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MANAGEMENT DISCUSSION SECTION

Operator

Hello, all, and a warm welcome to the Hansa Biopharma Second Quarter 2022 Business Update. My name is Lydia and I'll be your operator today. Please limit your questions to a maximum of three and return to the queue if there are any further questions that you may still have.

It's my pleasure to now hand you over to our host, Søren Tulstrup, President and CEO of Biopharma. Please go ahead when you're ready.

Søren Tulstrup

Thank you, operator: Good afternoon, good morning, and welcome to the Hansa Biopharma conference call on the second quarter of 2022. I'm Søren Tulstrup, the CEO of Hansa Biopharma. Joining me today is our CFO, Donato Spota; and, Head of Investor Relations, Klaus Sindahl. Today we will discuss the progress we made during the second quarter of 2022 and review our near-term milestones. After the presentation, there will be an opportunity to ask questions during the Q&A session.

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

Please turn to slide 3. Hansa's commercial launch activities and market access efforts for Idefirix in Europe continued to progress as planned. During the second quarter of 2022, we continued to see solid sales development as clinics are getting clinically ready and patients identified for treatment at leading centers across European markets.

Additionally, last month we're very pleased to announce that Idefirix had become the first and only product recommended by NICE for the desensitization of highly sensitized patients waiting for a kidney transplant from a deceased donor in England, Wales, and Northern Ireland.

This positive NICE recommendation represents an important step forward for Hansa's commercialization efforts and for patients in the UK who've been struggling to find a matching donor and in most cases have had no other alternative but to remain on long-term dialysis.

Following the NICE recommendations, market access has now been secured in 7 countries to-date, with additional 11 market access procedures ongoing throughout Europe. On the clinical development side, we're equally pleased with the advancements we've made during the first half of the year. I'm particularly excited about the on-time completion of enrollment in our Phase 2 program in AMR, which marks an important milestone for Hansa as we explore the potential of imlifidase in the post-transplantation setting.

Active and chronic active AMR episodes cause significant risk for kidney transplant patients of losing their graft function and ending up in long-term dialysis. In addition, there is no approved treatment today for patients suffering from rejection episodes. As previously communicated, we expect the first data readout in the second half of 2022.

In anti-GBM antibody disease, we're preparing to commence a new global pivotal Phase 3 trial in 50 patients this fall. We're very excited to start this pivotal trial in a serious autoimmune disease with high unmet medical need. As you may recall from our last call, the enrollment rate in our Phase 2 program in Guillain-Barré syndrome had seen a slowdown during the winter season due to the direct and indirect impact from the corona pandemic.

Since then, we've implemented several initiatives to improve the enrollment rate and during the second quarter we started to see a pickup in recruitment rate. Assuming the current COVID situation does not escalate further, we should see another step up in enrollment rate during the second half of the year.

Turning to the US, where our pivotal Phase 3 program in kidney transplantation, also known as the ConfIdeS study, is also progressing. As of today, 22 patients have been enrolled out of a target of 64. We will discuss our clinical development programs in more detail later in this presentation.

Lastly, I'm also pleased by the appointment of Peter Nicklin as new Chairman of the Board of Directors at Hansa Biopharma. Peter brings significant global experience from both non-executive and senior executive roles within the life science industry at companies such as Baxter, Bio Healthcare, Novartis and Bristol-Myers Squibb, and currently serves as Chairman of the Board of several life science companies.

Post our closing period, we've disclosed two major events, which we'll also address further in this presentation. First, on July 11, we announced that the first patient was treated with imlifidase in our mandatory post-approval efficacy study in kidney transplant in Europe. 50 highly sensitized patients in compatible to a deceased donor are expected to be treated with imlifidase during this trial.

Second, on July 18, we could also announce a $70 million product finance transaction with NovaQuest which will extend our expected cash run rate through 2024. We're very pleased to have secured this funding which will be deployed to support the continued development of our unique antibody-cleaving enzyme technology platform across multiple therapeutic areas. Donato will cover the transaction in more detail later during his presentation.

Now please turn to slide 4. As highlighted moments ago, we continue to see solid progress with our Idefirix commercial launch activities and market access efforts in Europe. During the second quarter of 2022 we achieved an important milestone when Idefirix became the first and only product to be recommended by NICE for desensitization of highly sensitized patients waiting for a kidney transplant from a deceased donor in the UK.

In addition to this recommendation, NICE also highlighted Idefirix as both a clinically and cost effective treatment, which is rare for orphan drugs. This recommendation is an important step forward for Hansa's commercialization efforts and for patients in the UK region who've been struggling to find a donor match and in most cases has had no other alternative but to remain on long-term dialysis. We're also pleased that Idefirix was granted a ASMR 3 rating by the Transparency Commission of the French National Authority for Health, which came in the wake of qualifying for the AP2 early access program, which was granted in the beginning of the year. Less than 6% of all new medicines in France are granted an ASMR 3 rating, which is another testament to the medical benefit that Idefirix brings to patients and society as a new transformative therapy.

Last, we're also pleased that the Swiss Agency for Therapeutic Products, Swissmedic, granted temporary marketing authorization in Switzerland for Idefirix in kidney transplantation, which comes on top of the already received marketing authorizations in the EU, the UK and Israel. We currently have market access procedures ongoing in 11 countries, including Spain and Italy, and expect to close additional agreements during the remainder of the year. Please turn to slide 5.

A week ago, we announced the first patient treated in our new European post-approval efficacy study of Idefirix in highly sensitized kidney transplant patients. This post-approval study, which is a mandatory requirement under the European Conditional Marketing Authorization for Idefirix, will be an open label Phase 3 study in 50 highly sensitized patients who've undergone kidney transplantation after treatment with Idefirix.

Patients will be enrolled across multiple countries and centers in Europe, with the aim of investigating long-term graft survival by determining the one-year graft failure-free survival of the Idefirix treated and transplanted patients. As a non-comparative concurrent reference cohort with no form of comparison, a total of 50 to 100 patients undergoing compatible kidney transplantation at the participating centers will be included to contextualize the one-year graft failure-free survival of the Idefirix treated patients. Now please turn to slide 6 and a review of our ongoing clinical programs.

As briefly mentioned in the beginning of the call, we announced in May the on-time completion of enrollment into our AMR Phase 2 program. A total of 30 patients with active or chronic active AMR episodes post kidney transplantation have been enrolled across 14 centers in Europe, Australia and the US. Acute AMR episodes post-kidney transplantation occur in 5% to 7% of transplanted patients and the risk of patients losing graft function is even significantly higher for sensitized and highly sensitized patients. There is currently no approved treatment for AMR and the completion of enrollment marks an important milestone for Hansa as we explore the potential of imlifidase in the post transplantation setting.

As previously noted, we expect the first data readout in the second half of 2022. Regarding our GBS program, we've discussed earlier this year the impact that the COVID-19 pandemic and the emergence of the new variants have had on the enrollment rate, both directly and indirectly. To mitigate this situation, we implemented several initiatives during Q2, including simplifying the protocol, adding new centers, and helping fund staff for the off trials (09:05). Assuming the COVID situation does not escalate any further, we expect these initiatives will help boost enrollment even further with the aim of completing enrollment by the year-end.

In anti-GBM, we expect to commence a pivotal Phase 3 study of imlifidase following FDA's acceptance of Hansa's Investigational New Drug application earlier this year. The new study is expected to enroll approximately 50 patients across the EU and the US, with the first patient expected to be enrolled later this year, as previously guided.

In the US, our pivotal ConfIdeS trial in kidney transplantation is progressing with 22 out of a target of 64 patients now enrolled for randomization. The ConfIdeS study 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.

We've initiated enrollment at 10 sites and expect participation by up to 15 leading transplantation centers across the US. Enrollment is expected to be completed by the end of this year, as previously guided. Results from the trial are expected to support a BLA submission under the accelerated approval pathway in the first half of 2024.

Now, please turn to slide 7 and a summary overview of our pipeline. As depicted on this slide, thanks to continued progress over the past few years, we've 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 Aspire, are progressing as planned.

With this overview, I'll now hand over the call to 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. In the first half of 2022, we started to see a strong impact on revenues as a result of the commercial launch activities carried out over the past 12 to 18 months in our early launch markets. Total revenue for the first six months of 2022 amounted to SEK 57 million, including SEK 44 million in product sales and SEK 11 million of revenue recognized under the Sarepta agreement.

In Q2 2022, product sales contributed SEK 19.5 million to our total revenue. Albeit still at a low level, this progress reflects continued solid quarter-on-quarter sales. As we are still in an early launch phase, though, we do expect that sales will remain volatile and continue to fluctuate on a quarter-on-quarter basis.

Please turn to slide 9. For the first half of 2022, SG&A expenses amounted to SEK 171 million compared to SEK 141 million for the same period last year. Q2 2022 SG&A expenses amounted to SEK 90 million and are in line with respective average quarter-on-quarter spend over the past four quarters.

R&D expenses amounted to SEK 164 million for the first half of 2022 compared to SEK 102 million for the first half of 2021, with SEK 93 million in R&D spent in Q2 2022. The step-up in R&D is mainly driven by the initiation of our ConfIdeS study in the US, the start of the post-approval study in Europe, the preparation for the pivotal Phase 3 program in anti-GBM disease, as well as a catch-up in expenses related to our ongoing Phase 2 programs in GBS and AMR, which were temporarily paused due to COVID in 2021.

Investments in R&D and our pipeline activities across all of our franchises remain a key priority as it underpins the company's long-term value creation strategy. The net loss ended at SEK 309 million for the first half and SEK 170 million for the second quarter, which reflects the increased spending level in both SG&A and R&D compared to last year.

Please turn to slide 10. Cash flow from operating activities amounted to minus SEK 136 million for the second quarter of 2022, which compares to minus SEK 113 million for the same period in 2021. Overall, our quarterly cash consumption has approximately stabilized over the past four quarters. Hansa's cash position, including short-term investments, amounted to SEK 617 million end of June. Post our recent financing transaction, which I will cover on the next slide, our cash position increased to approximately SEK 1.3 billion, corresponding to approximately $130 million.

Please turn to slide 11. As mentioned, we just announced a $70 million product line financing transaction with NovaQuest to support the continued development of our antibody-cleaving enzyme technology platform across multiple therapeutic areas. This transaction will extend our expected cash runway through 2024 and help us to further strengthen our position in kidney transplantation with the continued support of the European commercial launch of Idefirix and starting the preparations for a potential launch in the US.

Further, we now also have the resources to fully fund our US ConfIdeS trial as well as our global Phase 3 development program in anti-GBM, which is expected to commence later this year. And together with our existing cash also complete our ongoing Phase 2 programs in GBS and in AMR, as well as to advance our next generation of enzymes, the NiceR program, into clinical development.

Under the terms of the agreement, NovaQuest will provide Hansa with $70 million within the next two weeks from the execution of this agreement. In return, Hansa Biopharma make quarterly mid-single-digit royalty payments to NovaQuest for future worldwide annual net sales of imlifidase commencing upon approval by the FDA of imlifidase in either kidney transplantation or in anti-GBM.

In addition, Hansa will make certain milestone payments to NovaQuest upon FDA approval of imlifidase in kidney transplantation and in anti-GBM. Total payments by Hansa to NovaQuest will be capped at $140 million. The agreement also provides for time-based catch-up payments within the payment path if specific payment amounts have not been received by NovaQuest by specified dates with the last potential catch-up payment due on December 31, 2028. Hansa and NovaQuest have also entered into a security agreement to provide NovaQuest customary collateral to certain of Hansa's assets and IP. Importantly to note that there are no financial covenants.

I'll now hand back to Søren for his final remarks.

Søren Tulstrup

Thank you, Donato. Now, please turn to slide 12. Hansa's business operations and development programs continue to advance as planned despite an overall challenging environment. We've demonstrated solid progress in executing our key strategic priorities, including ensuring a successful launch of Idefirix in Europe and solid sales development so far in 2022.

In parallel, we're also advancing our pipeline of valuable drug candidates for rare immunologic diseases while we continue to see good progress with our partnerships as well. Looking at the milestones for the remainder of the year and the years to come, we're very encouraged by the potential of our unique antibody-cleaving enzyme platform as we continue our journey towards becoming a global leader in rare immunologic diseases.

As highlighted earlier, we expect to commence a pivotal Phase 3 study of imlifidase in anti-GBM following FDA's acceptance of our IND application earlier this year. The new global study is expected to enroll approximately 50 patients across at least 25 centers in the EU and US with the first patient expected to be enrolled later this year as previously guided.

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 the year with the potential to move into the clinic early in 2023.

In the spring, we announced the completion of enrollment in our imlifidase Phase 2 study in antibody mediated rejection episodes post-kidney transplantation and we expect to announce a first data readout in the second half of 2022 as previously guided.

Regarding our GBS program, we recently implemented several initiatives to increase the enrollment rate and enable the completion of enrollment in the second half of 2022, with subsequent first data readout in the first half of 2023. Last, we continue to see progress in enrolling patients into our US ConfIdeS trial in kidney transplantation and we expect to complete enrollment by the end of this year as previously guided.

Please turn to slide 13. 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. Our first question in the queue today comes from Dominic Rose of Intron Health Research. Your line is open.

Analyst: Dominic Rose

Question – Dominic Rose: Hi, it's Dominic from Intron Health. Thanks for taking my questions, I've got three. My first question is in the event that you're unable to get the US approval by 2025, how confident are you that you can meet your repayment schedule for NovaQuest? Question two is a short one. Does your new guidance for runway through 2024, does that mean to the start of 2024 or to the end? And question three is should we expect a material

increase in sales and marketing spend in Europe now that you have access to more funding? And is there likely to be any change in commercial strategy there? Thanks.

Answer – Søren Tulstrup: Well, thanks so much for the questions, Dominic. To take the first one first, in the event we shouldn't get FDA approval by 2025, how confident are we that we should be able to repay the debt? And I can say that we're confident. We have multiple shots on goal. And also, in the US, there is an ability to obviously get approval later on in 2025. And so we're quite confident and we think that this is a great setup for us.

The second question was about the runway and we said that we now have runway into 2024, and you asked how long that is, and we cannot get closer than saying that it is well into 2024. So, we've essentially materially extended the runway so that we're now past some very potential significant value inflection points, which is critically important for us.

And then the third question was around our expenditure on the launch efforts in Europe and the strategy. Let me take the strategy first. We're quite happy with the way that the strategy has played out so far. We've essentially seen all of the key launch metrics that we've put in place in advance of the launch being checked one by one, first, getting a great label, which really singles out the patients with the highest degree of unmet medical need, which has helped us in our dialogues with payers and through that obtain reimbursement and pricing at levels that adequately and fairly reflect the value that we're bringing to the table. So, that's the first key thing.

And the second is our focus on select number of key centers, and this is working out quite well. We're really seeing very nice progress there. We expect to have north of 20, 25 clinics being clinically ready to use the product, and a number of these clinics obviously having used it also. And so, that is making good progress.

We're also beginning to see now actually that the clinics are selecting good patients and I've previously said, we've previously said that we're not going to report on a patient level. But I can say that now that there is one report out in the public domain from the Netherlands on the first treated patient, this was in March. And it's a 29-year-old woman who's had a kidney disease since childhood, has undergone two unsuccessful kidney transplants and has been on or had been on dialysis since 2016.

And she then underwent successful desensitization therapy with imlifidase and subsequently also had a successful kidney transplant and was reported to be doing well. So that is very, very encouraging to see that we're getting also positive first outcomes in these clinics. So no, we do not expect to change the strategy. As far as the expenditure is concerned, it is a very efficient setup and obviously over time there will be some adjustments. We don't expect significant change, but there will be from time to time some bumps here and there as we roll out the product in additional countries and geographies.

Question – Dominic Rose: Okay. Thank you for all the detail. That was great. Cheers.

Answer – Søren Tulstrup: Cheers.

Operator

The next question in the queue today comes from Douglas Tsao of H.C. Wainwright. Your line is open. Please go ahead.

Analyst: Douglas Tsao

Question – Douglas Tsao: Hi. Good morning. Thanks for taking the questions. I'm just curious, Søren, when we think about the nice progress we've seen in terms of slowly seeing build in terms of patients treated on a quarterly basis, I assume you didn't have any sales into some of the newly accessed markets over the last couple of months? And at what point do you expect to see those beginning to contribute meaningfully?

Answer – Søren Tulstrup: Yes, so obviously, as I should point out, we've gotten access now to some quite important markets recently, France through the early access program. Germany, we got for reimbursement recently and NICE has just published its positive recommendation. It typically takes some months from that kind of decision making and communication to actually seeing some real impact and clinics beginning to get ready to use the product in a commercial setting.

In the UK, it will take some months before the NICE recommendation is implemented. But we certainly expect that to happen in the second half of the year. In France, they've actually taken early action also based on the early access program. And we're quite encouraged by the level of activity and the interest from the French centers. And so we would hope to see some good experiences in France. And France is one of the most important, I should say, transplant markets in Europe. So that's what I can say at this point, Douglas.

Question – Douglas Tsao: And, Søren, one follow-up. In terms of the US trial, transplant (25:23) trial, we've seen a nice progress on enrollment towards randomization. I'm just curious, do you think that that's a reflection of perhaps better market dynamics or put another way, sort of the potential for the commercial ramp in the US market. Thank you.

Answer – Søren Tulstrup: Yes. So, we are progressing, as I said. We are seeing patients being enrolled and in parallel we're also expanding the number of centers. So, we expect this to continue. And clearly, there is very, very strong interest in the US from these key leading centers to participate and also hopefully generate good results, which is also supported by the overall political environment, I should say, or the regulatory environment, with a focus on trying to double the transplant rate in the US between 2020 and 2030. So that's helpful.

I would say, though, that just in general for the US, both for the trial and the market, and that also applies to Europe, I have had the great privilege to be involved in a number of transformative product launches. It's always exciting. It can be very challenging and complex. In this case, it's certainly exciting. There is an added complexity in that we are also dealing with the kidney allocation, the organ allocation systems in multiple geographies.

We need to make sure that they're adjusted so that these patients that previously had not really been offered too many organs and so on, that they get offered organs at the appropriate rate. So, that's obviously something that impacts both the clinical trials we're running like the ConfIdeS trial, as well as the commercial uptake.

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

Answer – Søren Tulstrup: Thanks, Douglas.

Operator

Thank you. Next in the queue we have a question from Zoe Karamanoli of RBC Capital Markets. Please go ahead. Your line is open.

Analyst: Zoe Karamanoli

Question – Zoe Karamanoli: Hi. Thank you for taking my questions. Two questions for me, please. The first one, on the debt financing transaction, it would be helpful if you can give us some color how much of the $150 million of repayment is based on regulatory milestones versus royalties.

And the second question on the enrollment of patients, the rate of recruitment in the US kidney trials seems to have slowed down a little bit in Q2. So, I'm wondering, any reason why this might be and how are you still confident that you can complete the recruitment of the remaining two-thirds of the patients by year-end. Thank you.

Answer – Søren Tulstrup: Thanks. So let me take the second question first and then hand over to Donato on the debt financing we've just announced. And so, as I've said during the first part of the call, we are confident that we will be able to accomplish our goal of fully enrolling the ConfIdeS trial, getting these 64 patients by the end of the year.

And, yes, there has been some slowdown in short periods, but this will be by its very nature a little bit volatile. But generally what you are seeing and what we have been seeing is this kind of snowball effect if we go all the way back to when we started getting the first patient by the very end of last year. So this is normal for clinical trials and we certainly expect to see quite a number of patients and the remainder of the patients enrolled in the second half of this year. We see no signs that that should not be possible.

Of course, a big question mark is, and that links a little bit to what I said in response to Douglas' question, there is this complexity of organ allocation. So, look, clearly, we enroll patients, meaning that they provide consent, they are then in the study, they're waiting for an organ to be offered in the study and then be randomized at that time point. And that is still, we're still in early days, right? So we're following that very closely, how long does it take and so on. But clearly, as I said, enrolling patients, we do expect to have it fully enrolled by the end of the year as things currently stand.

And then I think I'll hand over to Donato. And you said, sorry, that was $150 million debt, it's $70 million debt but, Donato?

Answer – Donato Spota: Yeah. Yeah. So, yeah, exactly. So the repayment amount is 2x, so basically $140 million. We have not disclosed, obviously, as you've seen in the press release, how much is made at milestone and how much is royalty-related. But what I think I can say is that we obviously have tried to come up with a repayment schedule that on the one hand side obviously does not frontload everything.

And on the other hand, that also reflects the fact that we're expecting obviously increasing sales over time. So as also indicated, let's say the last day of when the $140 million would have to be repaid is end of 2028. So you can basically

assume that there is a meaningful spread or payment schedule over the period from when you expect potentially US approval versus the end of 2028.

Question – Zoe Karamanoli: Okay. Thank you.

Answer – Søren Tulstrup: Thanks, Zoe.

Operator

Our next question comes from Adam Karlsson of ABG Sundal Collier. Please go ahead, Adam. Your line is open.

Analyst: Adam Karlsson

Question – Adam Karlsson: Hi, all. Thanks for taking my questions and congratulations on the financing arrangement. The graph you showed on that financing deal suggests that the minimum payments of NovaQuest would be around $70 million. Is it fair to assume that that potential catch-up payments ensure that NovaQuest are at least made whole or would minimum payments imply sort of payments close to, say, $100 million, for instance, ensures a reasonable return for NovaQuest. Am I reading that graph accurately is the question, I guess. Thanks.

Answer – Søren Tulstrup: Yeah. Thanks, Adam. And again, I think I'll hand over to you, Donato, to...

Answer – Donato Spota: Yeah.

Answer – Søren Tulstrup: ...to start.

Answer – Donato Spota: So, first of all, let me say, obviously this graph is kind of illustrative. We have tried to capture the concept of this deal in this graph. So, it's not necessarily meant to represent the exact numbers. But I think what I would like to answer is, so the principal is $70 million.

What we have to be repaid by end of 2028 is obviously we need to pay back $70 million principal plus another $70 million in terms of their return. So, this is where the $140 million comes from and the 2x comes from. So, that's how this is structured. So, basically 2x overall repayment, which is $70 million, so 1x is basically repaying the principal, and 1x is providing the return to them, if that answers your question, Adam.

Question – Adam Karlsson: Yeah. Yeah. No, that's helpful. I guess the question is sort of how much of that difference, that second part of it, the $70 million that's variable, whether the structure of the deal is such that it's fair for us to assume basically that that it will be a 2x return for NovaQuest that we should count it as $70 million basically.

Answer – Donato Spota: Yes, I mean you have to – it's capped there, but it's also kind of the minimum. So, they're not going to get less and we are not going to pay more.

Question – Adam Karlsson: Okay. Now that's very clear. Thank you.

Answer – Donato Spota: Yeah.

Question – Adam Karlsson: And maybe a second question then on the capacity for expanding the clinical pipeline and the appetite for going into some of the potential new indications now following this funding. Does that guidance of a cash rate, the cash run rate in 2024, does that assume any potential of meaningful expansion of your clinical programs into new indications? Or is it based on the structure and size of the clinical program as it looks now?

Answer – Søren Tulstrup: Donato, can you take this one, please?

Answer – Donato Spota: Yes. Yeah. So the guidance does allow for, at least for initiating a certain expansion into maybe one or two more indications. And also we're also considering the fact that as mentioned that we obviously want to at the right point in time, certainly not this year. But going forward as we see the US trial progressing, and also want to start to invest in a potential preparation of the US launch. So that's considered.

Question – Adam Karlsson: Okay. No, perfect. And maybe a third and a final question for me on the AMR readout that we're expecting now in the second half. I was wondering maybe two parts to it, if you can share what parameters, sort of what endpoints we might expect in that readout? Will it just be sort of a top line that the trial was a success or not with the data to follow maybe into 2023 at a conference or so? Or can we expect sort of a hard data on primary and/or secondary endpoints? And there was a second part of that question, perhaps, whether there's any more detailed guidance on when that readout might come now that we're into the second half of the year, if you have a more granular picture of that. Thanks.

Answer – Søren Tulstrup: Yeah. Well, thanks for that question, Adam, so I mean the primary endpoint really is donor specific antibodies, right. And so obviously when we say that will come with a high level kind of readout, it's

going to relate to that essentially, do we consider what is our kind of tentative conclusion based on the topline results that we've seen.

I cannot be granular as to how granular it will be. But it will be the typical high level kind of readout and then you'll see subsequent more detailed reporting and using normal kind of timelines for that, right. So I think we'll have a pretty good picture by the end of the year as to whether we consider this a successful study or not. And I think that that's the main part.

Question – Adam Karlsson: No, perfect. And then on the timing of the readout, anything more than – more than second half or are you sticking to the guidance for now?

Answer – Søren Tulstrup: Yeah. I mean, I think we're looking at the latter part of this year before we are able to again, I mean, there's a six months follow-up period. So by the nature of when we have the last patient and so on, we're looking at the, yeah, the very last part of this year.

Question – Adam Karlsson: Okay, all clear. Thank you very much and congratulations again.

Answer – Søren Tulstrup: Thanks so much, Adam.

Operator

The next question today comes from Jacob Mekhael of Kempen. Jacob, please go ahead.

Analyst: Jacob Mekhael

Question – Jacob Mekhael: Hi there and thanks for taking my questions. My question is what are the timelines, the data updates on the post-approval study for imlifidase in the EU? And I have a second question on, we're seeing some interest on the subject of (37:22) re-dosing with imlifidase. Are there any studies planned to answer that question, or whether re-dosing is possible, or what are your thoughts on that issue?

Answer – Søren Tulstrup: Thanks, Jacob, for those questions. Of course, regarding the timeline for the post-approval efficacy study in Europe, so essentially, there is a – as we've communicated, we've gotten the first patient now. We'll see how fast the enrollment will be. It's a great way to generate experience in key centers and obviously generate additional data.

And we have a kind of a legal, a mandatory requirement to finish the study by the end of 2025. But I can't predict at what point we will kind of finish it. There's no urgency per se. Obviously, everyone wants to get additional results but, as I said, there's no urgency. There's several years for us to do this.

And then the second question was around the re-dosing. And here, clearly, we're talking about the next generation of enzymes, the NiceR program, which is in preclinical development currently with our lead candidate completing IND-enabling toxicology studies this year.

And then at the back-end of that, we'll hopefully be able to take a decision to move it into the clinic next year, and I can't say specifically in what area but hopefully we can do that. And I personally see that as a very significant potential value driver.

Question – Jacob Mekhael: Okay, I see. Thank you very much.

Answer – Søren Tulstrup: Thanks, Jacob.

Operator

Our next question comes from Johan Unnérus of Redeye. Your line is open.

Analyst: Johan Unnérus

Question – Johan Unnérus: Thank you for taking my questions and thank you also for clarification so far, especially the funding arrangement that it's also capped a minimum at $140 million. I presume that if it progresses according to scale, there is some benefit from your partner that they will receive the payments slightly earlier. And looking at the graph, it suggests that the majority of the payment if you're progressing to plan will come from royalties or shouldn't we read anything into that?

Answer – Søren Tulstrup: Thanks, Johan, and you're right in your overall statement there, but I'll hand over to you again, Donato, to just provide some details.

Answer – Donato Spota: Sure. Thanks, Johan. So I take that Klaus and I need to be more diligent when we do these graphs. As I said, I mean this is really just illustrative. It's not meant to indicate that we're paying more on royalties or paying more on milestones and so on. I mean, at the end of the day, I think what we have agreed with NovaQuest is that we will provide a 2x return latest by the end of 2028. And whether this is mainly through royalties or mainly from milestones, that will obviously depend very much on how the sales dynamics is going to be in the period from presumably 2025 through 2028.

So that's why I can't really answer those questions. But what I can just – the graph is not meant to kind of emphasize one over the other. It will really depend on how quickly we see the uptake in the US, for example, and where we are with our sales obviously in Europe at that point in time.

Question – Johan Unnérus: Yes. And my next question is perhaps also a bit difficult, but up until end 2024, if we look at the run rate, not any repayments or anything else, is there any – how close to breakeven could you come?

Answer – Donato Spota: You tell me. I don't know. I don't have a crystal ball. It just depends on so many things. I think what I want to say here is really that, yes, breakeven could be possible by 2024. But really our focus is really to create value out of the platform that we have, right? And we've just been – I think there was a question about adding maybe additional indications for imlifidase and so on and we're really looking into that because we really believe that we have a platform that is so versatile that it's really worth investing in it, and we want to invest in that. So, that's maybe how I can answer that question.

Question – Johan Unnérus: Yes. And the more successful you are, the more opportunities you will have, both in terms of partnership and partnering (42:27), of course.

Answer – Donato Spota: Indeed, indeed.

Question – Johan Unnérus: The last question is perhaps also a bit difficult to give a clear answer. You had a very good first half of the year now, both Q1 and Q2. And you also activated a lot of centers and even more centers are ready to accept patients. Is it reasonable to expect higher product sales in the second half or how should we think about the second half compared to the first half?

Answer – Søren Tulstrup: Well, let me take that question, Johan. So, we've not provided guidance, right? And we'll continue not to provide guidance for the short term at least, because this is a very, very complex market, there are lots of uncertainties. There's a high degree of volatility from quarter to quarter as we've discussed in the past when you have a situation where one patient is worth €300,000, and it's a few centers and they have patient one quarter and maybe no one in the second and so on. It's just impossible to predict. So, I'm not going to do this, but I can say that we're encouraged by what we've seen so far, right?

So, we're checking the launch metrics boxes and so far so good. And typically, you obviously see a pick-up, but I would really caution and say don't project anything, certainly not using any linear models based on what you've seen here. It's going to continue to be volatile from quarter to quarter. And the key thing is, are we seeing the right centers being activated? Are we seeing the right centers having good experiences? And we talked to that during the first part of this call.

Question – Johan Unnérus: Excellent. Thank you.

Answer – Søren Tulstrup: Thanks, Johan.

Operator

And finally, our last question today is from Christopher Uhde of SEB Bank. Please go ahead.

Analyst: Christopher W. Uhde

Question – Christopher W. Uhde: Hi. Thanks for taking my questions. Quick question on the AMR trial. So, in the past you've discussed the potential for a number of your programs where the Phase 2 trial could be a pivotal trial potentially. Do you intend to approach regulators just to see whether they would consider accepting the data for a potential accelerated approval or is that off the table at this point? And what can you...

Answer – Søren Tulstrup: Thanks, Christopher. So I'll tell you nothing at this point in time is off the table. Obviously we'll have to wait and see, get the results and then we'll make a decision based on that. It is a small Phase 2 trial, it's a first that we're doing in this space and we'll just have to wait and see and then have interaction with the regulatory authorities and based on advice and feedback and so on we'll kind of decide and obviously we will discuss that also. But at this point in time I just can't say.

Question – Christopher W. Uhde: Thanks very much. If I could just have one quick follow-up on the sales. Do you feel like this is a floor in the level of sales that we could expect, now it's around the same level for a couple of quarters? Thanks.

Answer – Søren Tulstrup: And again, what is I won't say unique but what is a little bit special about this situation, again, is the fact that this is not chronic therapy. It's a one-off shot, 15-minute infusion and that's it. And the patient hopefully is ready for transplant and would not come back. And in addition to that, the value of one patient is very high, as we just talked about, right. So for that reason, you would really expect this to be extremely volatile. And therefore, I cannot say that now we have a certain floor and therefore we just expect increases and steady growth or even exponential growth at some point. This is just too early.

But as I've said, it's very encouraging to see the general – the reception that the product has gotten in the market from the key centers, how they're taking action to actually put in place local protocols, identify patients relevant to therapy and putting them up for receiving organ offers. And then we've also seen, as I said and certainly one reported very good case in the Netherlands, which is quite encouraging. So, so far so good. But I just can't give any specific guidance on the sales numbers for the remainder of the year other than we've seen good progress so far and over the coming years we certainly expect this to continue.

Question – Christopher W. Uhde: Thanks so much.

Answer – Søren Tulstrup: Thank you.

Operator

We have no further questions in the queue. So, I'll hand the call back over to Søren Tulstrup for any closing remarks.

Well, thank you very much, operator, and thank you, everyone, for your time today and your interest in Hansa Biopharma. It's been a pleasure to report, I think, encouraging results and also a good financing deal that enables us to finance key projects, value adding projects for the coming years. And we look forward to keeping you updated as ever about progress. So with this, thanks so much and have a great day.