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Hansa Biopharma AB (publ) (HNSBF) Q4 2022 Earnings Call Transcript

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Hansa Biopharma AB (publ) (OTCPK:HNSBF) Q4 2022 Earnings Conference Call February 2, 2023 8:00 AM ET

Company Participants

Søren Tulstrup - President and CEO

Donato Spota - SVP and CFO

Conference Call Participants

Gonzalo Attali - ABG Sundal Collier

Zoe Karamanoli - RBC Capital Markets

Christopher Uhde - SEB

Johan Unnerus - Redeye

Douglas Tsao - HC Wainwright

Erik Hultgård - Carnegie

Operator

Hello, and welcome to today's Hansa Biopharma Fourth Quarter 2022 Conference Call. My name is Bailey, and I'll be the moderator for today's call. [Operator Instructions].

I would now like to pass the conference over to Søren Tulstrup, Hansa Biopharma President and CEO. Please go ahead.

Søren Tulstrup

Thank you, moderator. Good afternoon, good morning. Welcome to the Hansa Biopharma conference call to review year-end results for 2022. I'm Søren Tulstrup, CEO of Hansa Biopharma. Joining me today is our CFO, Donato Spota; and Hansa's Head of Investor Relations, Klaus Sindahl.

Today we'll discuss the progress we made during the last quarter of 2022 and review our near-term milestones. The presentation should take roughly 15 minutes, after which there will be an opportunity to ask questions during the Q&A session.

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

Please turn to Slide 3 and an overview of Q4 highlights. 2022 was a successful year for Hansa with solid performance and strong progress across our research, development and commercial projects and operations. The launch of Idefirix in Europe continues to progress according to plan. Based on the successful execution of our market access efforts, we have now secured pricing and reimbursement in four of the five largest markets, including most recently, Italy.

In total, positive reimbursement decisions have been secured in 11 countries and market access procedures are in progress in a total of nine countries, including Spain. We're also pleased with the progress in our engagement with the leading European medical societies, such as the British transplant Society, which recently published new guidelines for implementation in the United Kingdom. Importantly, these guidelines are in line with the recommendations from NICE in the U.K., all the way from patient selection to transplant and post-transplant patient management and protocols.

Outside the EU, we recently signed a distribution agreement with Icon, a leading Swiss health care product supplier to cover the distribution of Idefirix in Switzerland. On the clinical development side, we are pleased with the positive top line data that was published back in November from the Imlifidase Phase 2 study in AMR post kidney transplantation, demonstrating statistically significant superior capacity of imlifidase to rapidly reduce levels of donor-specific antibodies compared to standard of care plasmic taste.

In anti-GBM, we recently commenced the pivotal Phase 3 study with the first sites initiated at the end of 2022. This new global Phase 3 study will target 50 patients at 30 to 40 sites in the U.S., U.K. and EU. In our ongoing GBS Phase 2 program, patient enrollment is picking up again following several initiatives implemented during 2022.

I'm also very pleased with the solid progress seen in our preclinical development programs, specifically in the Duchenne muscular dystrophy program with Sarepta in gene therapy and the NiceR program, which is exploring utilization of second-generation enzymes for repeat dosing.

In the Duchenne program with Sarepta, imlifidase is being investigated as a potential pretreatment in patients with pre-existing IgG antibodies to Cereptas-SRP9001. Based on encouraging preclinical data, plans to initiate a clinical study during 2023 were announced in November last year.

As for NiceR, our program to develop second-generation enzymes for repeat dosing, I'm pleased to announce that IND-enabling toxicology studies have been successfully completed and that a clinical trial application was recently approved. We plan to initiate a Phase 1 study with our lead candidate in the NiceR program in the first half of this year.

Finally, while the capital markets for biotech companies remain challenging throughout 2022, I'm pleased that we're able to successfully secure additional financing through two financing events last year, enabling us to extend our cash runway into 2025. Donato will cover this in more detail later in this presentation.

Now please turn to Slide 4. During 2022, our market access efforts in Europe continued to progress as planned. In the fourth quarter, we secured positive reimbursement decisions in both Italy and the Czech Republic for highly sensitized kidney transplant patients. These positive reimbursement decisions were both aligned with the conditional approval granted by EMA and expect it to help change the clinical practice for desensitization of highly sensitized kidney transplant patients who are incompatible to a disease donor organ.

In Italy alone, more than 6,000 patients are waiting for a kidney transplant, and it is estimated that 1 in 10 are classified as highly sensitized with limited or no access to suitable donor with today's standard of care, effect, which serves to emphasize the unmet medical need for transformative treatments such as Idefirix.

With the positive reimbursement decisions in Italy and the Czech Republic, market access has now been secured in 11 European countries including larger markets such as Germany, U.K. and France. A reimbursement decision in Spain is expected in the near term.

Please turn to Slide 5 and a review of our ongoing clinical programs. As briefly mentioned at the beginning of our call, we announced positive top line data in November of last year from the Imlifidase Phase 2 study in antibody-mediated rejection episodes post kidney transplantation. The data readout demonstrated a statistically significant superior capacity of Imlifidase to rapidly reduce levels of donor-specific antibodies compared to standard of care plasma exchange in the 5 days following treatment start.

In AMR, the current treatment protocols can take up to several weeks to reach the decide effect and in some cases, the outcome remains incomplete or ineffective. We, therefore, believe there is a clear need for clinicians to be able to provide patients experiencing post-transplant AMR with a more rapid and effective therapy that can quickly eliminate donor-specific antibodies and thereby minimize the risk of damage to or loss of the kidneys.

These first results are another important milestone in executing our handset strategy to expand the reach of our IVIg antibody cleaning technology platform to address significant unmet medical needs in a wide spectrum of disease areas and indications. We plan to publish the full data set from the AMR study in the second half of this year.

With respect to our GBS Phase 2 program, we implemented several significant initiatives during 2022 to increase the enrollment rate in this trial as a shortage of IVIg as well as reduced capacity and availability of staff across a number of trial centers have negatively impacted the enrollment rate.

During the fourth quarter, we saw an increase in patient recruitment due to these initiatives, and we have now enrolled 25 out of the target of 30 patients. We expect enrollment to be completed in the first half of this year, as previously guided, with the first high-level data readout in the second half of 2023.

In anti-GBM, we've commenced a pivotal Phase 3 study, as previously guided, with the first sites initiated in December of last year. The new global study is an open-label 1:1 randomized controlled study targeting 50 patients to be treated with either Imlifidase and standard of care or standard of care alone at 30 to 40 sites in the U.S. and Europe.

In NTTBM disease, today's standard of care consists of a combination of plasma exchange, cyclophosphamide and steroids. For patients randomized to the Imlifidase on the first round of plasma exchange after annualization will be replaced by the administration of Imlifidase.

As a primary endpoint, kidney function will be evaluated by eGFR at six months from randomization while anti-GBM, antibody labels, pulmonary symptoms, safety, pharmacokinetic, pharmacodynamic and health-related quality of life measures, among others, will be assessed as secondary endpoints.

In the U.S., our pivotal capitas trial in kidney transplantation is evaluating Imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a disease donor kidney through the U.S. kidney allocation system. In this trial, patient enrollment continues to progress, and we have now enrolled 51 out of a target of 64 patients.

At this point, 13 clinics are open for enrollment and new clinics are continuously added, aiming for approximately 20 to further increase enrollment capacity and accelerate the study. Completion of enrollment is expected in the first half of 2023, while completion of randomization is expected in the second half of 2023. As previously guided, we are targeting submission of a BLA under the accelerated approval pathway in 2024.

Please turn to Slide 6 and a summary overview of our pipeline. As you can see on this slide, we have successfully developed a broad and exciting clinical pipeline in both transplantation and ordinary diseases. During 2023, we plan to further expand our clinical development activities following the successful preclinical work completed with both our lead NiceR candidate for repeat dosing and with imlifidase as a pretreatment to Sarepta SRP-9001 gene therapy in Duchenne muscular dystrophy.

As far as our NiceR program is concerned, we plan to enter the clinic this year with our lead candidate, HNSA-5487 following the recent approval of our clinical trial application. In gene therapy, Hansen Sarepta recently announced plans to initiate a clinical study this year with Imlifidase as a pre-treatment to Sareptas-SRP9001 gene therapy in Duchenne muscular dystrophy. The advancement of these programs into the clinic represents two major milestones for Hansa and our unique ITG antibody-cleaving enzyme platform as we continue to expand our activities across multiple therapeutic areas.

With this overview, I will now hand over the call to Donato, who will walk us through a review of the fourth quarter and the full year financials. Donato?

Donato Spota

Thank you, Søren.

Please turn to Slide 7. Total revenue for the full year of 2022 amounted to SEK 155 million, including SEK 87 million in product sales and SEK 64 million in contract revenue from the agreement with Sarepta and -- AskBio. This represents more than a quadruple year-on-year total revenue and an almost sixfold increase in product sales as compared to 2021.

For the fourth quarter of 2022, we saw again a confirmation of the solid progress that we have been making throughout '22 with respect to pricing and reimbursement and the further broadening our hospital reach. Total revenue for the quarter amounted to SEK 31 million, including product sales of SEK 20 million and contract revenue of SEK 11 million.

For 2023, we aim at building upon our market access achievements seen in 2022 to foster sales uptake across European markets. Nevertheless, we do expect product sales to remain somewhat volatile between quarters as we continue working with hospitals to strengthen the base for repeat business and in power also running the post-approval study throughout the year.

Please turn now to Slide 8. Total SG&A expenses for 2022 amounted to SEK 336 million compared to SEK 327 million for the full year of 2021. The moderate year-on-year increase is mainly related to our commercial launch activities and organizational expansion in Europe, partly offset by onetime expenses related to the U.S. IPO preparations in 2021.

In the fourth quarter, SG&A expenses amounted to SEK 82 million, which is basically on par with the level we saw during the prior quarters in 2022, but approximately 20% below Q4 2021 due to the previously mentioned one-time expenses.

For 2023, we do expect a managed increase in SG&A expenses, reflective of the inflation scheme in Europe and the U.S. throughout 2022 as well as us starting to strengthen our U.S. presence in support of our late-stage development activities and preparation for a potential market entry.

R&D expenses amounted to SEK 346 million for the full year of 2022 compared to SEK 231 million for 2021. For the fourth quarter 2022 R&D expenses amounted to SEK 92 million, which is on par with the recent quarters. In the fourth quarter, we started to capitalize the development cost related to MA post-approval commitments as we met the respective accounting criteria under IAS 38.

The capitalized development costs amount to approximately SEK 18 million. The increase in R&D expenses for the full year was mainly driven by the ongoing confine study in the U.S., our post-approval commitments in Europe and the preparations for our pivotal Phase 3 program in anti-GBM disease. Further, we have also been increasing our investments into our second-generation enzyme program as we prepare for taking our lead candidate into the clinic this year.

Looking at 2023, we do foresee to increase our investments in R&D as we initiate the clinical program with our lead second-generation molecule have the Phase 3 anti-GBM study fully up and running, the confides and the rebound study ongoing as others continue to work on the EMA post-approval commitments.

Net loss amounted to SEK 610 million for the full year of 2022 and SEK 147 million for the fourth quarter. The increase over 2021 primarily reflects our increased R&D investments and included interest costs related to our debt financing, partly offset by significantly increased year-on-year sales and revenues.

Please turn to Slide 9. Cash flow from operating activities amounted to minus SEK 112 million for the fourth quarter of 2022. For the full year of 2022, operating cash flow was minus SEK 504 million compared to minus SEK 481 million for the full year of 2021. The limited increase in cash consumption reflects a significantly increased year-on-year product sales and the Asbupfront payment.

As highlighted by Søren, we have extended our cash runway into 2025. Despite challenging financial markets, we have successfully completed two financing transactions in very competitive terms during the last year, again, confirming the potential value in our technology and business.

In July 2022, we raised $70 million in a non-dilutive debt financing. And in December, we raised $40 million through a direct share issue. The direct share issue included participation from our existing institutional investors, RedmanGroup and new investors, including Bradwell, HEIGHTS and other U.S. and institutional investors. With the cash injection in December, Hansa's cash position as of December 31, 2022, amounted to SEK 1.5 billion.

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

Søren Tulstrup

Thank you, Donato.

Please turn to Slide 10. 2022 was another successful year for Hansa with solid performance and strong progress across the organization. We anticipate an exciting year ahead in 2023 with the achievement of several key milestones across our platform and therapeutic areas as we continue the development of new transformative medicines for patients suffering from serious rare immunologic diseases. Looking forward, we are encouraged by the demonstrated potential of our unique antibody cleaving enzyme platform and the company's potential to become a global leader in rare immunologic diseases.

As discussed, first half 2023 milestones include patient enrollment into our pivotal global Phase 3 study in anti-GBM disease and the completion of enrollment in our Phase 2 program in GBS. Patient enrollment also continues to progress into our U.S. compritus trial, and we expect to complete enrollment during the first half of this year with subsequent completion of randomization expected in the second half.

As previously guided, we're targeting submission of a biologics license application to the U.S. FDA under the accelerated pool pathway in 2024. Further, we anticipate starting a new clinical trial in the first half of this year with our lead NiceR candidate, ANSA5487, following the successful completion of IND-enabling tox studies and the recent CTA approval.

In addition, together with Sarepta, we will advance our DMD program in gene therapy into the clinic this year following the generation of promising data from preclinical development. This program imlifidase is being investigated as a potential pre-treatment in DMD patients with pre-existing IgG antibodies to Serestos gene therapy SRP-9001.

Finally, I want to note that we also plan to announce this year, 5-year data from the long-term follow-up study in kidney transplantation from the 4 Phase 2 programs, which led to the conditional approval in Europe. The results from the long-term follow-up study are expected to be announced in the second half of 2023. During this time, we also expect to publish the full data readout from the AMR Phase 2 trial.

Please turn to Slide 11. This concludes our presentation, and we would now like to open the call for questions. Moderator, please begin.

Question-and-Answer Session

Operator

[Operator Instructions]. Our first question today comes from the line of Gonzalo Attali from ABG Sundal Collier. Please go ahead. Your line is now open.

Gonzalo Attali

Hi. Good afternoon and thank you for taking my questions. First one is on the U.S. trial, the confidence trial. So before you were aiming to enroll all patients in '22, but you still have 13 to go. And I don't know if you could give us some color on the actual reason for the slower enrollment. And apart from increasing the number of clinics, are you taking other measures that -- or are you trying to implement other measures to increase the speed of recruitment. And just like as a fast question here also on average, how long does it take from enrollment to actually being randomized for a patient? Thank you.

Søren Tulstrup

Thank you, Gonzalo, for those questions. So first of all, I'm sure you all appreciate it. It's very, very difficult to predict in advance of a study like this, which is quite complex with many moving parts, which is being launched in the middle of a pandemic to accurately predict when you will complete enrollment on whether it's December or whether it's a few months later, right?

So currently, as you say, we have 51 patients out of a target of 64%. Looking at the current enrollment rate and the initiatives we have taken recently, including expanding the number of clinics. We expect this study to be fully enrolled in the near term. Then of course, as you allude to also the key thing is how long will it take to then have all these patients randomized, meaning that they will have had an ordinary offer. And that's something we're monitoring very closely.

As I've discussed on previous calls, there is a delay. It's a number of months from the enrollment, i.e., you have patient cancer to then that patient actually being offered in organ. And the only thing we can say at this point is that we expect all patients to be randomized in the second half of this year. But it's obviously something we're watching very closely. And we want to make sure that there is an adequate and sufficient flow of organs to the patients, and we're working with the centers and relevant third parties to ensure that, that is the case. I think those were the two questions you have, right?

Gonzalo Attali

Yes, very clear. And I have another one is on the gene therapy segment. SRP-9001 has the PDUFA date set for May 29. So would it be fair to assume that the start of trial is conditional on the potential approval of the gene therapy. So therefore, starting potentially in?

Søren Tulstrup

That's not a necessity whether you think that it's realistic that it will happen only after the proof of rate is another question. What I can say is that based on the very, very encouraging preclinical data, Sarepta has taken a clear decision to take and into the clinic, right, because the value of enabling a broader range of patients to benefit from their gene therapy is very, very significant, not just for Sarepta, but more importantly, for the patients who have been excluded from trials so far and then patients who are out there waiting for the product to be approved. So we expect this clinical trial to commence this year, and I cannot be more specific on the guidance we provided so far.

Gonzalo Attali

All right. Thank you very much.

Operator

Thank you. The next question comes from the line of Zoe Karamanoli from RBC Capital Markets. Please go ahead. Your line is now open.

Zoe Karamanoli

Hi. Thank you for taking my questions. My first question is about Idefirix sales. I fully acknowledge that there is complexity in many variables around estimating timing of treating patients. But now you're two years into launch, and you have a good number of clinical centers activated, also reimbursement in most European countries. So I'm wondering if you could share your expectation on the level of sales for a number of patients that you hope to treat with Imlifidase. So a range here would be very helpful. Thanks.

Søren Tulstrup

Yes. So we have decided not to provide a range at this point in time. It's still very early days in the launch of a transformative product, where you need to have a lot of different things in place, change in mindset that needs to be infrastructure in place protocols, guidelines, a lot of different things.

So it would be a missed guidance rather than guidance to give a range. And if we gave a very, very broad range, it would be meaningless. So that's why we are not doing this at this point in time. However, as I believe we've discussed, obviously, and as you also alluded to, we have a growing number of clinics that have specific local protocols in place that have identified specific patients that are on a list waiting for an organ to be offered and where the supply chain has been set up so that they have access to product.

Then the question is how long does it take for these patients to get an organ offer. And that obviously varies and is very, very difficult to produce. But we're very, very comfortable with the progress seen so far. There is a growing number of clinics that have, as I said, put local protocols in place. We talked about in the U.K.

now where there is full market access. There is a total of, I believe, it's around 35 centers established themselves as a consortium. They put in place guidelines and so on, and they are ready to start seriously treating these patients. But again, it's difficult to predict a specific ramp-up in a country like the U.K. We got reimbursement in Italy very recently, I would say, ahead of the normal time line for Italy, which is very, very good.

But again, it's impossible to predict the specific ramp-up of patients and sales in a country like that. So altogether, all I can say is that we're pleased with the progress so far. We're seeing patients being treated. We're seeing good outcomes, some of which have been reported in the public domain. And we expect, obviously, as we increase number of countries that we have access to. And as clinics get the first patient treated, that will enter a phase where you see more repeat usage at the clinic level.

And this, together with additional countries being added, certainly, we expect would have a positive impact on the slope of the launch curve. So, so far, so good. And obviously, when we feel comfortable providing guidance via a range, we will do this, but we'll only do it when it makes sense on its actual guidance and not miss guidance.

Zoe Karamanoli

Okay. All right. Thank you. My second question is on AMR and the development path forward, which, from what I understand, it will require you to initiate a larger trial. So, do you have a time frame as to when you think this could happen? And do you have the funding in place? And are you -- or will you consider to find a partner for this indication, given the potential scale of the trial? Thank you.

Søren Tulstrup

Thanks for that follow-up question. Yes, I mean, we do think that the AR opportunity is a real one, and it's a substantial one. There is a clear unmet medical need in that space. And we believe in it has what it takes to potentially dramatically improve standard of care. We were very pleased with the outcome of the Phase 2 trial that we have recently completed.

We have reported high level, the fact that the primary endpoint was met. So you clearly see this very rapid and complete production of domospecific antibodies in a statistically superior manner in the lipids arm versus the standard of care on. We will now publish the full data set. It will be in the second half of this year. Next step is in addition to publishing the data to obviously engage in dialogues with relevant regulatory authorities and to discuss the path forward.

The fact is that it's actually quite challenging to run Phase 3 trials in this particular indication, as I'm sure you noticed from other attempts in the past because of the heterogeneity of the patients, right, and the difference in the protocols in different centers. So what is important for us right now has been and is to get the data out from our trial to make sure that this is appreciated and understood by relevant clinicians.

And then we'll see what the next step is from here. It's too early to speculate about that. But I think it's really encouraging and bring hope to these patients, some of whom have lost their kidney or will do so that there is potentially a better solution coming.

Zoe Karamanoli

Sorry, just to clarify, would you consider to find a partner for this? Or you intend to go alone?

Søren Tulstrup

In general, I think we feel quite comfortable operating in the transplant space. Obviously, we've demonstrated our ability to do so far. That doesn't mean that we would not potentially work with a partner as well at different ways that you can partner. So nothing is excluded. And that's something we'll determine as we get closer to the decision-making.

Zoe Karamanoli

All right. Thank you very much.

Søren Tulstrup

Thanks a lot.

Operator

Thank you. The next question today comes from the line of Christopher Uhde from SEB. Please go ahead. Your line is now open.

Christopher Uhde

Hi there, Christopher Uhde from SEB. Thanks for taking my questions. So my first question is the also you've talked about the importance of identifying suitable patients before using Idefirix and managing that as part of how to roll this out successfully. What can you comment on though, I guess, because there's another factor aspect of it is sort of reluctance of surgeons to allocate organs to highly sensitized patients? What can you talk about that aspect and how it varies from site to site. That's my first question. Thanks.

Søren Tulstrup

So the way I understood your question is there are issues around making sure that identified patients and the clinics have access to organs and that the practice there varies from clinic to clinic. And yes, you're right, absolutely. It's not -- certainly not enough to just identify the patients and then wait for an organ within the current setup of organ allocation systems. You need to be able to make sure that these highest sensitized patients are, in fact, offered an organ.

So there are certain things you need to do in terms of delisting certain HLA antigens so that you get something that is close to what you would want, but where you still certainly need desensitization. So that ensures that there is a work and offer. And then, of course, as you know, if there is a positive cross-match which cannot transplant, which would be the case here, then you initiate the immediate therapy. So it's still a learning exercise from any clinics.

And obviously, our role here is to work with all of the different parties and bring the clinics together to discuss how do you make sure that there is an optimal and ongoing flow of organs to the patients that you've identified and who are really in the high need of the transplant sooner rather than later.

Christopher Uhde

And so then, in terms of the extent to which some surgeons are more open to it than others. What can you comment about that and how you try to convince them to consider using it?

Søren Tulstrup

So it's not difficult for us to, again, to convince and to use Imlifidase in general. I think we've seen a very, very good reception of the message that this is a way to ensure that these patients that haven't had real access in the past now have access and that there will be better usage of available organs because you don't need to really consider again the specific matching you should only based on antibodies, but you should look at matching based on other factors, relevant factors.

But then I mean, clearly, it's our task to make sure that again, they are fully educated and informed about how should the system for auto allocation be set up. And here, we're working again, if you take the U.K., as I said, there is a consortium of 35 clinics now. So working together, leading clinics in the U.K. that after the nice recommendation and the decision to reimburse and provide financing for Imlifidase therapy. They are very keen to get started all of them, and they have put in place and guidelines.

And obviously, they're also discussing how the organ flow should be optimized and so on. It's a similar situation in France where we have early access, and it's actually the same across different countries in Europe. And you see different practices and different approaches. And again, our role is to make sure that there is optimal learning and appropriate action taking.

Christopher Uhde

Okay, thanks. And then my second question is, so obviously, well, not to downplay the achievement that you guys have done in terms of getting a drug to market, which is obviously phenomenal. But I think it's fair to say that trial recruitment pace has always been kind of on the slow side sort of across the board of the clinical program. And so far, it also doesn't really seem to reflect how trials have been reading out because they've been successful. So it seems like the delays related to processes in medical.

So what have you done to address this in the past? Why hasn't it been enough? And what should you do and what can you do to turn that around? I mean should you recruit more people with sort of hands-on experience in rare disease trials from like a CRO like IQVIA or yes. Thanks.

Søren Tulstrup

So I think, Christopher, if you look at the performance of other companies with similar trials in the same state, if you look at the transplant space, which really almost Pixalate has been affected by the COVID-19 pandemic and is a very complex space to operate in. You see similar kind of performance.

So I wouldn't necessarily conclude that there are very clear internal issues here, leading to slow patient enrollment. But it's clear that if you have more resources, you will see generally a better performance and faster enrollments and so on. We have more sites up and running of more frequent interaction with the sites and so on and so forth.

So the fact of the matter is that we've been a relatively small organization. We are growing significantly, as you know, if you look at our organization, we're 35 people back in 2018. Now we're 3x as well, 4x almost 5x as many. So it's a fast-growing organization, and we've been able to recruit really talented and experienced people. Again, it doesn't mean that we are not trying to optimize our investment and also working with external parties.

As you've heard me say several times also in previous calls, we are putting in additional resources and expanding the number of clinics and so on, we need to have more face-to-face time with the clinics, and that has been an issue during the pandemic. There's no doubt about it. But most of the delays that we've seen really have been due to the fact that pandemic has had a very serious impact, not just on the transplant space, where the transplant volume was down more than 20% in 2020, probably more in 2021.

We don't have the figures yet. But also in the imbursed in other spaces where you've had on the supply of IVIg and so on and so forth. So there's been a number of very specific issues that we've had to deal with. And I would say that I'm quite pleased with the way that this organization has been able to act in a very difficult and challenging overall environment. And again, it doesn't mean that we're not necessarily going to invest more, and we are on a continuous basis, a growing organization, and we're bringing in more and more new and highly qualified people. I appreciate that.

Christopher Uhde

Thanks very much. Appreciate that.

Operator

The next question today comes from the line of [Louise Mugarta] from Kempen. Please go ahead. Your line is now open.

Unidentified Analyst

Hi. This is Louise in for Jacobs from Kempen. I have a couple of questions. On the NiceR program, I was wondering what are the potential indications that you are considering here?

Søren Tulstrup

Thanks, Louise. Good question. So for the NiceR program, if you look you can actually bring to the market drug candidates that can be used in many different security universes. And essentially, all of the four big universes that we're currently active in transplantation, autoimmune diseases, gene therapy and oncology. If we take autoimmune diseases, clearly, you would want repeat dosing in the more chronic autoimmune diseases in our case, specifically those that are IgG-mediated where you have a rapid disease progression.

And where you have flares, meaning that you if when you have these flares needs efficacy beyond what the maintenance therapy can bring you, right? So that would be a natural space to look at, and that's certainly something that we have been doing and we are doing and we are considering for specific initiatives.

In the gene therapy space, with the Imlifidase, clearly, we're looking at pre-existing neutralizing antibodies many gene therapies, it seems like will have to be dosed, not just one but several times. Again, that is a relevant space for a repeat dosing version of Imlifidase. And obviously, in oncology, whether it's entortic stem cell transplantation or other oncology indications is almost by default and repeat dosing space, right?

So there's a lot of different potential indications that we can target. And we are really pleased with the fact that our NiceR candidate has shown good preclinical data and that we're now ready to take it into the clinic, we think it will be a very considerable value driver for the company.

Unidentified Analyst

Very clear. Thank you. And then on the Phase 2 GBS readout, what kind of data can we expect there?

Søren Tulstrup

So the GBS trial, just to summarize and repeat again, it's a single-arm study. We are putting it on top of IVIg, which is the approved therapy at this point and sign the standard of care. And then we compare to a patient registry in Europe. And so you would get data on functional functionality. There is a kind of a functional scorecard that is being used broadly for this indication, and that is a primary end point. And obviously, there's a number of other endpoints that will be part of the final readout. But the first readout, obviously, will be a high level.

Unidentified Analyst

Okay. Thank you very much.

Operator

Thank you. The next question today comes from the line of Johan Unnerus from Redeye. Please go ahead. Your line is now open.

Johan Unnerus

Thank you for taking my question. The first one, what is the prospect of the European centers starting to treat, let's put it this second patient sort of multiple patients, no centers are probably treated one patient as I understand it. Is that correct?

Søren Tulstrup

I'm not sure I fully got the question. But essentially, you're asking at what point do the centers are getting to initiating therapy.

Johan Unnerus

Yes, more or less, what's your feeling and impression what sort of signals can you not point to? Or should we expect some centers being close to treating the second patient?

Søren Tulstrup

Yes. So obviously, we've had a number of centers last year that treated their first patient. And as we've discussed, they will wait at least six months in general, to see the outcome of that first patient to this before, again, making a decision to continue using the product and so on. Then once that have made that decision, you need to wait for a working be allocated and so on.

So we do expect this year to have a repeat business happening at a growing number of clinics. Clearly, what we expect this year is given the fact that we've seen the big countries in Europe now, we've got reimbursement in Italy. We have it in the U.K. We have it in Germany. We have early access in France.

The only country we now lack out of the top 5 is Spain, and we are hopeful that we are quite optimistic, actually, we have a very good dialogue with the Spanish authorities, and we're hopeful that we could see a decision coming relatively soon. And Spain is a top three country in terms of volume. So now these more significant from a volume perspective, countries are getting online. We certainly expect also to see the peak business coming in some of these countries this year, and that will really help the growth of the product.

Johan Unnerus

Excellent. And a reminder what to expect for Sarepta in terms of potential milestones, assuming that the clinical study will start sort of by mid or early Q3 or something like that.

Søren Tulstrup

Yes. So there are, I think as you know, what we communicated is that there are potential milestones up just shy of $400 million. That includes early milestones and sales-related milestones and so on. So as this program progresses, obviously, there will be additional milestones, and we have not provided specific guidance there. So I think Donato there's not much we can add...

Donato Spota

I think what is important to note, Johan, and we discussed that before, is obviously that there is a certain acne milestone. So it's more related to sort of regulatory milestones and then obviously sales milestones. I don't want to say that there's no development milestones, but they're not going to make a break. Understand?

Johan Unnerus

No, what our understanding, and that's related to another question. You had, obviously, extended your access to growth capital, both the credit and the QT issue and strictly financial. We have repeated that you are comfortable financing '23 and '24. What about the actual equity level is that? I mean in Marten Sarepta or well to be not more than two in terms of exiting and strict financing.

Søren Tulstrup

So I hear you're right. I mean we're happy with the financing events in 2022. We have runway into '25 as just communicated. Donato, do you want to comment on the equity question?

Donato Spota

And obviously, we've been able to strengthen the equity now also with the last raise that we did a couple of ways. So we're looking at that as well. You're right. I mean, you need to look at both the cash and the equity. And of course, if there's a tomans coming, that would obviously help the cash and the equity.

Johan Unnerus

Excellent. And smaller things in this quarter, the gross margin was markedly better. Is that sort of related to inventory or other changes or should be read into that?

Donato Spota

Yes. I think you can't read too much into that at this point, Johan. I think what, again, also discussed at previous calls, what you need to consider is that, obviously, we have a manufacturing capacity set up, which is obviously directed to be able to serve the market once we are fully up and running in this indication, but also in additional indications.

So there is a bit of overcapacity right now. And so this is considered whenever there is a manufacturing happening then if there's an overage compared to what we have currently in our projections, and obviously, that will hit the P&L. So right now, I don't think you should put too much emphasis on that. I mean the in the long run or even in the midterm, I think what I can say is that the gross margin will be quite healthy.

Johan Unnerus

Yes. And also another question, R&D. Can you provide some portal more granularity into so increase in reported expenses and cash expenses for '23, of course, being only specific.

Donato Spota

Well, I mean, we do expect an increase in the R&D expenses. It's going to be well managed. We're not talking about 50% or 100% increase. I mean there's obviously an additional Phase 3 study now coming, and that's basically driving the increase. So there will be somewhat of an increase, but it's very well managed. It's anyhow considered in the cash guidance that we've given.

Johan Unnerus

Okay. And obviously, slightly higher in terms of cash, I suppose…Million times on really increase if you capitalize some of the R&D expenses that could be a higher number for '23.

Donato Spota

Yes. On the other hand side, we'll be able to offset from the expected increase in sales. Does that answer your question, Johan?

Johan Unnerus

Yes, that's perfect. Thank you.

Operator

Thank you. The next question today comes from the line of Douglas Tsao from HC Wainwright. Please go ahead. Your line is now open.

Douglas Tsao

Hi, good morning. Thanks for taking my questions. So Søren, in terms of the NiceR program, it sounds like we're getting a Phase 1 study this year. I'm just curious, I presume that's going to be in healthy volunteers. And I'm just curious, will the results from that determine or help inform what indications you're going to pursue with the lead NiceR asset? And how quickly do you expect to be in a Phase 2 study with that program? Thank you.

Søren Tulstrup

Thanks, Douglas, and Yes. I mean, obviously, that's a correct assumption. We'll go into healthy volunteers looking at safety and bancokinetics and dynamics and so on. But we have certainly already made a very clear kind of list of indications that are relevant, right? The results of this Phase 1 trial will inform the final decision-making.

But obviously, we have some pretty good thoughts on what indications would be relevant. I just discussed the following Louise's questions, what could be potential indication spaces for the candidate? And there is quite a number. So the final decision will be made at a later stage, but we're certainly preparing for that, and we are happy that we can now move forward with this Phase 1 trial.

Douglas Tsao

And just as a follow-up, how many doses do you expect patients to receive during the Phase 1 study?

Søren Tulstrup

So at this point in time, we're not providing more details. But obviously, at some point, this will be announced and available.

Douglas Tsao

Okay. Great. Thank you.

Søren Tulstrup

Thanks Douglas. Any more questions, moderator. We still have moderator on the line?

Operator

My apologies. The next question today comes from the line of Bo Zhang from Intron Health. Please go ahead. Your line is now open.

Unidentified Analyst

Thank you. This is [Bill] in from Intron Health. Thank you for taking my questions. I have two quick ones. One, going to market access. In terms of the receiving reimbursement from Spain and also potentially full access from France, would it be fair to assume this could happen sometime later this year within 2023?

And my second question is, you mentioned expanding in most of the days across multiple therapeutic areas. We saw the recent first case study in lung transplant patients, highly sensitized long transfer patients in France. Would it be in the pipeline or plan on considering exploring to this indication in particular, considering the increased market size caused by severe Coga patients?

Søren Tulstrup

Thanks, for those questions. First, on market access, -- we do remain optimistic that there will be a decision in Spain. And obviously, we're hoping it will be a positive decision to provide reimbursement and access for Idefirix in Spain and that this decision is coming in the near term, even very near term potentially.

So we're optimistic there. As far as France is concerned, we have full access now using the reaccess program. So there is no restraints or constrictions, if you will. Obviously, we do need at some point to get more permanent or permanent reimbursement. And that process is ongoing.

It's not critically important for us timing-wise to get it as long as we have access using the urea access program. So that was France. And then obviously, we have other countries where we have ongoing discussions like Belgium, Denmark and so on. And we're also hopeful that, that will bring these significantly forward in the coming months and this year.

Then as far as expanding into other organs, lung transplant, absolutely, you're right. There has been a good case report coming out of France. We know that there is a very high degree of interest here. There is certainly a high degree of unmet medical need. This is a very critical situation for these patients.

And so we do expect at some point that we will see that as a commercial opportunity for us long transplant. Similarly, we also expect that heart transplants will be a commercial opportunity for us. At what point we will have this in the label, obviously, will depend on trials being run and discussions with regulatory authorities and so on. So that's to speculate about. But I certainly expect, given the level of interest that there will be real usage at some point in these indications.

Unidentified Analyst

Thank you.

Operator

Thank you. The final question today comes from the line of Erik Hultgård from Carnegie. Please go ahead. Your line is now open.

Erik Hultgård

Hi there. Thanks for taking my questions. I have two, if I may. First, could you give us some sense of how the post approval study in Europe is progressing roughly how many of the 50 patients that you plan to enroll have been dosed with Imlifidase to date. And secondly, I'm just trying to understand the dynamics here. We have seen quite broad access, but still, we haven't seen any type of pickup in commercial demand. So trying to understand the dynamics here. What is the feedback that you're getting from physicians? Is it sort of a lack of long-term or more sort of more patient data that is keeping them sort of cautious and will sort of more data from, I guess, the U.S. trial and from also the post-approval study really changed that dynamic? Or do physicians still need to sort of test one patient at the time before we will start to see an acceleration.

Søren Tulstrup

Eric, for those questions. So first, we do have patients treated in the post-approval efficacy study. We are not reporting patient numbers here. We need to recruit and treat 50 patients in total when we need to keep this trial by the end of 2025. There is no urgency for us to complete it as quickly as possible.

But we're pleased with the progress is moving forward. We have three patients treated. And as we've discussed, I believe also is a great way not just to generate data, but to generate experience in relevant centers. So this is running in parallel to our commercial efforts. And obviously, there is some impact given the performance that we have, the good performance, I would say, from our market access team, getting access. There is competition in some countries. So this is not only being run in countries where we don't have access, but it's being run in parallel to commercial efforts.

On your second question, the observation that you don't see a very, very rapid uptake and very fast growth of patients being commercially treated. This is fully as expected. Again, you need to change the mindset of the physicians, create the awareness and interest. That certainly is the very, very broadly. We're getting extremely positive feedback.

I've been involved in a number of similar launches, and I'm really pleased with what we see, not just from individual physicians, but from centers and from societies, the European Society of Organ Transplantation has issued first batch of guidelines and mentioned in today's.

And as I just said, this transplant society has also come out with very good guidelines. So the physicians, the clinics want to treat. They see a real need for individual patients and they see a need to optimize the use of available organs and in some cases, actually increase the number of available audits. What is holding them back is the fact that the system has many moving parts, as we discussed during this call also, you need to optimize the organ allocation system and the clinics role there to make sure that there is a continuous flow of organs to the patients identified. And this is something that's been done now.

But there is a delay from identifying patients, putting up supply chain and so on and then actually receive an organ offer. So that is certainly holding things back a little bit and has been. The other is the fact that, yes, you get market access, right? Let's take a country like Sweden that you know quite well. But then after you have that decision at the state, at the national level, it needs to be pushed down to regions and from new regions down to the hospitals and the hospitals need to negotiate budgets and so on. It's a very compressing and long process.

And it's something that also politically, I think many people are trying to have changed because it just takes forever for new innovative therapies to be used. But there are those are some of the issues in play here.

Overall, as I said, our strategy has been to make sure that the centers become clinically ready to treat, and they are a very impressive number and a growing number that patients are identified that the first experiences are positive, and all of those things are happening. Then we're waiting for kind of the repeat usage time point, where you'll see more steeper growth. And as we discussed, we expect at some point this year to see that in a number of clinics.

Erik Hultgård

Thank you.

Operator

That concludes today's Q&A session. So I'd like to pass the conference back over to Søren Tulstrup for any closing remarks. Please go ahead.

Søren Tulstrup

Well, thank you very much, operator, and thank you, everyone, who called in here. Thank you for your questions and interest. As we've discussed, 2022 was a busy, but overall, also a very successful year. We have an exciting year ahead of us here in '23, and we all look forward to continuing the dialogue.

So thanks so much, and you can now disconnect.

Operator

This concludes today's conference call. Thank you all for your participation. You may now disconnect your lines.

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