Hansa Biopharma Q1 2024 Conference Call Transcript

Company Participants

Søren Tulstrup – Chief Executive Officer

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

Hitto Kaufmann – Chief Scientific Officer

Evan Ballantyne – Chief Financial Officer

Conference Call Participants

Johan Unnerus – Redeye

Christopher Uhde - SEB

Douglas Tsao - H.C. Wainwright

Alexander Krämer – ABG

Eric Young – William Blair

Operator

Hi, everyone, and welcome to the Hansa Biopharma Interim Report for Q1 2024. Today's call is being recorded. For the first part of this call, all participants will be in a listen-only mode. Afterwards, there'll be a question-and-answer session. [Operator Instructions] Speakers, please begin.

Søren Tulstrup

Thank you operator. Good afternoon, good morning and welcome to the Hansa Biopharma Conference call to review first quarter results for 2024. I'm Søren Tulstrup, CEO of Hansa Biopharma. Joining me today is our Chief Commercial Officer and U.S. President, Matt Shaulis; our Chief Scientific Officer, Hitto Kaufmann. I'm also delighted to welcome Evan Ballantyne as our new Chief Financial Officer. With Evans, deep international experience and successful track record as a CFO at public and private life science companies I am confident that Evan will be a strong addition to our team and will help drive our financial strategy, deliver on key strategic priorities, and help us build shareholder value.

Hansa's head of investor relations, Klaus Sindahl, is also with us. Today, we'll discuss the progress we made during the first quarter of 2024 and review our near-term milestones. Presentations should take roughly 15 to 20 minutes, after which there will be an opportunity to ask questions during a Q&A session.

Now, please turn to slide two. Please allow me to draw your attention to the fact that we will be making forward-looking statements during this presentation, and you should therefore apply appropriate caution. Please turn to slide three and an overview of Q1 highlights. I'm very pleased to see a promising start to 2024. In the first quarter, we continue to see strong commercial execution, making it our best-performing quarter so far, and the second

consecutive quarter with solid product sales. This strong sales performance is a continuation of the tracks you saw at the end of last year, where key large markets such as the U.K. and Germany started to contribute, supported by new and repeated use of Idefirix's leading transplant centers. Matt will cover the commercial performance in more detail during his section of the call.

Last week, we announced that additional financing has been secured, extending our cash runway into 2026 through a $34.6 million direct-to-share issue targeting national healthcare specialist investors. I'm very pleased to see a strong interest in the hands-on equity story from leading U.S. and European specialist investors. This transaction will help finance the preparation for potential U.S. launch of imlifidase in kidney transplantation, strengthen our ongoing product development in autoimmune indications and allow for the continued clinical development of HNSA-5487, our lead candidate from the NiceR program for repeat dosing.

On the clinical development side, I'm encouraged to see our progress in kidney transplantation continue to progress as planned. Enrollment and randomization in our U.S. pivots or ConfIdeS trial is advancing as expected. During the first quarter of 2024, four new sites were activated, and both screening and randomization of eligible patients have recently accelerated.

As previously guided, we expect randomization to complete mid-2024. We've also made significant progress in the European post approval starting with more than a doubling of the number of patients treated in trial in the last couple of quarters. As a reminder, the post-approval study is an obligation under the European Conditional Marks and Authorization and will be used to further investigate the long-term graph survival in 50 highly-sensitized kidney transplant patients treated with Idefirix. The study will also help generate important clinical experience in leading transplant centers in using Idefirix as a new transformative desensitization therapy in highly-sensitized patients.

Beyond kidney transplantation, we continue to advance our imlifidase clinical programs in order immunity. In our pivotal Phase 3 trial in Anti-GBM disease, our lead-order immune indication, we've reached 50% enrollment in the trial and expect completion in 2025 as previously guided.

In our Phase 2 study in the Guillain-Barré Syndrome, we expect to share contextualized efficacy data later this year following promising first high-level data shared in December of last year. Hansa's lead candidate from the NiceR program for repeat dosing, HNSA-5487, continues to progress as planned with expected further analysis around endpoints to be completed in the second half of this year as previously guided, including selection of a lead indication.

In Gene therapy, imlifidase is being investigated in the phase 1b study as a pretreatment to ELEVIDYS, also known as SRP-9001, Sarepta's FDA-approved gene therapy in Duchenne Muscular Dystrophy. As communicated earlier, Sarepta leads the communication around the progress of this program and we expect the first high-level data readout towards the end of this year.

With this, I'll hand it over to Matt to go through our commercial progress for the quarter. Matt?

Matt Shaulis

Thank you, Søren. Please turn to slide four. As Søren mentioned in his introduction, we saw strong commercial performance in the first quarter, with SEK47 million in product sales, which is the second consecutive quarter of strong sales and, as Søren highlighted, our best performing quarter so far. Growth this first quarter was driven by product sales in our largest European markets, including France, U.K. and Germany, as well as initial sales in Belgium.

At Hansa, we are launching a transformative new therapy in kidney transplantation. It is a paradigm change, rather than a product for a well-established use, as it enables the treatment of cross-match positive patients. Generating successful early experiences in key early adopter clinics will be highly critical for the long-term market uptake of this innovative product. So, ultimately, we must win the acceptance battle, both for treatment of the patient type and the subsequent adoption of the product.

To measure our progress, we are using a set of key launch metrics, which we introduced back in the fall of last year. These metrics will directly or indirectly impact future adoption and sales of Idefirix as a new transformative therapy. We will continue to revisit these on a regular basis to demonstrate our progress. These metrics include market building and market access activities, patient identification, and transplant center readiness and use.

Looking at our market access and market building activities first, we have seen Idefirix specific guidelines being implemented on a national level in seven key markets so far, including Germany and Italy more recently. These guidelines provide a new clinical practice framework for healthcare professionals on a management pathway for highly sensitized patients. Our medical teams are supporting further country-level guideline development in other European countries.

In addition, we have now secured pricing and reimbursement in 75% of the European kidney transplant market, including all of the largest five markets and expect to see utilization in new centers, which will support increasing sales growth in 2024 and in the years to come. HTA processes continue to run in several other markets. In fact, we have 11 processes ongoing, including markets such as Portugal and Switzerland, and a dossier was submitted in Ireland during the first quarter.

Third, let's look at patient identification. Following the conditional market authorization in Europe, Hansa is running a mandatory post-approval study in Europe in parallel with the commercialization. The post-approval study helps clinicians generate valuable experience in treating and managing patients as we build the foundation for Idefirix to become a new standard-of-care and desensitization. While in the short term, this study may affect commercial sales and patient uptake, long-term, the experiences from this study will positively impact sales growth.

During the last six months, we have seen more than a doubling of the number of patients treated in the trial, and we have now completed approximately 72% of the post-approval studies. The post-approval study is on track to complete treatment in 50 patients by the end of 2025, and will support full marketing authorization in Europe. On-going patient identification for organ allocation systems, such as Eurotransplant, is another critical factor, since increased access to organs is critical to equitable care for highly sensitized patients.

On that note, we're pleased to say that the first two patients were treated in Eurotransplant’s new desensitization program during the first quarter of this year, following the increased patient identification and selection at the end of last year where both the first and second wave patient assessment took place on a large number of patients for treatment with this

new desensitization program. The new pilot program, under the acceptable mismatch program, is intended to transform desensitization across eight European member countries, including Germany, the Benelux, and select Eastern European countries.

Fourth, scaling up the base of transplant centers with clinical experience is a key commercial metric. And, while uptake will remain volatile from quarter-to-quarter, even with a growing base, due to the unpredictability of organ allocation to highly sensitized patients on waiting lists, we are pleased with the continued progress in establishing new centers that use Idefirix.

Today, approximately 50 clinics qualify as Idefirix ready to treat patients, while the number of clinics that have treated patients commercially or through our post-approval study has grown steadily. When we received EMA authorization in 2020, only two centers had clinical experience with Idefirix. And, by the end of the first quarter of 2023, that number of centers had grown to 15.

Today, more than 25 centers across both clinical studies and commercial sales have experience with Idefirix. Furthermore, by the end of the first quarter, the number of centers with repeat usage had grown to 17. We obviously are very pleased that we achieved two consecutive quarters that each represent our best product [ph] sales quarter so far. And, in addition to continued sales in France, we anticipate further growth to come from the U.K., Germany, Spain, and Italy, as our efforts continue to have impact into 2024.

We also have to re-emphasize that as the base of centers grows, we will continue to see more patients identified on the wait list of these centers for Idefirix, but there will be some volatility in sales from quarter-to-quarter, as the timing and number of organs allocated are basically determined by factors that are out of our control.

Please turn to slide five. With regard to our pivotal U.S. ConfIdeS trial in kidney transplantation, enrollment and randomization continue to advance as expected. During the first quarter of 2024, four new sites were activated, taking our total number of activated sites from 17 to 21. Similarly, both consenting and randomization of eligible patients have recently accelerated to 122 patients consented and 49 patients randomized out of a target of 64.

The ConfIdeS study is designed to evaluate imlifidase as a potential disruptive therapy for highly sensitized patients waiting for a deceased donor kidney through the U.S. kidney allocation system. Approximately 2,500 highly sensitized patients in the U.S. with a CPRA score of 99.9% and above fit into this category, yet they are not transplanted today, despite prioritization points on the kidney allocation system.

As we have previously noted, we expect randomization of this study to be complete by mid-2024, with a BLA submission expected 2025 on the accelerated approval path. And now I will hand over the call to Hitto, who will walk us through the progress of our exciting pipeline projects. Hitto?

Hitto Kaufmann

Thank you, Matt. Please turn to slide six. Our proprietary antibody cleaving enzyme technology platform holds significant potential beyond kidney transplantation in several therapeutic areas, such as autoimmune disease and gene therapy. Our lead indication in the autoimmune space is Anti-GBM disease, also known as Good Pasture disease, where

HNSA is running a pivotal Phase 3 trial as an open-label, controlled, randomized, multi-center trial evaluating renal function and need for dialysis at six months in patients with severe anti-GBM disease. In this trial, in this adhesion, it is investigated as an addition to standard-of-care consisting of a combination of PLEX, steroids, Cyclophosphamide, versus acid of care only.

Anti-GBM disease, a rare acute, autoimmune disease affecting approximately 1.6 people in a million in which antibodies are directed against an antigen intrinsic to the glomerular base membrane causing acute injury of kidney and/or lung function. Today's standard-of-care has been flagged by many leading experts as insufficient and majority of patients unfortunately lose their kidney function requiring chronic dialysis and/or kidney transplantation. At Hansa, we are excited about the potential for imlifidase and anti-GBM disease also because it serves as a catalyst to potentially enter several other IgG-mediated autoimmune indications where our therapeutic enzymes may offer significant benefits as induction therapy and/or help manage flare situations where acute and effective treatment will be needed to stop the severe autoimmune attack. Such situations could be relevant in ANCA-associated vasculitis, and other indications for either the standalone or in combination with other IgG-depleting treatments. We are very excited by the prospects in anti-GBM disease following very encouraging data from a Phase 2 trial published in the period in the Journal of American Society of Nephrology in 2022.

Based on the promising generated data, we believe that imlifidase could play a significant role as a potentially transformative and life-saving drug helping thousands of patients suffering from an acute immunologic attack that otherwise would require dialysis and could ultimately reach a death.

Please turn to slide seven. As we discussed in the beginning of this call we were happy to report that our clinical programs continue to progress as planned. At the end of last year we initiated the first clinical study with imlifidase in gene therapy together with our partners at Sarepta Therapeutics. In this Phase 1b study, imlifidase is being investigated as a pretreatment to Sarepta's FDA-approved SRP-9001also known as imlifidase gene therapy in Duchenne Muscular Dystrophy.

I'll have a later readout from the Phase 1b program as expected later this year. Another exciting program is our first in-tune trial of HNSA-5487, our lead candidate from the NiceR program for repeat dosing. Following positive results demonstrating that HNSA-5487 was safe and well tolerated with fast and complete depletion of IgG antibodies at increasing doses further analysis of expletory endpoints will be completed in the second half of this year and will guide selection of lead indication.

In the Guillain-Barré Syndrome Phase 2 program, Hansa presented positive high level data in December of last year, demonstrating that imlifidase was safe and well tolerated when administered prior to standard-of-care and that rapid improvement in disease related efficacy measures was observed in imlifidase treated patients.

As previously communicated, a further analysis will contextualize the efficacy data and is expected to be announced later this year. In the investigate initiated Phase 2 trial in ANCA-associated vasculitis, three patients are currently enrolled of a target of ten patients with severe ANCA-associated vasculitis and acute respiratory distress syndrome due to pulmonary hemorrhage. Patients will be treated with imlifidase on top of standard-of-care

consisting of standard immunosuppression as per center protocol and intensive support care.

The study in ANCA-associated vasculitis is being carried out at Charité Universitätsmedizin in Berlin. In our anti-GBM program, we have recently seen an accelerated uptake in patient enrollment in the global pivotal Phase 3 study which has continued during the first quarter as we have expanded enrollment capacity with additional sites.

In total 25 patients out of the target of 50 patients have now been enrolled across centers in the U.S., U.K. and EU confirming that we are on track to complete enrollment in 225 as previously guided. The primary objective of the anti-GBM study is to assess the superior efficacy of imlifidase in combination with standard-of-care versus standard-of-care alone with a six month follow-up on renewal function.

Lastly we are planning for a potential publication in a peer-reviewed journal of the full data from the AMR Phase 2 program. Data from the study was announced at the end of last year demonstrating rapid and significantly superior reduction in donor-specific antibodies within five days of treatment as compared to standard-of-care.

With this overview, I will now hand over the call to Evan, who will walk us through reviews of the financials of the first quarter of 2024. Evan?

Evan Ballantyne

Thank you, Hitto. Please turn to slide eight. Revenue for the quarter totaled SEK56 million, including SEK47 million in product sales and approximately SEK9 million in contract revenue, mainly from the Sarepta partnership agreement. As Søren and Matt noted earlier, product sales for the period reflect Hansa's best-ever quarter. This was the second quarter of strong revenue growth driven by product sales in our largest European markets, including France, the U.K., and Germany, as well as initial sales in Belgium.

We are very pleased with the strong revenue generation over the recent two quarters. It is important to emphasize that quarterly revenue can be volatile, given our dependency on organ supply and the allocation of kidneys to highly sensitized patients. That said, we are starting to see a meaningful revenue base being built with increased demand across a number of European markets.

Please turn to slide nine. SG&A expenses for the first quarter of 2024 totaled SEK91 million, compared to SEK103 million for the same period a year ago. The decrease in expense reflects lower staffing levels following the recent restructuring actions taken by Hansa.

Investments in R&D totaled SEK103 million for Q1 2024, which represents a SEK10 million increase compared to Q1 2023. This increase was mainly driven by the ongoing U.S. ConfIdeS study. Our post-approval commitments in Europe and the on-going anti-GBM phase 3 clinical study.

Hansa's operating loss totaled SEK159 million for the first quarter of 2024, compared to SEK182 million for the same period in 2023. The improvement in operating loss for the first quarter is mainly driven by increased revenue from product sales. Lastly, the net loss for the first quarter decreased to SEK159 million, compared to SEK182 million for Q1 2023. The improvement was driven by higher product sales and lower SG&A expenses, partially offset by the impact of negative foreign exchange variances.

Please turn to slide 10. Cash flow used in operating activities totaled SEK189 million for the first quarter of 2024, compared to SEK207 million for the first quarter of 2023. The period-over-period improvement was mainly driven by the increase in product sales and lower SG&A expense.

As Søren noted at the beginning of the call, we are very pleased with the additional financing Hansa recently secured, extending our cash runway into 2026. Through the 34.6 million U.S. dollar directed share issue, which chiefly targeted U.S. and European health care specialists, the successful capital raise will help finance the preparation of a potential U.S. launch of imlifidase, including transplantation, strengthen our ongoing product development in autoimmune indications, and allow continued clinical development of HNSA-5487.

I will now hand the call back to Soren for his final remarks.

Søren Tulstrup

Thank you, Evan. Please turn to slide 11. I want to reiterate that Hansa has entered 2024 with a promising start, following strong commercial execution in the first quarter, which is a continuation of the traction we saw at the end of last year. In transplantation, our key focus is to continue to successfully launch Idefirix in Europe, with a particular focus on our core markets.

Second, we aim to complete randomization in our U.S. ConfIdeS trial by mid-2024, as previously guided. In our autoimmune franchise, we intend to complete and announce the full data from the Phase 2 trial in Guillain-Barré Syndrome, and then interact with regulatory authorities to determine the best path forward for this indication.

In our anti-GBM program, our goal is to complete enrollment by 2025, and as discussed, we have seen strong momentum from the end of last year continue into 2024. In gene therapy, we expect the first high-level data towards the end of the year from the Phase 1b study with a imlifidase as pretreatment to direct us to gene therapy Elevidys in patients with Duchenne muscular dystrophy.

In our second gene therapy program, following successful completion of preclinical work, Hansa and Genethon expect to initiate the first clinical trial later this year of imlifidase administered prior to the dosing of GNT-0003, Genothon's gene therapy in Crigler-Najjar syndrome. Last, in relation to HNSA-5487, we will assess further immunogenicity data from the phase 1 trial in healthy volunteers and select the lead indication to be pursued.

Now, please turn to slide 12. With this overview, our presentation is now concluded, and we would like to open the call for questions. Operator, please begin.

Question-and-Answer Session

Operator

Thank you. [Operator Instructions] The first question will be from the line of Christopher Uhde from SEB. Please go ahead. Your line now will be unmuted.

Christopher Uhde

Thanks for taking my questions, Christopher Uhde from SEB. I was just wondering, first, in terms of the -- trying to get a handle on the volatility, what can you tell us about the next market access steps to unlock, sort of more of the opportunity? That's my first question. Thanks.

Søren Tulstrup

Yes, sure. Thank you very much. I will turn over to Matt for this, but essentially, we have gotten our access in all the top five countries in Spain and Italy, where we got access most recently. We're still in the process of pushing the green person down to the regional level, and we've seen very solid progress in Italy, actually, and it's moving a little bit slower, as usual, in Spain, but that is certainly very, very promising.

And then you have a number of smaller countries where we have submitted HTAs, and the process is on the way, right? But I don't know, Matt, if you want to add some further color to this.

Matt Shaulis

I think those are really the principal ideas at play here, right? The largest markets are secured, and we're going regional in Spain and Italy, and we anticipate that with that access and our continued commercial efforts, we'll see further growth during 2024 in the U.K., Germany, Spain, and Italy. So the bigger parts of our growth for the future are going to come from that base of reimbursement that we've already begun to establish.

Now, there are other opportunities. We mentioned Portugal, Switzerland. These markets will have some volume, but they will take a bit of a backseat to the larger markets. And come later. Yes.

Christopher Uhde

Okay, thanks. And any kind of indications on sort of the timing of that gating?

Søren Tulstrup

So I would say, as I said, in Spain and Italy, the process is underway as we speak. So we're getting regions by the month, all this. And then you have smaller markets like Portugal and so on, Ireland potentially as well. That is more like two, four events, right?

Christopher Uhde

Right, okay. And then a question on the gross margin then. It's in the 60s percent. What do you expect the steady state margin to be now that you have a bit more clarity on the shelf life versus the time in channels? And my last question is on NiceR. When do you expect to say more about what your plans are? Thanks.

Søren Tulstrup

Yes, on the gross margin, I mean, we're not going to give you a specific number there, but maybe I have a new accent and color to this development.

Evan Ballantyne

Yes, given I've only been here a month and a half, I'm going to tell you I think we can get the gross margin up to between 80% and 90%.

Christopher Uhde

Great, thanks.

Søren Tulstrup

And then on NiceR, so as we said, we're currently collecting additional data in the healthy volunteer study, and we should have the data including the 12-month data at the other end of summer. So in the second half of this year is when we expect to be able to communicate more around this.

Christopher Uhde

That's all for me. Thank you so much.

Søren Tulstrup

Thanks, Christopher.

Operator

The next question will be from the line of Douglas Tsao from H.C. Wainwright. Your line will now be un-muted.

Douglas Tsao

Hi, good morning. Can you hear me? Yes. Congrats on all the progress. So just, it sounds like a lot of the growth is going to come from some of the new markets and the larger

markets. I'm just curious, when you think about how things should proceed in some of those key markets, especially markets like U.K. and Germany, do you expect the uptake to be a little faster than what we saw in some of the smaller markets in the early going? Do you just feel like they're better prepared to sort of incorporate in this way since they're sort of treatment paradigm? I mean, obviously, they have more patients and more volume, so that should lead to the growth. But I'm just curious if you have a sense that they're sort of more ready and willing and able to choose the product. Thank you.

Søren Tulstrup

And I'll hand over to Matt, but I would say that in general, the U.K. is traditionally a pretty conservative market where you don't see very, very fast uptake. Germany tends to be the same, depending a little bit on the therapeutic area. But clearly, we have significant volume in these two countries, right? So that's going to be an important factor.

And then you have markets like Italy and Spain. Overall in Italy, we are quite encouraged by what we've seen, including, engagement from even patient associations and so on. Spain is really a very, very well organized market in Europe looking at the organ allocation system and so on. So I don't know if you want to add to this, Matt.

Matt Shaulis

I think that's a great characterization, sir. And I think that there is some level of conservatism in the U.K. and also in Germany, but we're encouraged that we've seen initial patient treatment in both of those markets. I think the other encouraging factor is that there is the desensitization program as part of your transplant that's at play in Germany. That is protocol-driven. And, while it lends itself to identifying a large number of patients, it moves through the wait list at multiple different centers in a very steady and methodological way. So that particular market doesn't lend itself very well to sort of, greater acceleration beyond the pace of that particular protocol.

I think that in Italy, we're making progress on getting region-level, pricing and reimbursement into place. That should have some good volume. I wouldn't necessarily say that that's going to be faster perhaps than, say, France, but should move at a good pace. I think one opportunity for us later in the year will be in Spain. We have numerous centers that are a part of the post-approval study in Europe that have been identifying patients. Spain has a fairly good concentration of those centers. And we anticipate that later this year, some of those centers will run their course of having been a part of post-approval study. And then the patient volumes in Spain and in some of those locations will then pivot to being commercial by necessity.

So I hope that was reasonable commentary. I think that more of the growth will come from having multiple markets on board at the same time. It won't necessarily come from individual markets, accelerating faster than, say, France has.

Douglas Tsao

Yes, that's really helpful. And then, just sitting here in April of 2024, we're encouragingly not that far away from completion of the U.S. ConfIdeS trial and then potentially a filing. So when we think about commercialization, it's not too far away. At what point do you start to think about sort of increasing your market presence and sort of doing some market-building work, obviously sort of maybe activating sort of like patient advocacy groups just to ensure sort of equitable distribution of kidneys and making sure that highly-sensitized patients start to get access when, in the past or even today, right, they're not necessarily getting that same treatment? Thank you.

Søren Tulstrup

Again, I'll hand over to Matt. But fortunately, we already have good presence in the U.S. Matt is not just President of the U.S., he's also our Chief Commercial Officer and he's based in the U.S. The global head of the transplantation franchise is also based in the U.S. The global head of our market access team is based in the U.S. We have some MSL presence in the U.S. and option and so on. So we have a pretty good setup already and, of course, as you know, the ConfIdeS trial is essentially the best pre-launch activity you can engage in. But I will hand over to Matt for this.

Matt Shaulis

Sure. Thank you, Søren. It's a great question. I really appreciate it. I can add some color to this. Certainly the study, we're really pleased to see the way that the number of sites have increased and also the way that consenting and randomization have progressed. And that is, in fact, a substantial opportunity for us in the U.S. We're currently at 21 sites. We believe that we'll get to 24 or potentially 25. And that compares very favorably to the two centers that had clinical experience at the time that EMA authorized Idefirix at the end of 2020.

So that's a substantial improvement and is a form of market development. As Søren outlined, we have some personnel in the United States. This includes clinical operations and medical affairs people. And they've been engaging with the clinical trial sites, those 21 centers, as well as an additional three or four. They also are doing profiling and engaging with additional centers, beyond the footprint of the clinical trial. And I think that's an important part of our development and presence, which of course complements some of the things that we're starting to do with patient activation.

So you'll see, some of that takes place through the remainder of this year and into next year. We also see some increased interface with the organ procurement organizations in the U.S. That's an opportunity for us, again, as we end 2024 and we start to get into 2025. And then lastly, in addition to things like medical engagement, it will include medical education activity at various congresses. We'll also be working with various thought leaders and stakeholders to ensure that we have clinical guidelines in place before the time of the launch. We're quite pleased that there's a pan-European guideline in place with ESOT. And then seven different markets have country-level guidelines in Europe. That's an important model for us to replicate in the United States. And there are really influential physicians that are a part of our clinical study that have voiced their belief that this is important. We think that those and other stakeholders will be very important partners in helping to get that going.

Søren Tulstrup

Thanks, Matt. So clearly given the fact that at the time of launch we expect a very significant number of the leading transplant centers to have experience with imlifidase and essentially to have protocols in place, it's going to be a much faster uptake we expect in the U.S. compared to Europe overall. Another differentiating factor is the fact that in the U.S. you're actually allowed to engage in communication with payers, prior to actually getting authorization. So again, we expect that there's going to be an uptake significantly earlier in the U.S. post-approval compared to Europe. Thank you for the question, Doug.

Douglas Tsao

Thank you so much, Søren. That's really helpful to you and Matt. Thank you.

Operator

The next question will be from the line of Alexander Krämer from ABG. Your line now is unmuted.

Alexander Krämer

Yes. Hello. My name is Alexander Kramer from ABG. Thanks for taking my questions, first of all. And I would like to touch upon a topic that you have mentioned already, which is about the European post-approval study. When do you expect to start to see a patient flow into the number of commercially treated patients, like basically when the post-approval study is finished? Like when do you see the first impact on patients actually going like more into the commercially treated population? Do you expect it's still in 2024 or is it more something like more into 2025?

Søren Tulstrup

So thank you for that question. So clearly, as we said, we're very pleased to actually see the significant number of patients that have been treated as part of this study over the past two quarters, which again is an indicator of the ability to find these patients and actually have them transplanted. And what we're seeing and what we expect to see is that some of the centers that participate in this study will start using commercial products going forward. And that will be an increasing number of centers.

So we do expect certainly already this year to see some of these centers contribute to commercial sales of the product, and certainly in 2025. And as you know, we need to conclude this study by the end of 2025. That's also going to happen. So thanks for the question.

Alexander Krämer

Okay. And I also have two other questions. One relates to the Eurotransplant Program. So in the Acceptable Mismatch Program, you had only two treated. What are the reasons for the slow uptake in that program? Why doesn't this accelerate?

Søren Tulstrup

I will, I think, hand over to you, Matt, to take this one.

Matt Shaulis

Yes. So I think the two patients, we consider encouraging. This Acceptable Mismatch Program with a desensitization protocol within it is a very systematic way of looking at things. And so this program started by looking at some of the patients that had been on the wait list the longest. And taking that approach doesn't necessarily reveal the patients that are necessarily the best fit for the therapy. So I think what we've essentially seen is that first initial task, based on that particular criteria, that hasn't yielded a really large number of patients. But it has been encouraging that even amongst that, that cohort, there have been some patients that are suitable. We believe that there will be opportunities in the future for more patient identification through this approach.

Alexander Krämer

Okay. Thanks, Matt. And my last question is on the Sarepta, on the Phase 1b trial. Like when do you expect to communicate the next milestone for this one, like in terms of patient recruitment?

Matt Shaulis

So as you know, this is a study that's being run by Sarepta. And so it's up to Sarepta to communicate, which I cannot communicate, details on a quarter-by-quarter basis here. What we have said, of course, is what Sarepta said themselves, namely that the study has been commenced. And so, the setup of this study, it's a limited number of patients, single digit. There is a readout after 12 weeks looking at neutralizing antibodies as well as gene expression. So we certainly hope and would expect that that could be data from first patient study towards the end of this year.

Alexander Krämer

Okay. Thank you very much. That's it for my side.

Matt Shaulis

Thank you, Alexander.

Operator

The next question will be from the line of Eric Young from William Blair. Please go ahead. You line will now be unmuted.

Eric Young

Hi, Eric on for Matt Phipps. Thanks for taking the question. I was just wondering on the NiceR program, can you disclose what data you will show publicly in the 2024 update. And relatedly, how long are you following patients to take immunogenicity samples?

Søren Tulstrup

So we are following these patients through month 12, essentially. And what we're looking at is, again, ADAS [ph], right, antibody, looking at ITG levels and so on. And, again, as I said initially, when we have the full data set, we will communicate our conclusion around this and also certainly this year make a decision as to the lead indication. I don't know if you want to add anything here to this.

Matt Shaulis

Not much. Thanks, Eric. I think you have just to mention these are exploratory endpoints where we basically take serum samples six and 12 months and that's half the time horizon. And in in-vitro assays, we do all kinds of experiments that will inform us about our hypothesis that we can dose a second time six to 12 months.

Eric Young

Got it. Thank you.

Søren Tulstrup

Thanks, Eric.

Operator

[Operator Instructions] The next question will be from the line of Johan Unnerus from Redeye. Please go ahead. Your line will be unmuted.

Johan Unnerus

Thank you for taking our questions and thanks also for good previous questions. So we have some additional stuff. And the cost base, I presume we should expect R&D to increase

somewhat during 2024. And also, are there OpEx to reflect the efficiency and the saving program and [Indiscernible] as a result come down somewhat?

Søren Tulstrup

I think I'll hand it over to you, Evan R&D expenses and other types of things.

Evan Ballantyne

As you're aware, Hansa initiated a restructuring program in Q4 of last year. Full effect of that restructuring program won't be felt until Q3 and Q4. But during the next two quarters, Q1 and Q2, I would expect expenses to improve and to be really recognized the full impact of the R&D or restructuring program in Q3 and Q4.

Johan Unnerus

And what about R&D? I presume that the U.S. study, for example, will push that a bit.

Evan Ballantyne

I'm going to guess that R&D expenses are going to remain somewhat constant only because the compliance trial is slowly coming to an end, as are some of the other trials. So I would expect it to be somewhat constant.

Johan Unnerus

And perhaps some reflection on the financing side. You had a successful direct share issue recently, and you have a runway to 2026. Presumably, there are different options that you could consider. You have the NovaQuest relationship, and you may also have some options to engage with additional partners.

Evan Ballantyne

Yes, I mean, the company is very excited about the capital raise we just completed. I think you know this. We did the capital raise without a discount to the market price, which in this particular market is very impressive. We had really solid participation from some very high-quality funds. And to your point, completing a capital raise gives the company a lot of optionality over the next 18 months to 24 months. And again, very excited to have completed it.

Johan Unnerus

And finally, also, you have had a good momentum in both the U.S. study and in the post-approval study in Europe. And the post-approval study activity has been combined with a

much improved sales momentum. It looks like the post-approval study could be possibly completed earlier than initially thought, perhaps.

Søren Tulstrup

Potentially, it could. Again, we have an obligation, essentially, to complete it by the end of 2025, right? With the current momentum, it could conclude earlier, but it's too early to say, right? It's difficult to predict, but it's certainly very, very encouraging, again, to see the inflow of patients here. And as we've said previously, this is a great way to help generate experience. And we do expect commercial sales to come out of some of the participating sites already this year.

Johan Unnerus

And you're not in the business of providing quarterly guidance, but could we get some feel for if it's possible to come in with sales around the same level? Or should we expect somewhat lower, yet now enjoy two good quarters?

Søren Tulstrup

Well, you said it yourself. We're not going to give the quarterly guidance, right, because it is going to be volatile. So I will not step into that minefield. But I think, as you can hear from the tone here and what we've seen over the past six months, there is good momentum. We are seeing large countries starting to contribute. Last year, we saw that the year was back loaded. Given, again, the momentum and what is ahead of us, we're comfortable that we're going to see a year that, compared to last year, will reflect significant growth. So that's what I can say. But I'm not going to provide any guidance, certainly not on a quarterly basis.

Johan Unnerus

Great. Thanks. That's all from us.

Søren Tulstrup

Thanks, Johan.

Operator

The next question will be a follow-up from the line of Eric.

Eric Young

Hi, Eric on for Matt Phipps, William Blair. Thanks for taking the additional question. Just a question related to the GBS program. Can you guys disclose your thoughts on next steps for GBS development after the results of the comparative efficacy analysis later this year?

Søren Tulstrup

So the next step is, of course, to engage in thorough interaction with regulatory authorities and discuss the design of a potential Phase 3 trial. So that's essentially the next step. We're really encouraged, as we said, by the fact that we've seen very early recovery in these patients, clearly earlier than you have seen reported for IVIg in relation to parameters [ph] like ability to walk unaided and so on. So hopefully this will be further proven and documented in the comparison with patients from the patient registry. And that certainly is going to act as key input in our dialogues with regulatory agencies.

Eric Young

Got it. Thank you.

Søren Tulstrup

Thanks, Eric.

Operator

As no one else has lined up for questions, I'll hand it back to the speakers for any closing remarks.

Søren Tulstrup

Well, thank you very much operator. And thank you everyone, for your interest in Hansa Biopharma. As I said, we've had a good start to 2024, and we look forward to seeing that positive start continue throughout the rest of the year and updating you on further progress. Thank you very much.