications. And so, I think it's a little bit of just making sure that we have assessed all of those different options. And that when we do kind of come out, we are very clear on the rationale for the positioning of 5487. So that is correct.

Maria, I will hand over to you with regards to Germany.

Maria Tornsen
Sure. Thank you for the question. So, within the Euro transplant zone, there are several countries that collaborate on organ allocation and guidelines and things like that. And there are two programs. There's a general allocation program and there's a program for the highly sensitized patients, which has been in place for a couple of years.

In Germany, that is the highly sensitized program that has been paused for the moment. I would like to say that this has nothing -- first of all, it has nothing to do with the belief in IDEFIRIX as a product. What it has to do with is, I think a couple of things. If you look historically, Germany has had an organ transplant scandal many, many years ago, and there's a general hesitancy in terms of how to transplant organs in Germany. So that's sort of the situation that has been the case in Germany for many years.

When it comes to these highly sensitized patients, you -- they end up in this priority program for specific reasons. Let's say, they've had a previous transplant, they have been pregnant, they've had a blood transfusions. You know the reason why they're highly sensitized. And in Germany, what they have really been discussing is this health equity. That certain patients end up in this program.

So that is the reason for the pause, is that they are really evaluating, how do you ensure that you treat everybody the same and health equity and equal care for all patients that may be in need of a transplant. So, it has nothing to do with the belief in IDEFIRIX. We have physicians in Germany that have used IDEFIRIX in transplant and have had great success. So, there's a strong belief among the German physicians in the product itself. It only has to do with the health equity part of it.

Douglas Tsao
Okay. Great. That's helpful. And I guess, Maria, just as a follow-up, in terms of those physicians you do believe strongly in it but then sort of counterbalance with the sort of health equity issues. So, it sounds like this is, to some extent, a little bit more of a political issue than a clinical issue.

And how does that necessarily over the long term, impact the commercial opportunity in Germany? And then just a quick follow up also in terms of the restructuring that you took from the cost savings, is there any impact in terms of the size of the European commercial organization?

Maria Tornsen
So, I'll follow up on that Euro transplant question. So, you are correct that like the physicians in Germany, they believe in the product. We have had successful transplantations in Germany for several years. And they can continue to transplant through that general allocation system in Germany. We saw an impact in Q2 as we disclosed. We are expecting that it's going to have a near-term impact as we work through this by obviously speaking to German physicians and other policymakers and other stakeholders in Germany to see what is the best path forward.

At this point in time, we've said that in the near term, we expect that this will continue to have an impact in Germany. But obviously, we are looking at the long-term effect, we are evaluating that. And at this point in time, there's nothing that I can comment on because we are in discussions at the moment. Renee, do you want to take the restructuring question or?

Renee Aguiar-Lucander
Sure. So, with regards to the restructuring, we -- in terms of any impact on the European commercial kind of group organization, there was virtually very, very limited or hardly any, I would say, impact on the European organization. So, it was very limited. There was some, but it was very limited in terms of the impact on the commercial organization.

Douglas Tsao
Okay, great. Thanks for all the answers.

Conclusion

Operator
Thank you and this concludes our question-and-answer session. I'd like to turn the conference back over to the company for any closing remarks.

Renee Aguiar-Lucander
Thank you very much to everybody who's listened to this Q2 report, and we look forward to a very exciting rest of the year here at Hansa. Thank you.

Operator
Thank you. This concludes today's conference call. We thank you all for attending today's presentation. You may now disconnect your lines and have a wonderful day.