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MANAGEMENT DISCUSSION SECTION

Operator

Hello, everyone, and welcome to Hansa Biopharma First Quarter 2022 Conference Call. My name is Juan, and I will be coordinating your call today.

Now, I will hand over to your host, Søren Tulstrup, CEO of Hansa Biopharma. Please, Søren, go ahead.

Søren Tulstrup

Thank you, operator. Good afternoon, good morning, and welcome to the Hansa Biopharma first quarter 2022 conference call. I'm Søren Tulstrup, CEO of Hansa Biopharma. And joining me today is Hansa's Head of Investor Relations, Klaus Sindahl. Our CFO, Donato Spota, was also scheduled to join us today. However, as his wife is giving birth, as we speak, he's heavily engaged in the labor room of the local hospital, and we're sending him our best wishes. Hansa's mission is to preserve and improve human life and a necessary enabler to deliver on this mission is obviously that someone takes care of giving life. And so, I'd like to compliment Donato for his very strong personal leadership in this respect.

Today, we'll discuss the progress we made during the first quarter of 2022 and review our near-term milestones. After the presentation, there will be an opportunity to ask questions during a Q&A session.

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

Please turn to slide 3. Hansa's long-term goal is to become a recognized global leader in rare diseases across multiple therapeutic areas to the development of new transformative drugs that could be both lifesaving and life-altering for patients suffering from rare immunologic diseases and conditions. In order to do so, we need to successfully execute on our strategic priorities, which are to, first, continue the successful execution of our commercial launch strategy for Idefirix by obtaining pricing and reimbursement agreements in new key markets in Europe, making additional prioritized transplant centers clinically ready for initiation, and generating growing commercial sales; second, to complete enrollment in the pivotal US ConfIdeS trial; and, third, to further advance our pipeline of drug candidates for autoimmune diseases and post-transplant management by initiating a pivotal trial of imlifidase in anti-GBM disease and advancing our ongoing Phase 2 trials in AMR and GBS towards first data readouts.

Today, I'm pleased to report solid progress across our business and R&D activities during the first quarter of this year. On the commercial side, our launch activities and market access efforts for Idefirix in Europe are progressing as planned. During the first quarter, we achieved solid sales growth, mainly driven by product sales of Idefirix in our early launch countries. While we're still in a very early stage of the launch and numbers obviously are small with much volatility to be expected from quarter to quarter due to the single-dose high-value nature of Idefirix therapy, the fact that we are now seeing solid activity at the transplant center level is very encouraging.

Also, we're very pleased to have secured market access in two new major markets, mainly in France through an Early Access Program and in Germany with full commercial access on negotiated terms. Beyond Germany and France, we have market access procedures ongoing in an additional 11 countries, including Spain, Italy, and the

United Kingdom, while market access during 2021 was secured in Sweden and the Netherlands, as well as on an individual hospital basis in Finland and Greece.

At the end of March, Hansa and Medison Pharma announced that a marketing authorization was granted in Israel for Idefirix for desensitization treatment of highly sensitized kidney transplant patients. This is the first marketing authorization outside of our core markets and a great accomplishment for our new collaboration with Medison Pharma, which, beyond Israel, also covers Poland, Hungary, Croatia, and Slovenia.

In the beginning of March, key data from the investigator-initiated open-label Phase 2 study of imlifidase in patients with anti-GBM disease were published in the peer-reviewed nephrology publication, Journal of the American Society of Nephrology. And this publication really is an important recognition of the positive data from this Phase 2 data trial.

In the beginning of the year, we also announced a second collaboration in the gene therapy area as Hansa Biopharma and AskBio, a subsidiary of Bayer AG, agreed to evaluate the feasibility of imlifidase as pretreatment ahead of gene therapy in Pompe disease in patients with prove high titers of neutralizing antibodies against the AAV vector used. We see significant potential for our antibody cleaning enzyme technology to help overcome this barrier in gene therapy as NAbs against adeno-associated virus remain a major challenge, and the new collaboration with AskBio further validates our unique antibody cleaning enzyme platform's promise.

Now, I would like to turn to our ongoing Phase 2 programs for GBS and AMR. As of April 20, we have enrolled 28 out of the target of 30 patients in the AMR study, while 16 out of a target of 30 patients have been enrolled in the GBS study. As discussed on our last call, the Corona pandemic has negatively impacted the GBS patient enrollment rate, and we've taken measures to mitigate this, which we'll discuss later in the call. In the US, our pivotal ConfIdeS trial in kidney transplantation is progressing according to plan, and we've seen good momentum at a number of clinics as we've currently enrolled 16 out of a target of 64 patients, patients that are now either being randomized or waiting for an organ offer.

Please turn to slide 4. As highlighted in the beginning of this presentation, we have seen solid progress with our Idefirix commercial launch activities and market access efforts. During the first quarter, we reached an agreement with the German payer association and Idefirix was also granted early access in France by the relevant national authority.

For both Germany and France, commercial access was secured on negotiated terms. These two countries together performed more than 5,600 kidney transplants annually of which approximately 75% are transplanted from a deceased donor.

We expect to close additional agreements during the remainder of the year as we have market access procedures ongoing in 11 countries, including Spain, Italy, and the United Kingdom. During 2021, market access was secured in Sweden and the Netherlands as well as on an individual hospital basis in Finland and Greece.

Looking beyond the EU, Idefirix was granted marketing authorization in Israel for desensitization treatment of highly sensitized kidney transplant patients. This is the first marketing authorization granted outside Europe and a great accomplishment by our new collaboration with Medison Pharma, which grant Israel, also covers Poland, Hungary, Croatia, and Slovenia as previously discussed. Later this year, we also expect the outcome of our marketing authorization application in Switzerland, which was submitted last summer.

Please turn to slide 5. Idefirix is the first and only treatment approved in Europe for desensitization treatment of highly sensitized patients. The introduction of this potentially transformative drug is viewed by many leading experts, clinicians, and those in the peer (00:07:38) community as enabling a paradigm shift towards equity of access for highly sensitized patients to potentially lifesaving and life-altering kidney transplants.

At transplantation centers, procedures are managed by highly specialized teams of clinicians, including nephrologists, transplant surgeons, immunologists, tissue typists, transplant coordinators and nurses, as well as other specialty physicians such as psychologists, cardiologists and neurologists, all work tightly together before, during and after a transplantation.

As part of our launch strategy, we will initially focus on targeting leading centers that have the potential to become early adopters in centers of excellence. The long-term market uptake of this innovation is highly dependent on successful early experiences in key early adopter centers.

It is critical for the successful launch of Idefirix that positive outcomes are generated in the first patients, and for these clinical centers to build the foundation necessary for expanded use of Idefirix as a potential new standard of care in desensitization protocols.

The anticipated S-shaped sales response curve reflects this approach in the initial years of commercialization. As more accelerated growth occurs on the back of repeat business at the center level, which is anticipated midterm, we also expect to expand beyond the first wave of early launch countries by leveraging the full potential in the five largest

European markets and anticipated commercial launch in the US following FDA approval. Longer term, it is our intention to expand the label into new areas, such as AMR post kidney transplantation, as well as heart and lung pre- and post-transplantation enablement and management.

Please turn to slide 6. In the beginning of March, positive key data from the investigator-initiated open-label Phase 2 study of imlifidase in patients with anti-GBM disease were published in the leading peer-reviewed nephrology publication Journal of the American Society of Nephrology. The publication of the data is recognition of the study's significance in autoimmune diseases as it suggests that deactivation of autoantibodies could alter the course of an autoimmune disease, in this case, allowing restoration of kidney function. The positive study outcome is an indicator of the potential of imlifidase beyond kidney transplantation. Speaking about anti-GBM, we are also pleased to share the positive news that the US FDA recently accepted Hansa's investigational new drug application to proceed with the Phase 3 study of imlifidase in approximately 50 patients across the US and EU. The first patient is expected to be enrolled later this year as previously guided.

Now, please turn to slide 7 and a review of our ongoing clinical programs. In our AMR Phase 2 program, 28 out of a target of 30 patients are now enrolled, and we are on track to complete enrollment in the first half of 2022. We expect to announce the first data readout from the AMR Phase 2 study in the second half of this year as previously guided. Regarding our GBS program, we've seen how the impact of the COVID-19 pandemic, and the emergence of the new variants have affected the availability of staff across a number of trial centers. Additionally, a shortage of IVIg has affected the enrollment rate in the GBS program at a subset of participating hospitals.

To mitigate these hurdles, we have implemented several initiatives during the last couple of months to increase enrollment rate. These initiatives include simplifying the study protocol, actively supporting the hiring of additional staff at the clinics, and adding two additional sites for the recruitment of GBS patients in the UK and the Netherlands. We expect these initiatives to enable the completion of enrollment in the second half of 2022.

In the US, we are pleased to see that despite the challenging environment, our pivotal ConfIdeS trial in kidney transplantation is progressing according to plan with 16 out of the target of 64 patients now enrolled. This US pivotal 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 have now initiated enrollment at nine sites and expect participation from up to 15 leading transplantation centers across the US with the goal of completing enrollment by the end of this year. This randomized controlled trial will generate both valuable data and important experience at key transplant centers in the US. As previously communicated, we expect to complete enrollment in the ConfIdeS study in the second half of 2022 with a 12-month follow-up on EGFR to be completed second half of 2023. Results from the trial are expected to support a BLA submission under the accelerated approval pathway in the first half of 2024.

Please turn to slide 8 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, antidrug antibodies, and in the very promising field of gene therapy where we now have two ongoing collaborations with Sarepta Therapeutics and AskBio. The goal of both collaborations is to assess imlifidase as a pretreatment ahead of gene therapy. With Sarepta, we are investigating this approach in Duchenne and limb-girdle muscular dystrophy. And in the case of the AskBio collaboration, the focus is Pompe disease.

The preclinical development program with Sarepta is progressing according to plan while the program with AskBio recently commenced. Upon successful completion of these preclinical programs, we expect imlifidase to move into clinical trials. Beyond the gene therapy space, we also engaged in a preclinical collaboration with argenx to assess the potential benefits of combining imlifidase with efgartigimod, argenx's FCR inhibitor.

Please turn to slide 9. With Donato's absence, I'll now provide a high level review of the Q1 financials. Building on our strong execution during 2021, we have had a good start in 2022. Total revenue for the first quarter of 2022 grew to SEK 30 million, including SEK 24 million in product sales, and SEK 5 million of revenue recognition under the Sarepta agreement, albeit still on low levels, this reflects solid product sales growth of more than 60% compared to product sales for the entire last year, and almost a tripling over the last quarter. As we're still in an early launch space, however, we do expect that sales will remain very volatile on a quarter-to-quarter basis.

Please turn to slide 10. The first quarter of 2022, SG&A expenses amounted to SEK 80 million, compared to SEK 60 million for the same period last year. The increase in expenses is in line with the objective to grow Hansa as a fully integrated commercial stage biopharmaceutical company and as such mainly reflects our expanding commercial footprint related to the launch of Idefirix.

Our R&D expenses amounted to SEK 71 million for the first quarter of 2022, compared to SEK 47 million for the same period last year. The increase in our research and development expenses is mainly driven by the initiation of the US

ConfIdeS study, a post-approval commitment in Europe, the preparation for the anti-GBM Phase 3 study, and our ongoing Phase 2 programs in GBS and AMR, as enrollment accelerated.

Investing in R&D and our pipeline activities across all of our four franchises remains a key priority for Hansa as it underpins the company's long-term value creation strategy. The net loss for the first quarter of 2022 was SEK 138 million, compared to SEK 104 million for the same period last year.

Please turn to slide 11. Cash flow from operating activities amounted to minus SEK 130 million for the first quarter of 2022, which compares to minus SEK 121 million for the same period in 2021. Hansa's cash position including short-term investments amounted to SEK 754 million, corresponding to approximately $80 million. With our current cash position and projected burn rate, we expect Hansa to be financed well into 2023 as previously guided.

Now, please turn to slide 12. Despite a challenging environment, we have demonstrated solid progress in executing on our key strategic priorities including ensuring a successful launch of Idefirix in Europe while in parallel advancing our pipeline of valuable drug candidates for rare immunologic diseases. Looking at the milestones ahead, we expect 2022 to be similarly exciting. In our Phase 2 program in AMR, we expect to complete enrollment any day now, which also means that the first data readout from our AMR trial is expected in the second half of 2022 as previously guided.

Regarding our GBS program, as discussed, we have recently implemented several initiatives to increase enrollment rate, and expect these initiatives to enable the completion of enrollment in the second half of 2022 with subsequent first data readout in the first half of 2023. As highlighted earlier during the presentation, the US FDA recently accepted Hansa's investigational new drug application to proceed with a Phase 3 study of imlifidase in approximately 50 patients across the US and EU, and the first patient is expected to be enrolled 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 in 2022. Upon successful completion of these studies, we expect to advance NiceR program into clinical studies. Lastly, we've seen good progress in our efforts to enroll patients into our US ConfIdeS trial in kidney transplant, 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

The first question comes from Adam Karlsson from ABG. Please, Adam, your line is now open.

Analyst: Adam Karlsson

Question – Adam Karlsson: Hi, Søren. Thanks for taking my questions and congratulations on a strong quarter. First question if I could on the SEK 24 million in product sales recorded in the quarter, that would imply eight patients treated. Was all of this true demand or was there some component of stocking as more pharmacies at the relevant clinics are going live by product ahead of the first treatment?

Answer – Søren Tulstrup: Yeah. You cannot mechanistically make that calculation as this represents eight patients that have been treated. Obviously, it varies from geography to geography how this is accounted for, but clearly, it indicates an underlying demand from the clinics.

Question – Adam Karlsson: All righty. Perfect. Thanks. And then, I know you've been a bit hesitant to speak to this previously, but I wonder if there's some color you might be able to give around either the number of clinics that have used imlifidase in a commercial setting or if any clinics have had a chance to treat multiple patients yet.

Answer – Søren Tulstrup: Yeah. So, we are not again talking about patient usage at the clinic level. But clearly, what we're seeing is that an increasing number of clinics are becoming clinically ready to treat patients and that there have been patients treated. So, that is ongoing overall.

Question – Adam Karlsson: All righty. And maybe just one more, if I could. Let's see, so you're guiding to not necessarily treat the SEK 24 million in product sales here as a new baseline or to extrapolate from this going forward saying it's going to be volatile here in the initial launch phase. But perhaps just to kind of put that in context, I was wondering if you could help us sort of better understand your own internal visibility on sales, how much foresight you have in a given quarter? I mean, I guess, given that there is this lead time between identifying a suitable patient and the treatment taking place and so on. Is it the case that you can have a reasonable view of the number of patients treated in a quarter ahead of that quarter closing or is there still a lot of uncertainty right up until you close that quarter?

Answer – Søren Tulstrup: There's a lot of uncertainty, really. I – we've discussed on other calls. What we're really looking at is how many clinics are clinically ready, how many are commercially ready including having access to products. Then we look at, do they have patients identified, are they ready to initiate and so on. And so, that's essentially what we're looking at. Currently, we're north of 10 clinics that are clinically ready, and we expect by the end of this year to have more than 20 of these key clinics across Europe to be clinically ready to use the product in real patients.

But there will be significant volatility. It's very important to understand this. I mean, this is not a situation where you have, you get a patient, and you have ongoing kind of usage and repeat business in that patient. It's one-off therapy, right? The value of one patient is very significant. You have a price level of around €3,000 per patient. And so, you're going to see a high degree of volatility from quarter-to-quarter. Having said that, as I said earlier during this call, it is, of course, very encouraging for us to see this underlying growth in demand from the key clinics. And overall, we're very happy with the level of interest and increasing number of clinics becoming both clinically ready, but also commercially ready like we've discussed now, an increasing number of countries have taken positive pricing and reimbursement decisions or as in the case of France, we've been able to secure early access programs. So, overall, we're very pleased with the development.

Question – Adam Karlsson: Great. That's very helpful. Could I squeeze in maybe one final one on the preclinical gene therapy collaborations as well with Sarepta and AskBio? You said they're progressing according to plan. I was wondering whether there is anything you can say about when we might expect an update on I guess the Sarepta, one would be more timely. Is it the case that that you have sort of good visibility there and you're kind of tied to Sarepta communicating things there or is there not that good visibility there on your end when there might be something tangible to reports on that collaboration?

Answer – Søren Tulstrup: Well, we're very much involved. Obviously, Sarepta is in the driver's seat here, and they're also financing the research and development activities. But we have a joint steering committee in place and we have joint project teams and so on. So, we are very much involved. And currently, what they're doing is animal studies. Things are progressing according to plan. And so overall, we're quite pleased with the collaboration and the progress we've seen. It is up to Sarepta to communicate, what will happen at later stages. Clearly, the next expected step is to have filed overall readouts from these pre-clinical experiments taking place. And then once the full dataset is available and has been fully assessed, Sarepta would be in a position to take a decision as to what to do next, right, and that would likely involve taking these products in to the clinic. So but I can't be more granular and as I said, we are not really the ones driving the communication here, but certainly we are quite pleased with the progress we're seeing.

Question – Adam Karlsson: Got you. No, that's helpful. Thank you very much.

Answer – Søren Tulstrup: Thank you, Adam.

Operator

Thank you. Our next question comes from Douglas Tsao H.C. Wainwright. Please, Douglas, your line is now open.

Analyst: Douglas Tsao

Question – Douglas Tsao: Hi. Good morning. Thanks for taking the questions and Søren congratulations on the progress. Just maybe as a starting point, it sounds like in 2023 you expect to, next 18 to 24 months, be adding a lot of new country. I'm just curious, how long do you expect or do you have visibility or a sense, and how quickly from once you secure reimbursement and access in a particular country that you can be sort of getting centers ready to actually treat patients with imlifidase?

Answer – Søren Tulstrup: So, good question, and we have pretty good experience now. We've obviously worked with a high number of centers, and clearly we need to work with multiple players at the center level and make sure that a local protocol is put in place, and that all the infrastructure is built if you will, and so on. So, it's a multi-month process, but obviously this is something that we've already embarked upon, right? So we are in dialogue with these centers and obviously we're doing this prior to, in many cases, actually securing broad kind of pricing and reimbursement and market access. So, these two things are essentially happening in parallel.

Question – Douglas Tsao: Okay, great. That's really helpful. And then just from an SG&A standpoint, it actually looked like, it's up pretty significantly year-on-year, but it's sort of flat to where you've been in the last several quarters. Do you expect seeing some additional or incremental SG&A as you add some key markets over the next, whatever, 12 to 18 months?

Answer – Søren Tulstrup: There will be some increase. That's clear. It is a very efficient launch, if you will, because obviously it's a very concentrated target audience. So, again, as we've discussed, we don't need a high number of

boots on the ground. But clearly, as we add additional markets, you will see – you will expect to see an increase in SG&A.

Question – Douglas Tsao: Okay, great. And finally, just on the NiceR program. So obviously you're going to be finishing up your toxicology studies, hopefully filing an IND. Just curious, do you have initial indications in mind and when do you expect to sort of publicly discuss that? Thank you.

Answer – Søren Tulstrup: Yes. So, as I've said, we expect to have the IND enabling tox studies completed this year, and that will obviously enable us to take a decision to move forward. We're looking at several different options. We think that this actually is potentially a very important value driver for the company, and there are certainly opportunities in several of the broad indication universes where we are present, right? So clearly, there are autoimmune diseases where you have flares, and therefore you need again repeat dosing, and you need efficacy beyond what the maintenance therapy can bring you. So that's one opportunity in the gene therapy space. It is likely that many of the gene therapies will be dosed – will have to be dosed more than once. This is clearly what we're seeing. And then, you will have not only the problem with preexisting neutralizing antibodies, but also neutralizing antibodies occurring post the first dosing.

Oncology clearly is, almost by definition, a repeat dosing space. And there might be also in the transplant space some indications like AMR, where you would want to have the ability to dose multiple times. So, we see many different potential avenues here and we'll take that decision once we have the full dataset and that will be on the back side of these IND-enabling tox studies.

Question – Douglas Tsao: And Søren, do you anticipate would this be something that after your first clinical studies would be in healthy volunteers or do you think that you would first perhaps pursue indications where you can go straight to patients? Thank you very much.

Answer – Søren Tulstrup: Well, that's something we'll assess at that point in time. So we'll discuss that when we get closer. Thanks.

Question – Douglas Tsao: Okay. Great. Thank you very much, and congrats on the progress.

Answer – Søren Tulstrup: Thank you.

Operator

Thank you. Our next question comes from Christopher Uhde from SEB. Please, Christopher, your line is now open.

Analyst: Christopher W. Uhde

Question – Christopher W. Uhde: Hi. Thanks. So a few questions from me. I guess the first thing I was wondering is, in terms of the patient profiles treated, let's say pre-Idefirix, the highly sensitized and very highly sensitized patients were often not transplanted in many European countries. What's the cPRA spread in patients who've been treated with Idefirix so far, to your knowledge? And can you, I mean – yeah, let's say, for example, have a few – has a few, has it been used in patients with less than 99% or is it all greater than 99% or any greater than 99%? Any color you can give there would be helpful (00:29:42).

Answer – Søren Tulstrup: First of all, yes, so I can't give you any color on the patients that have been treated commercially. But I can say, as you know very well is that during our Phase 2 trial, we have very, very good data in very highly sensitized patients, right, with 99.5% being the mean in Phase 2 and with many patients being at the 100% cPRA level.

And so from our perspective, the ideal patient really is someone who is highly sensitized, right, but who otherwise is a relatively healthy patient with good prognosis, right, that would benefit tremendously from a kidney transplant. What you want to try to avoid is to have too many of the very marginal patients that tend to be the first ones to become in focus. So, that's the general approach we're taking. But obviously, we're not the ones taking the decisions. We're in dialogue with the different centers, and they are then identifying a range of patients that they're putting up for this, and then, they're waiting for an organ to actually be allocated.

Question – Christopher W. Uhde: Okay. But so, would you – are you able to say whether there are any indications that the way it's being used is potentially changing how clinicians decide – well, whether clinicians decide or not to transplant?

Answer – Søren Tulstrup: Okay. Can you – how – what do you mean by the question?

Question – Christopher W. Uhde: So, is it – I mean, from baseline – compared to previous or historical practices, do you have any indications, obviously very early, but any indications as to whether it's changing how clinicians, what

kind of patients clinicians would consider for a transplantation?

Answer – Søren Tulstrup: Absolutely, I mean, so in general, in Europe, as you know, these very highly sensitized patients have very rarely been transplanted at all, right? And the practice varies a little bit from country to country. In some countries, there's kind of a self-censorship, if you will, that if they're highly sensitized, and they're unlikely to be transplanted, they're not even put on the wait-list. In other countries, they are put on the wait-list, they're just not transplanted.

Analyst: Douglas Tsao

Question – Douglas Tsao: Exactly.

Answer – Søren Tulstrup: So what we are expecting to see is that, again, there is this change in paradigm that patients that previously were not really considered candidates for transplant are suddenly being considered. And this is the important kind of mind shift that we need to help occur in the clinics. And I have to say that the dialogues we're having, and the response, and the initiative taken, and the real progress we are seeing in terms of making centers clinically ready is very (00:32:43). So obviously, it's still early days, right? But I have to say that is really encouraging and that comes on top of what we're seeing on the payer side where, again, most recently in France, and so on, we're seeing very, very positive decisions and recommendations being put in place. So that's the current situation.

Analyst: Christopher W. Uhde

Question – Christopher W. Uhde: Okay. Thanks. Very helpful there. My second question is in terms of the commercial strategy. In what ways has it evolved since launch? I mean, I noticed when you talked about it on slide -- one of the earlier slides, it looks obviously pretty similar clearly. But have -- what are the learning so far?

Answer – Søren Tulstrup: Well, I would say the learning is essentially that our assumptions have proven right so far, right, that we can actually, by concentrating on leading centers, we can generate a true change in behavior and activate these centers, making them clinically ready. So, we're checking that assumption box, if you will. We're also seeing that we're making, as I've said, very good progress with the payers. So, we are not hitting any real roadblocks so far.

So, we're not adjusting the course, for us, it's a question of persisting here, making sure we retain focus on the key clinics and obviously expecting some volatility from quarter-to-quarter, but obviously also looking for over [Technical Difficulty] (00:34:34) consistent kind of change in behavior and real uptake of the product with positive outcomes.

And you need sufficient basis of experience in order to have a real assessment of kind of what the first experience is generally speaking in these key clinics. And remember, this is a very – this is a very international or European market in many ways. These few clinics across Europe, they are very much in contact with each other, right? So, there's a lot of experience sharing. And so, that's why again it's important for us to make sure that the right centers are getting the right experiences and it's cascaded through the system.

And we're quite pleased with the way that these -- the clinics are organized both nationally, as well as across Europe, and also within the European Society of Organ Transplantation. And they will come with some guidelines during the course of this year. So overall, as I said, good progress and a good establishment of infrastructure, if you will, so far.

Question – Christopher W. Uhde: Thanks. If I could have a follow up on that one, what can you say about the process in the UK so far?

Answer – Søren Tulstrup: Well. So, we have submitted, obviously, the dossier and we're engaged in the usual negotiations with NICE and the processes, as expected, with the back and forth and so on. And we would hold, obviously, for a positive outcome in the near term in the UK. But that's 1 of 11 countries where we have ongoing dialogues with HTA submitted. And as I said, in addition to the UK, we expect quite a number of these countries to hopefully grant a market access during this year.

Question – Christopher W. Uhde: Okay. Is there any reason at this point to think that it may not be possible to get reimbursement in the UK or is everything on track?

Answer – Søren Tulstrup: Well, the fact is that as long as you're negotiating, it may be possible, it may not be possible. It depends on whether you can agree, right? So, that's the current status. We think we have a very strong case. We have strong support also. But in the end, it's a process, it's a negotiation back and forth. And you want to make sure that it's a good outcome for the patients in the short term, but also in the long term. So it's an ongoing process. And as I said, we expect and hope for a resolution in the near term.

Question – Christopher W. Uhde: Thanks. If I could just ask one more question. How do you anticipate your approach to addressing future capital needs could be affected by changes in real yields one way or another?

Answer – Søren Tulstrup: I mean, our need for capital is, I mean, the basis for our projection here is obviously the ongoing and projected activity level. And I think we have a pretty good insight here. And so far, looking at the launch itself and other factors, we're happy with what we've seen. So, I think we know more or less what is needed. And we also have a clear strategy to move forward.

Question – Christopher W. Uhde: Okay. Thank you very much.

Answer – Søren Tulstrup: Thank you.

Operator

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

Analyst: Dominic Rose

Question – Dominic Rose: Hi, there. This is Dominic from Intron Health. Thanks for taking my questions. I've got three. Question one is you've obviously now got some reimbursements in France and Germany. I just wondered whether any of the product sales in Q1 were from those regions? Question two was on R&D with the US Phase 3 trial completion next year, just hoping you could give – make a few comments around how we should think about R&D cost over the longer term, for instance, likely in 2023 and likely (00:39:00) this year. (00:39:02) would you anticipate still growing as you go into your (00:39:05) indications?

And then finally on question three, maybe related to the previous questionnaires on, what your thoughts are on how you would approach extending the current runway guidance looking into 2023. Would you look at raising debt facilities, for example, is that one possibility? Thanks.

Answer – Søren Tulstrup: Thanks for those three questions. And so first, on your first question, we don't give a kind of granular info on the specific source of the sales. So, I can't be more specific. I'd say that in France really, we've just – upon getting or securing the agreement with the French authorities on the Early Access Program, obviously, there's certain infrastructure and things that need to be put in place and we're now getting fully ready.

So, I would say as of next week is when we start being engaged on the Early Access Program part of things in France. Obviously, we've had – and we have boots on the ground in France, and we've had very good dialogues with French centers. France is one of the few countries in Europe where there's actually a little bit of experience in desensitization therapy. And we also had a French center involved in our Phase 2 trials.

Germany, we are also quite happy with the progress we're making in Germany. We have a general agreement in place now for pricing and reimbursement, and there is a number of key clinics in Germany that are quite fired up. And so, again, overall, I can say that we're pleased with the progress in Germany, but I can't be specific as to the source of the sales in the first quarter and will not be granular at that level going forward either.

And then, on your second question around R&D expenses, longer term. So we have a very versatile and we think productive R&D platform, technology platform overall and we have a number of very exciting potential projects that we are also considering initiating, some are at an advanced stage. So overall, we do expect R&D costs to go up, also obviously as we enroll additional patients. So that's the general expectation.

And then linked to this and the need for capital, yes, we are commercial stage and we have I think a very significant commercial opportunity with Idefirix just looking at Europe and certainly looking outside Europe as well, in the US and Asia Pacific and Latin America, et cetera. But given again the fact that we see a potential to really create significant value by advancing our pipeline of valuable drug candidates and putting new candidates into the pipeline, we do envisage to meet – to raise capital also going forward and there are various options, obviously, that are being looked at. We've been quite successful in the past raising capital on the back of catalyst and issuing equity, but we will address that when we're in the position and the need to do so.

Question – Dominic Rose: Okay. Thanks. That's very helpful. Thank you.

Answer – Søren Tulstrup: Thank you.

Operator

Thank you. Our next question comes from Johan Unnérus from Redeye. Please, Johan, your line is now open. Johan, your line is now open. Please ask your question. We have no audio coming from the line of Johan. We move to the next question from Zoe Karamanoli from RBC Capital Markets. Please, Zoe, your line is now open.

Analyst: Zoe Karamanoli

Question – Zoe Karamanoli: Hi. Thank you for taking my question. Two questions for me, please. First one, can you remind us the size of your field force and how you expect this to expand during this and next year? And then I have a question on AMR. So, in patients that are at risk of AMR, if you can give us some more details around the timing? And in particular, from the time a patient is identified with elevated DSA levels, how long it takes to be at risk of AMR? And then following treatment, if antibody levels decrease to a normal range, how long you need to monitor the patient in order to – in order they are over the risk of rejection? Thank you.

Answer – Søren Tulstrup: Yes. So, as far as your first question is concerned, our current sales force is low-double digit number of reps. We also have those MSLs in place, and we expect this to remain at that level. Obviously, as we add additional countries, we will scale up a little bit, but it's going to be, as I said, a very efficient launch looking across Europe. So, I hope that answered your question there.

As far as AMR is concerned, it really varies quite a lot from, I would say, clinic-to-clinic and there is no – I couldn't speak of a very clear kind of approach here. But typically when you have these episodes of AMR, right, you put in place standard of care, which is then, steroids as plasma exchange. And despite a generally good outcome here, you do see, of course, losses of – complete losses of kidney function and then the patient ends up on the wait list again for a kidney transplant. They will have to be – once you start seeing decreases in donor-specific antibodies, you will have to monitor the patient for a while. And I can't give you a specific kind of clear number of weeks or months, but clearly that will be in place for quite a while.

Question – Zoe Karamanoli: Okay. Maybe if I can just add a clarification on that. So, is the short – is the risk of the patient to reject the kidney more within the first 10 days? Or is it higher also in the next three months?

Answer – Søren Tulstrup: It can be higher also for – again, depending on the response to standard of care. But typically you see fairly fast development, right? When you have these episodes, and many of these are, as you know, they are driven by lack of compliance with immunosuppressive therapy. So you can have a pretty fast development, but it will vary from patient-to-patient. I'm not the one to provide specific kind of info on how this develops.

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

Answer – Søren Tulstrup: Thank you, Zoe.

Operator

Thank you. We currently have no further questions. I will hand over back to the management team for any final remarks.

Well, thank you very much, operator, and thank you, everyone, for your interest in Hansa Biopharma. I hope you've seen we've had a exciting first quarter. We're happy with the overall development, both on the commercial launch side, as well as on the pipeline building activity side. And we're looking forward to an exciting remainder of the year. And we also, of course, look forward to keeping you apprised of developments.

So, thanks so much for your time and interest today, and have a nice day. Thank you.

Operator

This concludes today's call. Thank you so much for joining. You may now disconnect your lines.