Hansa Biopharma

Quarter 3 2025 Results Conference Call

Thursday, October 30, 2025, 08:00 AM ET

CORPORATE PARTICIPANTS

Renee Aguiar-Lucander--*Chief Executive Officer*

Evan Ballantyne--*Chief Financial Officer*

Richard Philipson--*Chief Medical Officer*

Maria Tornsen--*Chief Operating Officer and President U.S.*

PRESENTATION

Operator
Good day, and welcome to the Hansa Biopharma Quarter 3 2025 Results Conference Call. [Operator Instructions]. Please note, this event is being recorded.

I would now like to turn the conference over to Hansa Biopharma's CEO, Renee Aguiar-Lucander. Please go ahead.

Renee Aguiar-Lucander
Thank you very much, operator. Good afternoon, good morning. Welcome to the Hansa Biopharma conference call to review Q3 and results for the first nine months of 2025. I'm Renee Aguiar-Lucander, CEO for Hansa Biopharma. And joining me today is Evan Ballantyne, CFO; Richard Philipson, Chief Medical Officer; and Maria Tornsen, Chief Operating Officer and President of the U.S.

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

Please turn to Page 3, and today's agenda. Today, we'll discuss the progress we've made in the nine months of 2025 and review the quarterly performance. I'll also share my reflections and insights based on my first six months in the role. The presentation itself should take roughly 20 minutes, after which there will be an opportunity to ask questions during a Q&A session.

Please turn to Page 4. Over the past several months, Hansa has been through quite a transformation, including a significant reshaping of the capital structure involving debt restructuring and significant strengthening of the cash position through two successful equity raises.

In addition, the reporting structure of the company has been changed to provide for enhanced accountability and transparency as well as results in a simpler and leaner organization. We have in parallel added key competencies to the senior team, which are crucial for a successful BLA filing review and prelaunch preparations as well as the requirement for a successful product launch subject to approval in the U.S.

I believe that the market opportunity in the U.S. is very substantial, and this brings me to the last but ultimately most important point and key event of this quarter, the successful outcome of the Phase 3 ConfIdeS trial. This trial randomized patients between 2022 and 2024 with a 12-month follow-up period, and we're truly delighted that we could report at such a strong p-value of 0.0001, which I believe reflects the unmet medical need for these highly sensitized patients. And we're now looking forward to submitting the BLA filing before the end of the year.

Moving to Europe. This summer quarter reflected lower-than-expected transplant rates, further impacted by the absence of transplants in Germany due to the situation flagged already in Q2 as well as continued challenges related to local reimbursement. I'll comment further on this shortly.

Regarding pipeline developments, we were excited to report the very first clinical data from the gene therapy area, which clearly showed imlifidase's ability to successfully reduce antibodies related to AAV vectors by over 95% reduction from baseline and thus enable dosing of patients who otherwise would have been excluded. These data, in conjunction with further clinical data

obtained from our collaboration with Genethon, bolsters our view that gene therapy could become a significant future market opportunity for Hansa.

Please turn to Page 5. As I already stated in my Q2 address, I was expecting Q3 to be a weak quarter for reasons which should not be a surprise to anyone who's actually tried to obtain a hospital appointment during the summer in many European countries. This actually ranges from difficult to close to impossible, except for reasonably acute situations in many regions. However, this was exacerbated by a variety of country-specific factors already mentioned.

As we've now had the opportunity to review the situation in Europe somewhat in more detail over the last couple of months, our conviction regarding the significant growth opportunity has not been diminished, but we do believe that there are several areas which can be improved and strengthened to enhance both performance and predictability. We have identified several of these and intend to start rolling them out in this quarter. However, as a backdrop to these initiatives, I'd like to review some of the key situational facts of the kind of European market.

So, as I've already kind of stated previously, at the time of launch in Europe, there was limited clinical data available. There were only two sites that were actually in Europe, which participated in the Phase 2 trial. So very few KOLs had any experience of this procedure in Europe at the time of launch. There was also obviously need for drafting and implementation of guidelines. And as we know, Europe has a long and complex reimbursement process to deal with.

Due to the fragmentation of the market, obviously, there are different national organ allocation systems, and they do not all kind of operate in the same way. And obviously, at the same time, as the company was really challenged with the kind of limited KOL support and experience and clinical data, there was also a large clinical study initiated at 23 of the European sites, many of them very large academic institutions to recruit 50 patients in a transplant trial.

There's also been the strategic decision earlier to go very broad in Europe rather than have a more focused approach. So, what we are going to do, since we do believe that there is an extremely large growth potential based on where we are today, is to really review the organizational structure overall. We're looking for accountability, focus and efficiencies, and we've identified some areas that we think would benefit to be strengthened.

We're also going to invest in Europe in terms of systems, clarifying KPIs, reporting lines and provide additional education and training. We will obviously focus on dissemination of the clinical data that we now have in terms of the Phase 3. I do think that this kind of Phase 3 trial and the clinical data that stems from that will become extremely important in conversations with European KOLs and transplant surgeons. And we'll focus on all of that in terms of best practice and peer-to-peer interactions. So, in summary, we will be refining and implementing these activities over the next three months, and we'll keep you updated as we move through this process.

Please turn to the next page. Following the strong Phase 3 data, I just wanted to provide a brief overview of the U.S. market opportunity, where there are several key differentiating factors from Europe, which we believe will impact both the potential size of the overall opportunity as well as the adoption rate compared to what we've experienced in Europe. So, a large -- a significant differential is obviously that we have a large and robust clinical trial that just read out with data that's going to be available to the community prelaunch. As part of that, we also have a lot of KOL engagement and experience as part of the very large trial that's being conducted in the U.S.

In terms of pricing, if we look at kind of reimbursement, obviously, the price that can be managed by the company will be based on research and the clinical and payer settings. There is a national organ allocation system which is centralized with clear guidelines for how these matches are being made and with also a specific kind of focus on highly sensitized patients. In terms of this, we are going to focus on the 25 sites we were part of the Phase 3, which represent about 25% of all transplants in the U.S., where these transplant surgeons will be familiar with the procedure, and we'll have a subsequent rollout plan with an initial target of about 100 clinics.

In addition, the data that we'll read out from the European-based PAES study will also be available; as will real-world data from Europe, which we hope will also in the near future, we will see in form of some publications. We have a well-researched, externally validated and structured launch plan, and we have very strong market analytics capabilities internally. There is an active patient advocacy in the U.S., strong kidney organizations and a clear physician demand for the product.

So, in conclusion, we're extremely excited about the upcoming regulatory process and look forward to engaging with the FDA with a purpose and focus of bringing imlifidase to patients in the U.S. With that, I'll hand over to Maria, who will provide some more details on these topics.

Maria Tornsen
Thank you very much, Renee. Next slide, please. Our Q3 performance was, as Renee mentioned just earlier, impacted by the seasonality and the pause of the German Prioritized Program for highly sensitized patients.

As mentioned in our Q2 report, Germany paused participation in the Eurotransplant prioritized program earlier in the year. And as a result, we did not recognize any sales in Germany in Q3. The prioritized program continues in the other smaller countries in the Eurotransplant zone. While German physicians can still use IDEFIRIX in the normal ETKAS program, it will require publication and adaptation of new guidelines for broad adoption.

And we, therefore, expect this to continue to have a negative impact in the near to midterm on our sales performance in Germany. We continue to work with physicians to understand the timing of these new guidelines, and we have also initiated various public affairs efforts to better understand how and when the prioritized program can be reinstated in Germany. In addition to Germany, our sales were also negatively impacted by regional dynamics in the Spanish market where the lack of transplant protocols in the region of Andalusia is limiting usage of IDEFIRIX.

From a market access perspective, we have been very successful in gaining national reimbursement in 21 European and international markets. Over 90% of the European population are covered by national reimbursement. However, in some European markets, we also need regional reimbursement to enable IDEFIRIX usage. We still have some key regions in Europe where this reimbursement is lacking. And one such example is the Catalonia region in Spain, where the overall health care budget has been blocked at the regional level, impacting IDEFIRIX negatively. As Catalonia and Andalusia are two of the largest regions in Spain, our Spanish sales were lower than expected in Q3.

Despite some of these market challenges, we have a strong support in many European and international markets with one example being France, a country where there are clear guidelines for IDEFIRIX usage, strong support from key opinion leaders, significant positive clinical experience over several years and a clear path to reimbursement. We are building on these positive experiences as we look at how we can optimize performance across Europe.

As Renee mentioned earlier, Europe represents a significant growth opportunity and as such, we are implementing multiple activities to address the European performance. We are reinforcing our peer-to-peer education on guidelines and delisting practices, and we are arranging multiple educational events with one example being a large scientific event in November with around 80 European key opinion leaders.

We're also, as mentioned earlier, reinforcing our public affairs efforts to address some of the systemic barriers we are observing in some key regions and markets. And finally, our market access team are working on addressing the regional access challenges mentioned earlier. Please turn to Slide 9.

Let's now turn our focus to the U.S. market, which represents a significant opportunity for Hansa. As Renee mentioned, a few weeks ago, we presented positive top line data from ConfIdeS, our Phase 3 trial in highly sensitized kidney transplant patients. When we look at the U.S. market, it is important to remember that these highly sensitized patients have no approved desensitization therapy available today and the unmet need is therefore significant.

There are approximately 15,000 highly sensitized patients with a cPRA over 80% in the U.S. today and more than 7,000 with a cPRA over 98% and 3,500 patients in the most sensitized group with a cPRA at 99.9% or above. In total, 100,000 patients are in the U.S. transplant waitlist. And each year, 45,000 patients are added to the waitlist with highly sensitized patients representing 20%.

Unfortunately, due to the long wait list, each year, there are 10,000 patients who pass away or become too sick to transplant while waiting for an organ and the median wait time for an organ for these highly sensitized patients is seven years. Please turn to the next slide. With the recent announcement of the positive Phase 3 ConfIdeS data, our U.S. organization is focused on preparing for a potential launch in the second half of 2026, subject to FDA approval.

As mentioned, the U.S. market represents a significant opportunity. And while there are important learnings from the European launch, there are also obvious reasons why the U.S. launch will be different. The market opportunity is significantly larger than in Europe. As you saw on the previous slide, there are today 16,000 highly sensitized patients in the U.S. wait list, and this list is growing each year. Unfortunately, 2,500 highly sensitized patients pass away while waiting for a matching organ or they become too sick to transplant each year.

If we look strictly at the ConfIdeS criteria, cPRA over 99.9%, there are today 3,500 patients on this waitlist. Half of them have waited over seven years for a suitable organ, which is a sign of the tremendous unmet need that exists for these patients. The burden of being on dialysis should also not be underestimated. These patients need to undergo dialysis for several hours, multiple times a week, and the cost for Medicare is approximately $100,000 per patient per year for dialysis. For those patients who are fortunate to find a matching transplant, they will have a significantly better outcome, with more than 80% being alive after 5 years, compared to 40% on dialysis.

The recent patient preference study also shows that these patients are waiting for an approved desensitization therapy, with 61% of U.S. patients today practically discussing this with their physician. While our European launch has been impacted by the regional market dynamics described earlier, the U.S. market is vastly different, and we should, therefore, expect a stronger launch. In the U.S., there is a national organ allocation system where highly sensitized patients are prioritized.

As you heard earlier, this is one of the challenges we're facing in some European markets. There is also significant efforts from the current U.S. administration to improve transplant care and ensure better outcomes for patients and better usage of organs. From a market access perspective, we know that kidney transplants are covered by Medicare. Our market access team will work with various stakeholders to ensure adequate reimbursement through both outlier payments and NTAP, New Technology Add-On Payment.

It is also worth noting that Hansa will enter the U.S. market with significantly more clinical experience and data compared to the situation we're launching in Europe. The ConfIdeS centers are collectively responsible for 25% of all transplants taking place in the U.S. each year. This puts us in a much better situation compared to the European launch, as these centers already have clinical experience using imlifidase and have seen the benefit of desensitizing their highly sensitized patients with imlifidase.

As the U.S. market is highly concentrated, with 200 adult kidney transplant centers and 100 of these representing 80% of the transplant volume, this is a launch we can manage successfully ourselves with a small footprint. We expect to hire around 20 field-based key account managers who will be responsible for the sales of imlifidase.

Finally, already today, we have a very experienced team leading this exciting launch. Current team members all bring significant therapeutic area experience and launch experience. Over the coming 12 months, we will also add to this team to ensure we are ready to launch Imlifidase successfully, assuming FDA approval.

And with that, I would like to hand it over to our Chief Medical Officer, Richard Philipson, to discuss our pipeline. Richard?

Richard Philipson
Thanks, Maria. So, I'm going to start by presenting a short summary of the efficacy and safety outcomes of the ConfIdeS study, which is a Phase 3 open-label randomized controlled study evaluating kidney function at 12 months as measured by estimated Glomerular Filtration Rate, or eGFR, in highly sensitized kidney transplant patients treated with imlifidase prior to transplantation compared to a control group. I'll begin with a brief summary of the study design.

Patients considered potential candidates for the study were consented and entered the prescreening period. One or more unacceptable antigens were delisted from the patient's HLA profile to increase the likelihood of the patient receiving an organ offer. When an organ offer was received, patients entered screening and underwent a final evaluation of eligibility. Eligible patients were then randomized to the imlifidase arm or the control arm in a 1:1 ratio. The period of follow-up in the study was 12 months from the time of randomization.

Patients randomized to the imlifidase arm accepted the organ offer and were treated with imlifidase. If treatment resulted in crossmatch conversion from positive to negative, and patients were transplanted and entered follow-up. Patients randomized to the control arm either accepted the organ offer, were treated with non-approved desensitization and then proceeded to transplant or the organ offer was rejected and the patient waited for a more compatible organ offer or offers later in the 12-month follow-up period.

Next slide. A total of 64 patients were randomized in equal numbers to either treatment with imlifidase or the control arm. So, there were 32 patients in each arm of the study. Two patients

randomized to the imlifidase arm did not proceed to treatment. In one case, the organ offer was refused. In the other case, the patient withdrew consent to be treated with imlifidase.

The overall rate of completion of the study was excellent; a total of 58 patients or just over 90% in the study completed the 12-month follow-up period. The treatment groups were balanced with respect to sex and age. Overall, there are almost equal numbers of males and females in the study and the mean age of the study population was 45.3 years. The treatment groups were also balanced with respect to race and ethnicity, and representative of our highly sensitized kidney transplant waitlist population.

Next slide. So with respect to the primary efficacy outcome at 12 months mean eGFR was 51.5 mLs per minute in the imlifidase arm, compared to 19.3 mLs per minute in the control arm, with a statistically significant and clinically meaningful difference between the two groups of patients of 32.2 mLs per minute with a p-value less than 0.0001. This outcome reflects the excellent graft survival that was observed in the imlifidase treatment arm.

So, looking at of the supportive analyses of the primary endpoint, these provide outcomes consistent with the primary analysis. So, when we performed an analysis of 12-month eGFR using a non-parametric test, which doesn't assume normally distributed data, the outcome remains statistically significant.

Similarly, when we look at 12-month eGFR in patients transplanted based on organ offer randomization, again, the outcome remains statistically significant. These supportive analyses of the primary endpoint give us additional confidence in the robustness of the primary outcome. Also of note, a key secondary endpoint of dialysis [audio loss] significant with a p-value of 0.0007 in favour of imlifidase.

Turning to safety. The tolerability of imlifidase was good. It was a low instance of infusion reactions and no infusions were interrupted due to infusion reactions. Infections observed in imlifidase-treated patients were typically not related to treatment. And the AE and serious adverse event profile of imlifidase reflected a population of patients undergoing kidney transplantation and most serious adverse events were considered unrelated to imlifidase treatment.

So in conclusion, with respect to the outcomes of the ConfIdeS study, the treatment arms were well balanced at baseline, and the demographic characteristics reflected a highly sensitized dialysis-dependent population waitlisted for transplantation. Retention in the study was excellent. Just over 90% of patients completed the study.

The primary endpoint was statistically significant and showed a clinically relevant difference, where at 12 months mean eGFR was 51.5 mL per minute in the imlifidase arm versus 19.3 mL per minute in the control arm. The tolerability of imlifidase was good and the safety profile was consistent with previous clinical trial experience, reflecting a population of patients undergoing kidney transplantation.

Next slide. I want to turn now to our Phase 3 clinical trial in patients with anti-Glomerular Basement Membrane Disease, also known as Goodpasture syndrome or Goodpasture disease. Hereafter, I'll call the condition anti-GBM. We have previously conducted an investigator-sponsored single-arm Phase 2a clinical trial in Europe in which a single dose of 0.25 milligrams per kilogram of imlifidase was given to 15 adults with circulating anti-GBM antibodies and an eGFR less than 15 mL per minute. All patients received standard-of-care treatment with cyclophosphamide and

corticosteroids, but plasma exchange was only administered if anti-GBM autoantibodies rebounded.

The primary outcomes in this study were safety and dialysis independency at six months. The study population comprised nine men and six women with a median age of 61 years who were enrolled at sites in five countries in Europe. At the time of enrolment, 10 patients needed dialysis with five of these patients being anuric or oliguric. The remaining five patients had eGFR levels between 7 mLs per minute and 14 mLs per minute at the time of enrolment. At six months, 67% of patients were dialysis independent, which is significantly higher when compared with an outcome of 18% at the corresponding endpoint in a historical control cohort.

So based on the outcomes of this previously conducted Phase 2a study, we have now conducted a randomized open-label Phase 3 trial in 50 patients with anti-GBM in the U.S., U.K. and Europe, in which the primary endpoint is eGFR at six months, and the key secondary endpoint is the proportion of patients with functioning kidneys at six months.

Patients randomized to the imlifidase arm received this treatment on top of standard-of-care, which is compared to a control arm of standard-of-care alone. In this study, standard-of-care comprises a combination of immunosuppressives, glucocorticoids and plasma exchange. We expect top-line data from this study by the end of this quarter.

So I'd now like to hand over to our Chief Financial Officer, Evan Ballantyne.

Evan Ballantyne
Thank you very much, Richard. Let's walk through the company's financial performance for Q3 and the year-to-date 2025 results. Next slide. Total revenue for Q3 2025 was SEK31 million and was SEK17.9 million or 37% below the same period a year ago of SEK48.7 million.

Contract revenues from Sarepta, which have been fully recognized, totalled approximately SEK8 million in 2024 and accounted for a portion of this difference. IDEFIRIX product sales for Q3 2025 were SEK31 -- SEK30.1 million, which is 25% -- 24% below Q3 2024 of SEK39.8 million. Year-to-date, Q3 2025 product sales totalled SEK143.6 million reflecting a 25% increase compared to the same period a year ago of SEK114.5 million.

As Maria mentioned, sales were negatively impacted in Germany by regional dynamics and in Spain by the lack of transplant protocols. Quarterly volatility reflects the unpredictability of the organ allocation market in Europe. We expect quarterly fluctuations to diminish over time once the post-approval efficacy study is completed and Hansa expands its market footprint.

Next slide, Slide 21. For Q3 2025, SG&A expenses totalled approximately SEK88.4 million, which is SEK12.6 million or SEK16.6 million unfavourable compared to Q3 2024. R&D expenses in Q3 2025 totalled approximately SEK7.2 million and were SEK9.4 million or 11.8% favourable compared to Q3 2025 -- 2024.

In -- the Q3 2025 quarter-over-quarter changes in financial income and expense net compared to the same period a year ago were immaterial. Year-to-date, changes in financial income expense compared to the same period a year ago were primarily driven by favourable changes in the U.S. dollar exchange rate against the Swedish krona of SEK141.6 million, non-cash interest expense related to the NovaQuest note and a SEK59.4 million charge taken by the company to reflect the NovaQuest loan restructuring modification.

The company's Q3 2025 operating loss was approximately SEK147.6 million and was SEK30.7 million or 20.8% unfavourable compared to Q3 2024 of SEK116.9 million. The year-to-date Q3 2025 operating loss of SEK395.8 million was 17% favorable compared to the same period a year ago. On a year-to-date basis, Hansa's cost of sales was approximately SEK10 million favorable compared to the same period a year ago. The company's gross margin for the 9 months ended September 30, 2025, was 60% compared to 50% for the same period in 2024.

Slide 22, please. On a year-to-date basis, cash used in operations at Q3 2025 totaled approximately SEK353.3 million, an improvement of SEK173.8 million compared to the same period a year ago. For the period ended September 30, 2025, cash and cash equivalents totaled SEK252.1 million.

However, on a pro forma basis, cash and cash equivalents, including net proceeds from the October 1st capital raise amounted to SEK888 million. Headcount at Q3 2025 totaled 133 employees. On a pro forma basis, headcount is 116, including 17 FTEs currently serving notice periods related to the Q2 restructuring actions.

And now I'd like to turn the presentation back to Renee for closing remarks and Q&A.

Renee Aguiar-Lucander
Thank you, Evan. Please turn the page. So, in summary, the business is in significantly better shape than it was 6 months ago with a strong balance sheet, clear organizational structure and focus, excellent Phase 3 data from ConfideS supporting a BLA filing with the FDA and an exceptionally strong and experienced senior team.

Everybody on the team that you see on this slide has done this before. And that, in my view, is crucial for any successful execution in a complex environment. The European commercial business was continuing to show healthy growth on an annual basis, will fluctuate quarterly.

However, based on the recent Phase 3 clinical data and the readout of the PAES study in combination with some key areas of investment improvement, we strongly believe that 2026 will provide improved visibility, performance and start to reflect the innate potential of the European opportunity.

Finally, I just want to remind you all that we will host a KOL event on the 12th of November with two highly distinguished U.S. transplant surgeons, namely Professor Montgomery and Professor Cooper, who will share their view of the top line data of the Phase 3 and provide insights into clinical practice and the medical needs of highly sensitized patients in the U.S.

That concludes the presentation, and we can open up for questions.

QUESTION AND ANSWER

Operator
We'll now begin the question-and-answer session. [Operator Instructions]. The first question comes from Farzin Haque with Jefferies. Please go ahead.

Farzin Haque
Hi. Good morning. Thank you for taking my question. So what are your expectations for the U.S. FDA review process? You noted that you will request priority review, but do you expect an

AdCom? I mean the data is pretty robust, but are there specific areas where FDA may be more focused on?

Renee Aguiar-Lucander
Sorry, we are not expecting an AdCom, but we are expecting to ask for Priority Review. The issues, obviously, with the FDA at this point in time are a little bit inscrutable, more than usual because obviously, as we know, there is a government shutdown in the U.S. And so it is unclear, obviously, when the FDA will reopen and what the backlog at that point in time will look like.

However, I completely agree with you with all of the kind of strong data, the unmet medical need, the fact that it's an orphan indication, we have Fast Track Designation. I believe that, you know, I really -- I think I had high hopes of the fact that we should get Priority Review. However, with the existing situation in the FDA, there's obviously nothing that we can see as a guarantee. So, we obviously also have to assume that there is a chance for us to get standard review.

Farzin Haque
Got it. And quickly, where are you at with the CMC aspects for the U.S. launch?

Renee Aguiar-Lucander
I'm sorry, can you repeat that?

Farzin Haque
For the CMC aspects for the U.S. launch? The status of that.

Renee Aguiar-Lucander
Yes. So, we are going to -- there's not going to be any change in terms of our CMC setup or manufacturing setup for the U.S. launch compared to the European commercial production. So from a manufacturing perspective, we're going to stay with the same providers. And those providers are at the moment both located in Europe.

We do not have a U.S. based manufacturing site at this point, but we are as confident as we can be with regards to being able to kind of get through kind of also on the CMC and manufacturing side. But I'm sure there will be review issues. There always are review issues with regards to CMC, but we feel reasonably confident with where we are.

Farzin Haque
Got it. Thank you so much.

Operator
The next question comes from Sushila Hernandez with Van Lanschot Kempen. Please go ahead.

Sushila Hernandez
Yes. Thank you for taking my questions. So, on the challenging situation in Germany, do you foresee that this could have an impact on the rest of Europe? Are other countries revising their prioritized kidney allocation system? And do you already have visibility on when the situation in Spain could be improving? Thank you.

Renee Aguiar-Lucander
Maria, do you want to take this?

Maria Tornsen

Yes, happy to take the question. So, when it comes to Germany, this is a very local issue in Germany. The highly sensitized program that we're talking about was implemented a few years ago across the Eurotransplant zone.

Germany have recently looked at that program and really sort of asked the question, is this providing health equity for all patients independent of their CPRA score? So, it's more of a health equity sort of moral ethical question in the German health care system. There is no whatsoever spillover to the Eurotransplant zone or to other countries at all. So, it's very specific to Germany.

And as I mentioned, we have, I would say, strong support from the key opinion leaders who are looking at revising guidelines to enable transplants for these patients through the typical ETKAS program. And we're also initiating some public affairs initiatives to really see what we can do from a corporate perspective in terms of raising the highly unmet need for these highly sensitized patients and see if there's anything we can do to impact so that this program gets implemented again.

And I think your second question relates to Spain. And I think what is worth noting for Spain is that Spain is comprised of many regions. And in these regions, you have various numbers of hospitals. And the challenge in Spain relates to regional reimbursement in Catalonia, where the health care budget as a whole is, I guess, stuck at the regional level.

So it's not unique to imlifidase at all. But obviously, it impacts the hospital's ability to get paid. So, they -- we need to have sort of some funds released from that regional budget. So that's the Catalonia situation.

And Andalusia is somewhat different because they have a local allocation system for organs. So, you need some guidelines to be implemented in that region to enable the reimbursement and enable the physicians to order imlifidase for their patients. I would say that in Spain, we have also very strong support from the key opinion leaders. So that is worth noting. So, these are sort of structural policy issues that we're dealing within Spain.

Sushila Hernandez
Okay. And then just one more question, if I may. What kind of top line data will you be releasing from the anti-GBM study later this quarter? Thank you.

Renee Aguiar-Lucander
Richard?

Richard Philipson
Yes, sure. So, as I think I mentioned in the presentation, the primary endpoint is eGFR at 6 months, and we'll be looking at dialysis dependency. And then beyond that, there's a whole range of secondary endpoints relating to Outcomes relating to anti-GBM antibody levels, eGFR at other time points, etcetera. And then, of course, there is, there will be safety. But I imagine what we will talk about when we release results at the end of the year will really be focused on the primary outcome, the key secondary outcome and comments on safety.

Sushila Hernandez
That is clear. Thank you.

Operator
The next question comes from Richard Ramirez with Fidelity. Please go ahead.

Richard Ramanius
Hello.

Renee Aguiar-Lucander
Yes. Hello.

Richard Ramanius
Yes. So, I think they said the wrong name. My name is Richard Ramanius and I'm calling from Redeye. Never mind. I have a few questions. Let's start with a financial one. Could you specify what cost of revenues made up if there are any fixed parts? And also what you would expect for a long-term gross margin?

Renee Aguiar-Lucander
Evan?

Evan Ballantyne
Yes. So cost of revenues at the current time are obviously made up of drug substance, drug product and finished product. However, currently, we have manufacturing agreements that require us to manufacture more product than we actually sell. As we bring additional markets online and as the U.S. comes online, we expect our gross margin to increase because we won't have to write off unused or excess product into cost of goods sold. So I think gross margins will improve significantly.

Richard Ramanius
Yes, that's what I expected. And I have a market question on European sales. Could you discuss a bit which countries in Europe have generated most of your revenue thus far? And where do you see growth in 2026?

Renee Aguiar-Lucander
Maria?

Maria Tornsen
Sure. So we don't specify our sales per country. But what I can say is we noted that our Q3 performance was impacted by Germany. We had zero sales in Germany, and this is related to this highly sensitized program being paused, as I mentioned. When it comes to growth potential, I mean, we have looked for the last several months at the business and we see significant growth potential. I mean there's been a lot of work done in Europe in terms of getting guidelines in place, getting reimbursement at national level, working on the regional reimbursement, getting physicians and their teams ready to use imlifidase.

And we have many centers that have significant experience and very positive experience. So, we think that all of these things have set us up for future growth in Europe. And when it comes to where that will come from, I mean, it is a typical market. I mean the big five markets bring the majority of sales that's where you have the most patients and the most transplant centers. So, I hope that answers your questions. But I think in general, we're very optimistic about the potential in Europe despite sort of these structural barriers that we are dealing with currently.

Richard Ramanius

Yes, sure. Then I wanted to ask you about the -- any potential future clinical studies with imlifidase in the U.S. after the U.S. approval. And also if there are any, rather what are the further studies you need to do in gene therapy before you can start selling the product?

Renee Aguiar-Lucander
So in terms of imlifidase clinical trials, I don't think that we have any kind of real plans for additional clinical trials with imlifidase in the U.S. market. So, obviously, that will then hopefully obviously be an approved product and commercially available. In terms of additional or other kind of clinical trials, that is something that we would potentially undertake with our second enzyme.

And that is with regards to any kind of thoughts with regards to clinical trial development with 5487, that is something that we've done a fair amount of work on internally and externally to arrive at an answer and we should be in a position to announce that later this quarter. But at this point in time, there's still some pieces missing in order for me to kind of announce that on this call. And with that, maybe if you go back in the queue and we can allow someone else also to ask some questions. Thank you.

Richard Ramanius
Yes sure. Thanks.

Operator
[Operator Instructions] The next question comes from Matt Phipps with William Blair. Please go ahead.

Madeleine Stone
Great. Thanks. This is Madeleine on for Matt Phipps. Do you have any updated thoughts on the next steps for development in GBS, potentially any details on study design for a potential Phase 3 study? Thanks for taking the question.

Renee Aguiar-Lucander
Yes, I think that's kind of all part of the review that we have been conducting over the last several months. I include that in the kind of overall pipeline assessment that we've been doing both externally and internally. And so we will comment on that as well in the next couple of weeks or so, hopefully, when we have these kind of last bits and pieces in place. So it's a very timely question, unfortunately. It will be a little bit longer until I can be addressing that as well.

Madeleine Stone
Great. Thanks

Operator
We have a follow-up from Richard Ramirez. Please go ahead.

Richard Ramanius
I also wanted to ask about the antibody-mediated rejection - AMR indication. What are your plans there?

Renee Aguiar-Lucander
So I think at this point in time, we don't have any further plans for AMR. I think that, again, this is something that we're going to have to, we can discuss or kind of take into account potentially when the product is commercially available. There may obviously be investigator-led interest in terms of studying this in a variety of different indications, but we will probably deal with that within

the context of the medical affairs and the investigator-led request that we might get once the product is on the market. So that is probably how we're going to be dealing with any kind of related or other kind of transplant-related potential kind of unmet medical needs that relates to imlifidase use.

Richard Ramanius
Thanks. That's all from me.

Renee Aguiar-Lucander
Great. Thank you.

Conclusion

Operator
This concludes our question-and-answer session. I would like to turn the conference back over to CEO, Renee Aguiar-Lucander for any closing remarks.

Renee Aguiar-Lucander
Thank you for listening to this quarterly report. We hope that you will join our KOL event on the 12th of November or catch us at some of the upcoming November investor conferences in either New York, London or Stockholm. I look forward to speaking to you again to review our Q4 and full year results. Thank you.

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