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MANAGEMENT DISCUSSION SECTION

Operator

Hello, everyone, and welcome to the Hansa Biopharma Interim Report for January through September 2022. My name is Daisy and I'll be coordinating your call today.

I would now like to hand over to your host Søren Tulstrup to begin. So Søren, please go ahead.

Søren Tulstrup

Thank you, operator. Good afternoon, good morning and welcome to the Hansa Biopharma conference call in the third quarter of 2022. I'm Søren Tulstrup, CEO of Hansa Biopharma. Joining me today is our CFO, Donato Spota; and, Hansa's Head of Investor Relations, Klaus Sindahl. Today, we'll discuss the progress we've made during the third quarter 2022 and review our near-term milestones. The presentation should take roughly 15 minutes, after which there will be an opportunity to ask questions during a Q&A session.

Please turn to slide 2. Please allow me to draw your attention to the fact that we'll be making forward-looking statements during this presentation and you should therefore apply appropriate caution. Now, please turn to slide 3 and an overview of Q3 highlights. Back in July, we executed a $70 million non-dilutive financing transaction with NovaQuest Capital Management strengthening our existing cash position to support the continued development of transformative drug candidates based on our unique antibody-cleaving enzyme technology platform and the commercial launch of Idefirix in Europe. With this cash injection from NovaQuest, our current cash on hand at the end of the third quarter Hansa's cash run rate currently extends through 2024.

On the operational side of things, our launch activities and market access efforts for Idefirix in Europe continue to progress as planned. A growing number of transplant clinics in countries where reimbursement has been granted are becoming clinically ready-to-use Idefirix and initiate therapy and in parallel with this, we are also gaining market access in additional countries. Thus during the third quarter, we are pleased to obtain positive reimbursement decisions by payers in both Poland and Scotland as dialogues continued in other countries where our HTA dossiers have been submitted. Total revenue for the third quarter amounted to SEK 67 million, including (00:02:25) in product sales. Donato will cover the financials in more detail later.

As discussed in previous calls, it has been a priority of ours to work with the relevant European healthcare providers to put supranational guidelines in place for desensitization therapy. And we're very pleased, therefore, to see the publication in the journal Transplant International of the first international guidelines for desensitization treatment of highly sensitized kidney transplant patients by the European Society for Organ Transplantation. We will cover these guidelines in more detail on the following slide.

In addition, I'm pleased that we could announce during the third quarter the first patient treated on new European post-approval efficacy study of Idefirix in highly sensitized kidney transplant patients. This patient was treated in Barcelona, Spain, with a reported successful outcome. In the US enrollment in our pivotal trial in kidney transplantation, the ConfIdeS trial is progressing according to plan, with 39 out of the target of 64 patients now

enrolled across the US. Randomization of all patients is expected to be completed in the first half of 2023 with BLA submission under the accelerated approval pathway anticipated in 2024.

As for our AMR clinical development program, we look forward to the first data readout from our Phase 2 study later this year, following the completion of enrollment back in the spring of 2022. With respect to our GBS Phase 2 program, patient enrollment is ongoing and we currently have enrolled 20 out of the target of 30 patients in this trial. Further measures will be implemented to accelerate recruitment in the coming months, and we expect completion of enrollment in the second half of this year or first half of 2023. Last, I also want to highlight that, Hansa was recently certified as a Great Place to Work for the third consecutive year. This certification reflects our successful efforts over the past years to not only build and maintain a high performance team, but also to create a rewarding and stimulating workplace for our employees.

Please turn to slide 4. We're very pleased with the continued progress of our market access efforts. During the third quarter, we secured positive reimbursement decisions in both Poland and Scotland to highly sensitized kidney transplantations. The recommendation by the Scottish Medicines Consortium follows the recent positive recommendation from NICE for Idefirix, England, Wales and Northern Ireland expanding access for eligible patients across the UK.

In Poland, we're also very pleased working with our partners at Medison to have reached an agreement with the Polish Ministry of Health. As a result of this agreement Idefirix has now become the first and only product approved and reimbursed for the desensitization of highly sensitized patients in Poland. This decision to reimburse Idefirix follows last year's inclusion of Idefirix onto the list of technologies with a high level of innovation by the College Medical Fund. Market access has now been secured in nine European countries, including Germany, France, and the UK, while market access procedures continued to progress in eight additional countries, including Spain, and Italy.

Please turn to slide 5. In early August, the European Society for Organ Transplantation announced the release of the first set of guidelines targeting the management of highly sensitized kidney transplant patients. This first phase of the ESOT guidelines represents the first international consensus on the management pathway for highly sensitized patients and articulate the variability in definitions, approaches and outcomes, as well as the perceived success of HLA-related transplantation. These guidelines provide a new clinical practice tool for healthcare professionals to help achieve the best possible outcomes for highly sensitized kidney patients and I expect it to be a key driver for harmonization in the approach to transplanting highly sensitized patients.

An expert working group led by Professor Nizam Mamode, Professor of Transplant Surgery, previously at Guy's and St Thomas' Hospital in London and other leading experts in the transplantation field has been instrumental in driving this project. The second phase, which is now ongoing, will focus on the first experiences and patient outcomes as a knowledge and practice with imlifidase growth within the transplant community.

Please turn to slide 6 and a review of our ongoing clinical programs. As highlighted in the beginning of this call, we could recently report the first patient treated in our European post-approval efficacy study of Idefirix in highly sensitized kidney transplant patients. The patient, a 54-year-old Spanish man with chronic end-stage renal failure due to a malformation of the urinary tract that required dialysis since 1984. After two unsuccessful transplantation attempts in 1991 and 1996, the patient's immune system became sensitized and his antibody levels were very high, making it impossible to find a compatible donor for all these years.

In May 2022, the patient received imlifidase treatment, followed by a kidney transplant. After five months, the patient continues to be followed up on an outpatient basis and does not require dialysis. As for our AMR program, we look forward to announcing later this year the first data readout from our Phase 2 study in kidney transplant patients with active and chronic active antibody-mediated rejection episodes. AMR is a large indication with a high unmet medical need, with AMR episodes occurring in 5% to 7% of patients post kidney transplantation and with a significant risk of patients losing graft function. In highly sensitized patients, the frequency of AMR episodes is even higher, and there is currently no approved treatment for these rejection episodes.

The primary endpoint of the Phase 2 study is to investigate how effectively imlifidase therapy reduces the amount of donor specific antibodies in comparison with plasma exchange therapy in patients who experience an active or chronic active antibody-mediated rejection episode after recent kidney transplant. A secondary endpoints, DSA levels, kidney function and graft survival will be measured up to 180 days after treatment. Based on the data from this study we'll determine the path forward for imlifidase in the AMR indication. With respect to our GBS Phase 2 program we've implemented several significant initiatives to increase enrollment rate as the trial has been impacted by the pandemic in various ways, including a shortage of IVIg, as well as reduced capacity and availability of staff across a number of trial centers.

We believe we'll see an acceleration in recruitment due to these initiatives as well as additional measures that will be implemented in the coming months. Also, we expect higher infection rates to be seen as we approach the winter season leading to increasing incidence of GBS. Completion of enrollment in the GBS trial is anticipated in the

second half of 2022 or first half of 2023 with the first high level data readout in the second half of 2023. In anti-GBM, we plan to commence a pivotal Phase 3 study of imlifidase before year end as communicated earlier.

The new global study will enroll 50 patients across sites in the US and Europe. Last in the US, our pivotal ConfIdeS trial and kidney transportation is evaluating imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a deceased donor kidney through the US kidney allocation system. Enrollment is progressing according to plan, with 39 out of a target of 64 patients now enrolled across the US. Randomization of all patients is expected to be completed in the first half of 2023 with BLA submission under the accelerated approval pathway in 2024.

Please now turn to slide 7 and a summary overview of our pipeline. As depicted on this slide, we have successfully developed a broad clinical pipeline in both transplantation and autoimmune diseases. In addition, we have exciting preclinical projects ongoing in cancer and antidrug antibodies, as well as in the very promising field of gene therapy, where preclinical studies with imlifidase, led by our partners from Sarepta Therapeutics and AskBio are progressing as planned.

Regarding Sarepta, we're pleased to observe the recent progress of the SRP-9001 program to treat ambulant patients with Duchenne muscular dystrophy as Sarepta announced during Q3 that it had submitted a BLA to the US FDA under the accelerated approval pathway. This is indeed also positive development for our collaboration with Sarepta, where imlifidase is being investigated pre-clinically as a potential pre-treatment for inactivation of neutralizing antibodies ahead of Sarepta's gene therapy and where a good progress has been made in the past period.

With this overview, I'll now hand over the call to the Donato who will take us through a review of the quarterly and half year financials. Donato?

Donato Spota

Thank you, Søren. Please turn to slide 8. The fourth quarter of 2022, we have seen again very solid revenue with product sales amounting to SEK 23 million. Revenue recognition and our agreements with Sarepta and AskBio increasing to SEK 44 million and total revenue amounting to SEK 67 million. Overall, this is reflective of the continued good progress and market access expansion across our early launch markets and the progress with our partnerships within gene therapy. The Q3 increase in revenue recognition under our gene therapy partnership agreements is mainly driven by the AskBio collaboration, where Hansa has been having increased contributions in Q3. For the fourth quarter, we do not assume the same level of increased contributions.

Looking at the September year-to-date performance, total revenue for the first nine months of 2022 amounted to SEK 124 million of which SEK 66 million or 54% resulted from product sales. While SEK 55 million of revenue is recognized under the Sarepta and AskBio agreement and SEK 2.4 million related to Axis-Shield license. Although it's still on low levels, this represents an almost sevenfold year-on-year increase in total revenue and a tenfold year-on-year increase in product sales again confirming our commercial progress. Over the past nine months, we've continued to make significant progress regarding pricing and reimbursement and broadening our hospital sales base across markets. However, we do still expect that sales remain volatile between quarters until we have established a foundation for repeat business at hospital levels through positive outcomes in the first patients now treated.

Please turn to slide 9 for the first nine months of 2022 SG&A expenses amounted to SEK 254 million compared to SEK 225 million for the same period last year. The fourth quarter SG&A expenses amounted to SEK 83 million which continues to be roughly on par with the levels seen during the previous quarters. R&D expenses amounted to SEK 254 million for the first nine months of 2022, compared to SEK 163 million for the same period last year.

For the third quarter R&D expenses amounted to SEK 91 million compared to SEK 61 million for the same quarter last year. The increase in R&D is mainly driven by the ongoing ConfIdeS study in the US, our post-approval study in Europe and the preparations for pivotal Phase 3 program in the anti-GBM disease. Further, we have also increased our investments in our second generation NiceR program as we move the lead candidate closer to a potential first clinical study next year.

As discussed at previous earnings calls, investments in R&D and our pipeline activities across all four franchises remains a high priority, as it underpins the company's long term value creation strategy. Net loss amounted to SEK 463 million for the first nine months of 2022 and SEK 154 million for the third quarter. The increase over last year primarily reflects our increased R&D investments, partly offset by increased sales and revenue.

Please turn to slide 10. Cash flow from operating activities amounted to minus SEK 129 million for the third quarter of 2022, which compares to minus SEK 132 million for the same period in 2021. For the first nine months of 2022, operating cash flow was minus SEK 393 million, compared to minus SEK 365 million for the first nine months of last year. Hansa's cash position at the end of September was SEK 1.2 billion, including the proceeds from a structured

debt financing with NovaQuest, as alluded to by Søren earlier. We expect that this will finance our operations through 2024.

I'm now handing back to Søren for his final remarks.

Søren Tulstrup

Thank you, Donato. Now please turn to slide 11. As discussed, we continue to demonstrate solid progress across our business operations and clinical program activities as we build and advance a pipeline of valuable drug candidates for rare immunologic diseases. During the first nine months of 2022, we achieved solid revenue growth despite an overall challenging market including continued negative impact from the pandemic, increased geopolitical uncertainties and inflation. Looking at the milestones for the remainder of the year and the years to come, we're very encouraged by the demonstrated potential of our unique antibody-cleaving enzyme platform as we continue our journey towards becoming a global leader in rare immunologic diseases.

As discussed, we anticipate communicating at first high level data readout from our Phase 2 study in AMR before year end. The data from this study, we'll inform our decision-making regarding the path forward in the post-transplantation setting. In anti-GBM, we anticipate commencing this year as well a new pivotal Phase 3 study of imlifidase 50 patients across the US and Europe. As far as NiceR is concerned, our next generation enzyme program for repeat dosing scenarios, we expect IND-enabling tox studies to be completed towards the end of this year with the potential to move this program into the clinic early in 2023.

In our US ConfIdeS study, we expect to complete enrollment by year end as previously communicated, while randomization of all patients is aimed for completion in the first half of 2023, with a BLA submission under the accelerated approval pathway in 2024. In GBS, we expect to see an acceleration in enrollment of patients due to a number of initiatives we've implemented as well as high infection rates as we approach the winter season and we expect enrollment to be completed in the second half of this year or first half of next year.

Please turn to slide 12. This concludes our presentation. And we would now like to open the call for questions. Operator, please begin.

QUESTION AND ANSWER SECTION

Operator

Thank you very much. Our first question is from Christopher Uhde from SEB. Christopher, your line is open. Please go ahead.

Analyst: Christopher W. Uhde

Question – Christopher W. Uhde: Thanks very much for taking my questions. I had a couple on the clinical (00:18:45) program and then one on the gross margin. So I noticed you listed a live donor trial, which seems really exciting. Can you give us a little bit of details about – I'm just thinking about what extent – because it's 12 patients (00:18:59) and an academic center running it at the moment? So what extent is this adaptable? Or what opportunity is presented in your R&D (00:19:09) program? That's the first question, yes.

Answer – Søren Tulstrup: Well, so what we have is, we're looking at rebound of donor-specific antibodies (00:19:23) essentially, which is a small trial that we're running. If we look at the broader opportunity to expand the labels to also include living donor scenarios, obviously there's quite some potential in that indication. You wouldn't have – this would actually acts, of course, in (00:19:41) organs and donors to the pool and therefore. It's market expansion very much. And so it's certainly something that will be pursuing at some point. But the path-forward to getting this into the label has not been determined at this point in time.

Question – Christopher W. Uhde: Great. Okay. And then for AMR, obviously you have a readout coming up pretty soon. I just wanted to hear what your take is on how good PLEX is in this population in terms of lowering DSA? And if you can talk about the sort of the extent to which there is an overlap between highly sensitized and the AMR populations in terms of DSA levels, inflammatory response, I mean, just trying to gauge, obviously a complex issue, but to what extent is there a cross-read between success in desensitization and AMR?

Answer – Søren Tulstrup: Yeah. So, if you look at the way PLEX works versus the way imlifidase works and the results in terms of lowering donor-specific antibodies, you would expect to see a faster and more complete reduction in general in patients undergoing imlifidase therapy compared to PLEX therapy. So PLEX is part of the standard of care currently. And if you look at it overall, standard of care is something that can manage the majority of patients. But there's clearly a number of patients where you need efficacy faster and above what you can get with standard of care. So clearly, there is a high unmet medical needs and in our discussions also with key opinion leaders and clinics that is something that is clearly recognized.

So then you asked about the overlap between highly sensitized patients in AMR. AMR affects approximately 5% to 7% or so of kidney transplanted patients. And the majority of these events happen in the first six months. There is a higher incidence in patients who are highly sensitized. So highly sensitized patients represent a larger proportion of these patients than less sensitized, moderately sensitized patients. So again, given this, we do expect that certainly we hope that will have benefit in the imlifidase arm versus the PLEX arm as far as the primary endpoint is concerned.

Question – Christopher W. Uhde: Thanks. Just coming back to the PLEX, has – to what extent has it been quantified? I mean, is that the amount of DSA reduction, to what extent has been quantified? And what's the consistency right across studies that have done that?

Answer – Søren Tulstrup: Well, there's is quite some variability there and really depends on the specific – centers and specific circumstances. So I can't give you any specific number, but certainly this is something that has been studied and been part of considerations prior to designing and initiating the study.

Question – Christopher W. Uhde: Okay. Thanks. And then lastly, on the gross margin, so does the COGS for the quarter include Idefirix used in trials? And I guess, just kind of trying to get at, why it's at the level that it's at and when do you start enjoying scale?

Answer – Søren Tulstrup: I'll hand over to Donato for this.

Question – Christopher W. Uhde: Yes.

Answer – Søren Tulstrup: But I mean, if you look at the margin in general, obviously it has to do also with the production of batches, right, where there's quite some variability there. But Donato can you take this?

Answer – Donato Spota: Yeah. Yeah, absolutely. So to the first part of your question, Christopher, no, the cost of goods do not include materials that are used in clinical studies. That's not how the accounting is running. The reason why you can see a gross margin, which is actually pretty variable across the quarters, if you look on quarter-by-quarter basis. And may be appears a bit higher as indeed as Søren , I know started with you – was alluding to. I mean, we are in (00:24:07) manufacturing batches, we are obviously manufacturing those batches on a commercial scale that takes into account where we want to be in a few years from now. And obviously, this is relative to the sales that we are seeing right now. This is obviously more costly than where it's going to be when we are more on well, reached in that kind of peak sales levels or close to the peak sales level. So this is really an effect that is hitting the P&L now during the launch phase, but we'll even out (00:24:41) going forward. So that's not representative of what cost of goods are going to be in a few years from now.

Question – Christopher W. Uhde: Okay. Thanks so much.

Answer – Søren Tulstrup: Thanks, Christopher.

Operator

Thank you. Our next question is from Adam Karlsson from ABG. Adam, your line is open. Please go ahead.

Analyst: Adam Karlsson

Question – Adam Karlsson: Hi. Thanks for taking my questions. A couple on AMR as well, if I could. So kind of building on a previous question, in terms of the level of antibody reduction you would expect to see in AMR patients using imlifidase. Is there any reason sort of mechanistically or other? Why this would be sort of materially different from the level antibody reduction we've seen already in the approved indication and in desensitization? Or I guess if – I'll try to put it another way or yeah, I think maybe that's the best way to put it? Yeah, that's the first question.

Answer – Søren Tulstrup: Yeah. Thanks. Thanks, Adam. And the answer is no essentially. We would expect to see the same level of reduction in the same pattern, if you will, in terms of, how fast the reduction takes place as we've seen in highly sensitized patients being readied for the kidney transplant.

Question – Adam Karlsson: Okay. Great, thanks. And then on the study itself, it's a small study, obviously with 30 patients, a lot of potential noise from confounding factors, as you were alluding to. Are we realistically looking at sort of from a statistical point of view, sort of non-inferior results perhaps with a trend towards superiority? Or was the study powered to show statistical significance? And if so could I draw you to comment on your estimate for the power calculation? What differences were you hoping to see and at what level of power?

Answer – Søren Tulstrup: I'm not going to comment on the last part of your question there. But, yes, I mean, it is – obviously we do expect and hope to see superiority as far as the primary endpoint is concerned, which is really around how much donor specific antibodies are reduced and how fast, right? So it's around what happens in the

first five days. And then we have a number of secondary endpoints looking at 180 days that includes donor-specific antibodies, but also quite a number of endpoints related to graft function. So that's essentially being the set-up, right? You initially look at donor-specific antibodies, immediately after therapy and then there's this 180-day follow up.

Question – Adam Karlsson: Okay. No, great. And previously, you've said that there might be potentially depending on the – I guess, the strength of the data that the possibility to take that to regulators and see if it would be sufficient for a filing. Now that we're getting closer to that readout, are you able to offer any more specifics on what you need to see? Or sort of qualitatively anyway (00:28:04)? What might make you feel confident enough to discuss that with regulators (00:28:13)?

Answer – Søren Tulstrup: I mean, obviously, you would have to see what the response of regulators is. But I would say that it would be expected that, that we would have to run a larger and longer term trial to get this into the label. I think this is, if you look at the field, this is what has happened in the past. It has been quite challenging to run these larger and long-term studies in AMR. And so currently, there is essentially no approved therapy, right? There is standard of care and that's what's there. So what we're currently focused on is really generating encouraging data, so that this can kind of be part of the information package available to clinicians in the field, as they plan for therapy. And then clearly, based on the dialogues that – or the dialogues that we're going to have with regulatory authorities, based on the first set of data here from this Phase 2 trial, we'll determine what the path forward is? What a potential Phase 3 trial would look like, and so on? So that's, I hope, in response to your question there.

Question – Adam Karlsson: No. That's very helpful. Thank you. And maybe a brief final question then on, I mean, we're getting towards the end of 2022, headcounts as you were showing stable and operating costs, fairly stable quarter-over-quarter now. Could you comment on sort of what we should be thinking, perhaps high level on the trajectory of SG&A and R&D costs, looking into, say, 2023?

Answer – Søren Tulstrup: So, I'll hand over to Donato, to have him chime in here on this. But overall, I mean, we are building up the organization, but you're not going to see a massive expansion. But there will be some continued buildup of the organization. And then, as far as our, de-costs are concerned, obviously, we have a ConfIdeS trial, we have the anti-GBM trial getting readied, right? And GBS is ongoing as well. And we might initiate at some point additional trials, but we do not expect a significant increase in R&D cost. But over to you, Donato.

Answer – Donato Spota: Yeah. I think you've given the answer. I think we would be expecting somewhat of an increase on the run rate versus Q3 this year. But really, as Søren mentioned, I mean, really something which is very much under control. Obviously, there's three aspects which is a bit difficult to estimate. One is inflation, the other one is the FX impact. But generally speaking, we're not – let's say, we're planning to gradually invest in the commercial space still. And then on the R&D side, we will have obviously, I think the most important impact to come from the Phase 3 anti-GBM, which will add a certain level, of course, on top of where we are today.

Question – Adam Karlsson: Great. That's very helpful. Thank you.

Answer – Søren Tulstrup: Thanks, Adam.

Operator

Thank you. Our next question is from Douglas Tsao from HC Wainwright. Douglas, your line is open. Please go ahead.

Analyst: Douglas Tsao

Question – Douglas Tsao: Good morning and thanks for taking the questions and congrats on the progress. I'm just curious, in terms of imlifidase, the commercial performance, we started to see sort of a lot NICE consistency (00:31:50) in terms of several patients being treated each quarter. I'm just curious as to where we're starting to see increased activity or what's really driving it right now? Is just that we're starting to see consistent patient flow in the original countries? Or has this been a function of sort of gaining reimbursement in some new markets? Thank you.

Answer – Søren Tulstrup: I mean, overall, it is a combination. So clearly, what we're seeing right now is in France, for instance, there's been a good ramp-up in terms of Early Access Program. There's strong interest from quite a number of centers. And so they're quite far advanced in terms of identifying patients and so on. So that we're seeing good developments there.

In the UK, it's still early days after the agreement with NICE and dialogues with the National Health Service. There's quite a number of clinics there that are having internal discussions as to kind of the structure, who should be involved and so on, the specific approach. So we have yet to see kind of an impact from the UK, but we expect that to be coming in the coming months.

And then we have, of course, Germany, where we've had our reimbursement and overall market access and where, again, we're seeing overall lots of interest and activity in terms of identifying patients. What is always difficult to again predict, as we've discussed from this, how long it's going to take for these patients that have been identified. Put on a list in a specific center that is clinically ready and commercially ready to initiate therapy. How long is it going to take to find an organ that will be offered to this patient, right, so – but it's good to see the progress in Germany as well.

And then we have, as we've discussed and seen activity in the Netherlands and we had this, but this is from the post-approval. I think as we're starting this patient and we have a couple now, one patient from Spain has been reported. So we are seeing kind of broad activities across Europe, primarily, of course, in those countries where we have access at this point in time.

Question – Douglas Tsao: Okay. Great. And Søren is it taking roughly the same amount of time to ramp-up in new markets and new centers as it did in the original countries that you were in? Or are you able to shorten that cycle? Thank you.

Answer – Søren Tulstrup: Yeah. I would say that it takes more or less the same time. There's obviously kind of inter-clinic variability here. But in general, I mean, they have to go a number of – go through a number of steps, right. And one of the most complex really is after a patient has been identified to make sure that there is delisting of antigens so that there is a sufficient flow of organs to the center and to the specific patient so that there is a chance that a specific organ will be offered to that patient who's top of the list. But in general, I would say, yes, it does require some time from being clinically ready to actually having a patient to transplant.

Question – Douglas Tsao: Okay. Great. Thank you.

Answer – Søren Tulstrup: Thanks, Douglas.

Operator

Thank you. Our next question is from Zoe Karamanoli from RBC Capital Markets. Zoe, your line is open. Please go ahead.

Analyst: Zoe Karamanoli

Question – Zoe Karamanoli: Hi. Thank you for taking my questions. The first question is with regards to the Sarepta and AskBio revenue recognition. Can you provide some details as to what it relates to and the progress in the preclinical settings? And are you still expecting entry into Phase 1 for the Sarepta collaboration in the first half of next year? That's the first question.

Answer – Søren Tulstrup: Thanks, Zoe. I'll hand over to Donato for the specifics around the revenue recognition. But just let me address the Sarepta question overall. So what we have been doing so far is preclinical work. And as I reported earlier during this call, we're seeing good progress here, real team effort. And the next step, hopefully in the near future would be for Sarepta to make a decision as to whether they would take it into the clinic and that could happen in the not too distant future, as I said. And then as far as the revenue recognition is concerned, Donato, I'll hand over to you.

Answer – Donato Spota: Sure. Hi, Zoe. So under the accounting rules, the contributions that the company makes into collaboration drives obviously the recognition of the revenue then into the P&L. And under the AskBio agreement, I mean this – our contribution is basically dominated by providing imlifidase product and other materials on top of our know-how. But the dominating factor in terms of overall value because that's a much shorter – obviously, as you know, a much shorter agreement. It's a feasibility – focused on feasibility at this point.

The imlifidase product and other material delivery is kind of the dominating factor here and that drives revenue recognition. So it's much more an on and off approach than we have on the Sarepta where our resource contribution and know-how contribution is actually to the driving factor, which makes it a much more stable quarter-on-quarter recognition, if that makes sense.

Question – Zoe Karamanoli: Yeah, it does. Okay, that's great. Thank you. And then the next question is around recruitment and randomization for the ConfIdeS trial. Given the complexity at randomizing patients and availability of a suitable kidney organ, how should, we be thinking the ramp-up in the US once imlifidase will be launched, will a slow ramp-up there as well be a sensible approach just interested in getting your thoughts here.

Answer – Søren Tulstrup: Yeah. Thanks, Zoe. So you're right, obviously, there are complexities around making sure that there is a consistent and adequate flow of organs to the clinics participating in the ConfIdeS trial. And that's a little bit of an arch, they've have to – as you said earlier, they have to look at how they can deal antigens to make sure that these highly sensitized patients are still getting organs offered. And we see that, that is happening

with some delay after the involvement of the patients. It's a question of months. What is good is that, during this trial – through this trial, the centers – which are some of the leading centers across the US, they're gaining very valuable experience in doing this, right? And so when we're ready to launch, hopefully in the US in some years, there will be this very, very valuable experience in the key centers in the US.

So we do expect a faster ramp up in the US compared to Europe just because of this. But also, of course, because of the fact that in general you see a faster ramp up of transformative drugs, very innovative drugs in the US compared to Europe. At this point in time, we have 10 centers actually involved in the study and we expect to expand that to 15 or maybe even more. The 10 centers that we currently have in, I mean they represents 10% or so of the annual kidney transplant volume. So really very important centers. And we're very encouraged by the interest shown by the heads and all the staff involved in these centers.

Question – Zoe Karamanoli: Okay. That's great. Thank you.

Answer – Søren Tulstrup: Thanks, Zoe.

Operator

Thank you. Our next question is from Luísa Morgado from Kempen. Luísa your line is open. Please go ahead.

Analyst: Luísa Morgado

Question – Luísa Morgado: Hi. Luísa for Jacob from Kempen. Thank you for taking my questions. I wanted to first ask, what do you expect in terms of imlifidase sales to be like in the last quarter of this year? And also a second question, when do you expect to complete the post-authorization study?

Answer – Søren Tulstrup: Thanks for those questions, Luísa. So we're not providing any guidance for sales in general and certainly not by quarter. What we have said is that you should expect quarterly sales to be quite volatile from quarter-to-quarter because this is not again – this is not a chronic therapy, right where you have a certain number of patients and then you have new patients and you have patients that are flowing out. And then you have a certain base that is growing with a certain cadence.

Here you have one-off therapy in volumes of number of patients with a product that has a very high price tag, optical price tag. So, it will be volatile from quarter-to-quarter. What has been very encouraging is to see actually over the past few quarters the consistency, right? And that there seems to be now quite a consistent pattern. But again, we would expect over the next quarters again to see quite some volatility. And as I said, initially, we're not providing any sales guidance at this point in time because we would know – and that would be wrong.

Then the second question you asked was, sorry, can you just repeat the second question?

Question – Luísa Morgado: Sure. When do you expect to complete the post-authorization study?

Answer – Søren Tulstrup: Yes. So, that we have to complete it by the end of 2025 and there is no urgency here. We have reported the first patient in this study, we currently have a couple. We need to enroll 50 patients. And so, there is a number of years to do this.

As we've discussed in past calls, this is a great way not just to generate data, but also to, of course, make sure that the centers get experience with imlifidase. But there is no urgency from our point of view other than that we need to, as I said, complete the trial by the end of 2025.

Question – Luísa Morgado: Thank you. Just one more question. Could you maybe provide some guidance on when in 2024 do you expect your cash rate – run rate to go to?

Answer – Søren Tulstrup: In what year, sorry?

Question – Luísa Morgado: So, you said, that your cash flow...

Answer – Søren Tulstrup: So the cash run rate, which we've said. Yeah, so the cash run rate, we've said, it takes us to 2024.

Question – Luísa Morgado: And, maybe more specifically...?

Answer – Donato Spota: No. We are not guiding...

Question – Luísa Morgado: Thank you.

Answer – Donato Spota: ... any number specifically. I mean there are so many factors that depend, which this depends on. But I think overall, we believe that according to transplants that, yeah, through 2024, we'll have cash run rate with the existing cash.

Question – Luísa Morgado: Okay. Thank you very much.

Answer – Søren Tulstrup: Thanks, Luísa.

Operator

Thank you. Our next question is from Johan Unnérus from Redeye. Johan, your line is open. Please go ahead.

Analyst: Johan Unnérus

Question – Johan Unnérus: Thank you for taking my questions and also thank you for some good questions earlier. So basically more or less some follow-up. First on the AMR setting could you remind us and give us a flavor of what to expect in the current standard of care in terms of the success rate or the ability to save these episodes when they start to happen, so to speak?

Answer – Søren Tulstrup: Well, if you look at higher endpoints in terms of graft survival and graft function and so on, in general, I mean, standard of care has a relatively good track record in terms of managing these episodes. Still there's quite a number of patients that end up losing their graft life and have damage and so on that will impact the durability and life extension of the graft. So there's clearly, as I said, an unmet medical need in this field.

Question – Johan Unnérus: And if this also related to the level of sensitized. Among the patients, it's sort of a more problematic graft survival among more highly sensitized patients.

Answer – Søren Tulstrup: Yeah. So what you see is, as I said, you know, in general, 5% to 7% of all kidney transplanted patients have these episodes, sometimes more than one. But there if you look at the highly sensitized patients there, it's reported, as high as 40%, 45%. What we've seen in our long-term follow up study from, from Phase 2 so far is also 38% if I recall correctly of our patients had these episodes of AMR. Again, they're in general manageable using standard of care. But there are still a number of patients that lose their graft.

Question – Johan Unnérus: Yeah. And after 12 months or 18 months, or is – and is that proportion also higher among highly sensitized patients?

Answer – Søren Tulstrup: Yes. Well, if you look at our own data, that's not the case. But in general, as I said, there are more highly sensitized patients that have these episodes, I cannot say that highly desensitized patients suffering these episodes have a higher graft loss incidence than other patients. I certainly haven't seen those data.

Question – Johan Unnérus: Okay. And there is probably some level of transparency in terms of how to say extra contribution from collaboration. There is a run rate of some $4 million or $5 million, but this quarter it was more obviously. And you alluded to that there could be expected some activity over the next 6 months to 12 months, could you give us a little bit more flavor of what to expect on that side?

Answer – Søren Tulstrup: No, I mean what we've reported as far as the Sarepta collaboration is concerned is that we're eligible for milestone payments up to just shy of $400 million and we've not specified kind of the specific milestones or communicated any expectations around the timing and so on. As far as AskBio is concerned this is a different collaboration agreement in that it's a feasibility-focused collaboration. Both preclinical feasibility and clinical feasibility studies will be implemented and we have then qualified for a $5 million upfront that was paid, of course. And then we're just recognizing this based on as Donato talked to specific activities. But the Sarepta collaboration, we have not been more granular than just the total amounts. Donato, do you want to add anything to this?

Answer – Donato Spota: Yeah. I think one thing that we have been saying in the past is obviously that, it's rather back-loaded and I'll not to go into details or updates. A more significant amount coming in terms of regulatory milestones upon filing and potential approval. And then – also then obviously commercial milestones, sales milestones.

Question – Johan Unnérus: Yes. I guess that's what you should expect, especially if you're sitting on the other side of the table. I suppose. So thank you very much.

Answer – Donato Spota: Yeah. Sure. Thanks, Johan.

Answer – Søren Tulstrup: Thanks, Johan.

Operator

Thank you. Our next question is from Dominic Rose from Intron Health. Dominic, your line is open. Please go ahead.

Analyst: Dominic Rose

Question – Dominic Rose: Hi, this is Dominic from Intron Health. Thanks for taking my questions. I've got three. The first question is on Medison Pharma, can you give us an update on when we can expect to see first revenues from that collaboration?

Answer – Søren Tulstrup: Sorry, I didn't hear your question very well. Can you repeat that?

Answer – Donato Spota: Me neither.

Question – Dominic Rose: Sorry I was asking on Medison Pharma. Can you give us an update on when we can expect to see the first revenues from that collaboration?

Answer – Søren Tulstrup: So the Medison collaboration or agreement is focused on Israel and certain East European countries. And we have now secured the reimbursement in Poland. We obviously need to see that implemented, but it is clearly a priority area for the system in Poland. As I talk to you, I cannot give any specifics around when we expect revenue to be coming there. But it could come in the near future. And then we have the product approved in Israel. And again, I can't be specific here, but it wouldn't necessarily take a long time, but I can't be very specific on this.

Question – Dominic Rose: Okay. Thank you. And on the ESOT guidelines, I was hoping to get some idea of how important you think these could be in terms of driving European sale? And also whether you think that imlifidase could become the recommended desensitization option in the second phase of the guidance?

Answer – Søren Tulstrup: Well, we certainly think that they're quite important for say the long term commercial opportunity, right? To have these supranational European wide guidelines in place and certainly, if they are quite specific as to the place of imlifidase and they recommend use of the imlifidase that would be very helpful. First phase here has been helpful and that it has engaged the key opinion leaders in the key clinics, heads and academics across Europe that they have recognized that highly sensitized patients really had a clear problem. And that the medical community needs to do something about it. And that there is now one additional option, namely imlifidase. So that's really, really helpful in increasing the awareness across Europe.

And it has certainly been very helpful to see this taskforce also engaged internally with other clinics and ourselves, quite frankly. Then we would certainly hope that based on positive experiences with imlifidase and, as you know, several of the very early transplants having taken place post the approval. And also post gaining market access have been positive that this would lead to a benign wording around the place of imlifidase in therapy. So we do think, as I said, yes, they will have a clear positive impact, hopefully, but more long-term or medium to long-term or even short-term it certainly helpful in increasing the awareness around the problem. And the fact that the medical community needs to do something about it.

Question – Dominic Rose: Okay. Many thanks. And finally on the – to go back to the AMR readout, could you talk us through what options do you think you will have for this program once the readout is positive? Also thinking about whether there's the funding in place for Phase 3? Thanks.

Answer – Søren Tulstrup: Yeah, I mean, so clearly one option again with good data hopefully would be to again agree with the regulatory authorities on the path forward towards getting this in the label that would as I discussed earlier likely include having to run a Phase 3 trial. We've seen in the past that they tend to be quite large and have a long duration. And all of this is something we need to consider. How would we in this scenario, best be able to get it into the label. But also we're certainly, as I said, looking to get positive data that can be published so that it's in the public domain because this will inform decision making and thinking around how these patients are treated in general. So I hope that this helps.

Question – Dominic Rose: Yeah. Thank you.

Answer – Søren Tulstrup: Thanks, Dominic.

Operator

Thank you. We have no further questions. So I'll hand back over to the management team for any closing remarks.

Thanks so much. All right and thank you, everyone, for your interest in today's call. As I hope you all have seen, this has been another solid quarter. We've seen solid progress in our launch activities and also clinical development programs. Looking ahead, we have some important milestones coming up. We'll discuss the AMR readouts next

year. We also have the GBS readout. We are getting ready to put NiceR into the clinic hopefully in the first half of next year. And we have some important decision-making for our partner in the gene therapy at Sarepta as well as hopefully seeing progress with the AskBio collaboration, also in the gene therapy space. So exciting times and I look forward – we all look forward to keeping you updated on coming progress. So thanks so much.