Hansa Biopharma AB (publ) (HNSBF) Q1 2023 Earnings Call Transcript

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Hansa Biopharma AB (publ) (OTCPK:HNSBF)

Q1 2023 Earnings Conference Call

April 20, 2023 08:00 ET

Company Participants

Søren Tulstrup - President & Chief Executive Officer

Donato Spota - Senior Vice President & Chief Financial Officer

Conference Call Participants

Christopher Uhde - SEB

Gonzalo Altek - ABG Sundal Collier

Douglas Tsao - H.C. Wainwright

Ingrid Gafanhao - Bryan Garnier

Johan Unnerus - Redeye

Operator

begin. Please go ahead.

Søren Tulstrup

Thank you, moderator. Good afternoon, good morning and welcome to the Hansa Biopharma conference call to review first quarter 2023 results. I'm Søren Tulstrup, CEO of Hansa Biopharma. Joining me today is our CFO, Donato Spota; and Hansen's Head of Investor Relations, Klaus Sindahl. Today, we'll discuss the progress we made during the first quarter of 2023 and review our near-term milestones. The presentation should take roughly 15 minutes, after which there will be an opportunity to ask questions during a Q&A session. 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 Q1 highlights. In the first quarter of 2023, we continue to advance several key priorities, including progress with the European launch of Idefirix and our exciting pipeline. First, during this quarter, we are pleased to receive a positive reimbursement decision in Spain. Spain were the largest markets in Europe for kidney transplantation with more than 3,400 kidney transplants carried out in 2022 alone. This is important news, especially for the thousands of patients in Spain who are still disadvantaged and in urge of need of more personalized and innovative desensitization options like Idefirix that can enable incompatible kidney transplantation. Our goal in kidney transplantation is to change the approach to desensitization and organ allocation by integrating Idefirix into clinical practice as a new standard of care for highly sensitized patients.

seen the first repeat business of Idefirix at clinics in Europe. Securing repeated sales at the clinic level is a testament to our highly focused loan strategy and we anticipate additional repeat orders as clinicians build valuable experience from treating and monitoring their first patients over several months. I'm also pleased to announce that we have expanded our commercialization partnership with medicine Pharma for Idefirix and kidney transplantation to cover the Baltic region. As you may recall, in December 2021, Hansa Medicine announced the formation of a multiregional partnership to accelerate the commercialization of Idefirix into new markets through Medicine's commercial platform. The additional agreement covered Israel and select Eastern European countries. The partnership has resulted in market access being secured in Poland and more recently in the Czech Republic, while marketing authorization in Israel was obtained in 2022.

Now if we turn to the pipeline, we are pleased with the recent advancements in GPS and with a lead molecule HNSA-5487 from our important second-generation enzyme program. In GBS, we announced completion of enrollment at the end of March and we are also excited to have recently initiated a new clinical Phase I trial in healthy volunteers with HNSA-5487. With regard to our U.S. provides study in kidney transplant, enrollment continues to progress as expected. We continue to see strong interest from clinics to participate in this trial and we will add more centers up to a total of 20 to accelerate randomization. On the organizational side, we welcome Matt Shales as our new Chief Commercial Officer and President of our U.S. affiliate. Matt joins Hansa from Pfizer, where he has held several senior executive roles, including Preston, Inflammation and Immunology for the international developed markets President, North America Oncology and most recently, Senior Vice President responsible for the company's global commercial and medical go-to-market model transformation. With more than 20 years of international experience in the pharmaceutical industry, will further strengthen our commercial and in-market leadership team and create a U.S.-focused organization that will help deliver our goal of bringing in Lipids to the U.S. market.

classified as highly sensitized. With Spain secured, market access has now been secured in 5 of the largest markets in Europe in the last 12 months. This represents approximately 15,000 annual kidney transplants. And in total, we now have access in 12 European markets with ongoing efforts in an additional 8 countries, including Portugal, Belgium and Switzerland.

Please turn to Slide 5 and a review of our ongoing clinical programs. At the end of March, we announced completion of enrollment in our GBS Phase II program. GBS is an acute autoimmune attack on the peripheral [indiscernible] system which affects approximately 1 to 2 patients per 100,000 annually. Top line data on safety, tolerability and potentially the early effect in Lifidase-treated GBS patients is expected to be announced in the second half of this year. The full data from the GBS Phase II studies expected in 2024 following a comparative efficacy analysis between the [indiscernible] treated group of patients in the trial and the match cohort from the IQOS database at the Rasmus Medical Center in Rotterdam. In GBM, a pivotal Phase III study began with a target of treating 50 patients with either imlifidase in standard of care or standard of care alone at 30 to 40 sites in the U.S. and Europe. The first site was initiated at the end of last year and we'll continue to add centers aiming at enrolling the first patients before summer, as previously guided. With regard to our pivotal U.S. confides trial and kidney transplantation, 62 out of 64 patients have been enrolled.

We continue to see strong interest from U.S. clinics to participate in this trial and we have taken a decision to increase the number of study centers from 13 to up to 20 to accelerate randomization. Increasing the number of centers will also help build valuable clinical experience in desensitization of highly sensitized patients among KOLs in preparation for our planned launch in the U.S. market. Completion of study enrollment is expected shortly, while randomization should be completed by the second half of 2023 as previously guided.

broader range of patients and potentially to increase durability of response, reduce the AAV vector dose and enable redosing of the gene therapy. Back in 2020, a paper published in Nature Medicine demonstrated the capacity of unifies to remove AAV antibodies and enable efficient transduction of the transgene in vivo in nonhuman primates and mice. We've since been working to demonstrate similar results in an illegal study where mice with severe combined immunodeficiency were pre-immunized with and then treated with the MiFIDs before gene therapy using AAV8.

In the imlifidase treated mice transduction to all target opens was significantly improved compared to the group that was not treated with fits. These results further highlight the bilixofilipidase to remove anti-AAV antibodies and support the rationale to use imlifidase as a pretreatment to enable gene therapy in natostil patients. In line with this and as previously discussed, our partner Sarepta, has announced their decision results from our collaborative preclinical efforts within their Duchenne muscular dystrophy program to take imifidase into the clinic as a potential pretreatment ahead of their SRP-9001 gene therapy candidate. On this note, the preclinical data with imlifidase will be presented by Serata at the American Society of Gene and Cell Therapy Annual Meeting which takes place in Los Angeles next month.

Please now turn to Slide 7 and a summary overview of our pipeline. As you can see on this slide, we've successfully developed a broad and exciting clinical pipeline in both transplantation and autoimmune diseases. In line with previous guidance, we have now advanced HNSA-5487, lead molecule from our second-generation program into the clinic following the approval of our clinical trial application end of last year. HNSA-5487 will be targeted towards relapsing immunologic disease where patients may benefit from more than one dose of an IgG-modulating enzyme. It may also have significant potential in the gene therapy space and within oncology. Readout the Phase I program will help determine which potential indication area we will initially pursue with our second-generation enzymes.

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

contract revenue, mainly from the agreement with Sarepta. Now in Q1, we saw the volatility in quarter-on-quarter sales as discussed earlier on our earnings calls, we are also starting to see repeat business at the first clinics which we anticipate to increase throughout the year. At the same time, we do foresee sales benefiting going forward from new guidelines recently published by the British Transplant Society for the U.K. the ongoing revisions to the euro transplant allocation system as well as new countries such as Czech Republic, Italy and Spain, where we more recently secured market access. So in summary, we continue to expect a significant step-up in sales in 2023 compared to the last year, while quarter-on-quarter volatility may remain.

Please turn to Slide 9. Total SG&A expenses for the first quarter of 2023 amounted to 103 million compared to 80 million for the first quarter of 2022. The increase reflects Hansa's broadened commercial activities and organizational expansion related to the launch of Idefirix in Europe but is also partly driven by inflation and devaluation of the Swedish krona against the euro and the U.S. dollar. Q1 SG&A expenses to include certain nonrecurring one-off costs. However, for the full year 2023, as previously guided, we do expect an increase in SG&A expenses over last year from initiatives to drive sales growth in Europe as well as from starting to strengthen our U.S. presence in support of late-stage development activities and preparation for a potential U.S. market entry. The inflation and foreign exchange rates are also expected to impact costs for the year.

R&D expenses amounted to SEK93 million for the first quarter 2023 which is on par with the recent quarters and reflects an increase of SEK2,022,000,000 compared to the first quarter of last year. The increase over the same period last year is mainly driven by expanded pipeline activities such as the ongoing U.S. confide study, the initiation of the Phase III study as well as the initiation of the clinical Phase I trial and CMC development activities for Hansa 547, our lead molecule from the second-generation enzyme program. R&D costs are also impacted by price adjustments due to inflation and devaluation of the Swedish krona. As discussed at the last earnings call, starting with Q4 2022, we capitalized development costs related to the EMA post-approval commitments as we meet the respective accounting criteria on the IAS 38. Capitalized development costs for Q1 2023 amount to approximately SEK23 million.

study in Kidney transplantation. Net loss from operations amounted to SEK182 million for the first quarter 2023 which was up from 135 million in the same period of last year.

Please turn to Slide 10. Cash flow from operating activities amounted to minus SEK207 million for the first quarter of 2023 compared to minus SEK130 million for the first quarter a year ago. The increase is mainly driven by the increase in operating expenses and the positive cash flow effect of the US$5 million upfront payment related to our agreement to AskBio received earlier last year. Again, inflation and FX changes do also impact. In comparing the Q1 cash flow to the fourth quarter 2022, the difference is, to a large extent, driven by seasonality with regard to incoming and outgoing payments, for example, related to accounts receivable, accounts payable and accrued expenses which helped the Q4 cash flow and burdened Q1 cash flow. Our cash position at the end of March was approximately SEK1.3 billion which is expected to provide runway into 2025 as previously guided.

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

Søren Tulstrup

Thank you, Donato. Well, please turn to Slide 11 and an overview of near-term milestones. We're encouraged by the advancements being made across our platform and therapeutic areas. Looking ahead, there are several milestones we must deliver in 2023 in the years to come. As highlighted earlier, we continue to see strong interest among clinics to participate in our U.S. provides trial and will continue enrollment to accelerate randomization by adding further centers up to total of 20. Randomization is expected to complete in the second half of this year as previously guided. In our pivotal global Phase III study in anti-GBM disease, we initiated the first site at the end of last year and we're currently working to add sites. As previously guided, we expect the first patient to be in row before summer.

first high-level data readout in GPS following the completion of enrollment at the end of March.

As discussed earlier, top line data is expected later this year with the full data set, including the outcome from the comparative efficacy analysis to an externally matched cohort from the IGOS database expected to be available in 2024.

Lastly, I want to highlight that we plan to announce 5-year data from the long-term follow-up study in kidney transplantation from our 4 Phase II programs which led to the conditional approval in Europe. The 5-year data is expected to be announced in the second half of 2023, during which time we also expect to publish the full data readout from the AMR Phase II trial. Please turn to Slide 12.

This concludes our presentation and we would now like to open the call for questions. Operator, please begin.

Question-and-Answer Session

Operator

[Operator Instructions] Our first question comes from Christopher Uhde from SEB.

Christopher Uhde

So I guess one thing that hasn't really been addressed so much in the presentation or the report was the news about the allocation system changes in some of the countries you're launching in. And I guess -- so what -- perhaps you can talk a little bit about that, just how broadly is that being applied. But I guess -- so emergency use reimbursement overcoming a culture of not transplanting across an immunological barrier and on a backdrop of limited published outcomes data, competing with your own post-approval study and kidney allocation have all been a lot of quite a lot of obstacles to getting a good ramp up of Idefirix sales, right? So is the allocation kind of the reorganization, the last big obstacle to expanded access? Or are there other things besides what I mentioned. That was my first question.

complex. It's not just a question of making sure that the clinics are actually ready to use the product. You also need to look at the flow of organs which is based on different organ allocation systems that are in place throughout Europe. And so specifically, if I take that point first, you're right that if you look at the organ allocation system that is really relevant for countries like Germany and Benelux, the Europe transplant organ allocation setup and system. A key barrier so far has been the fact that, that has been based on productibility also finding a compatible recipient for an available organ with a range of kind of acceptable mismatch. But really now with the availability of Idefirix, the key question is, who would be the most relevant patients to transplant and how do we ensure equity of access.

And so that necessitates for the countries that are dependent on the transplant program, a tweaking of the setup so that there is a list of patients that would qualify for organs that are not a good match on appearance. And that change will be implemented now in June, it's the latest that we've heard has been some months in process and that will open up the Germany essentially [indiscernible] key countries, even though we did have on transplant in Netherlands, we're really looking for this change to see repeat business and wider usage. Then there are other countries where the transplant set up is not that relevant like the U.K. but still there is a delay from actually getting the reimbursement overall, like we did in the U.K. last year negotiating with NICE and national health service and all of that. It has taken many months and they're actually only ready now to develop local and protocols, how -- what patients should be treated, would qualify? How should they specifically be treated in the clinics, who should be involved in this and so on and so forth.

Germany, we expect a change becoming effective in June that were also impacted Netherlands and Benelux broadly and some other countries. France is moving ahead quite nicely. And that really demonstrates the value of having experience, right? So we're very happy to get conditional approval based on Phase II what is a little bit tricky and challenging is the fact that, obviously, only 53 patients were included in Phase II and 46 of those for transplant and France and Sweden are the 2 countries that actually had gotten some experience with that.

And now we're seeing kind of the importance of getting that kind of experience and that's why we're working in a very focused manner, including, as you mentioned, through the post-approval efficacy study to generate appropriate successful experience in key centers. And as we mentioned during the call, we're now seeing also the effect in that we're getting repeat business and some centers. Thanks for the question, Christopher.

Christopher Uhde

And then, if I could just a quick follow-up on that. Could you give us a bit more detail on the status of the post-approval study, I mean, in terms of the recruitment target. And then also, when it comes to the cost base. So between now and 2025, when do operating cash outflows start to decrease from the current level to -- yes, enable that into 2025 runway to be met. And also, can you give a bit of color on how to expect net financials to evolve going forward?

Søren Tulstrup

Thanks for the follow-up questions, Christopher. First, on the post-to-post efficacy study, current status is that we have enrolled less than 10 [ph] patients but we're in good shape there. And the target is, of course, to have this study concluded by the end of 2025. And as I said, this is a great way to generate relevant experience in some of the key centers here. As far as the financials are concerning the cash flow through 2025 and what to expect, I'll hand over to Donato.

Donato Spota

should turn in the other direction. And we would see some reduction in the cash burn everything else being equal, obviously. And then on the general cost base going forward for this year I mean, I would like to point a view then maybe to our consensus model that is available on the -- on our website. There, the EBIT for the year, the median EBIT for the year is estimated at 635 million. So I think that's probably a good ballpark and also the patient uptake that is modeled in the consensus is probably something where we have no major disagreements.

Operator

We have our next question comes from Gonzalo Altek from ABG Sundal Collier.

Gonzalo Altek

I have a question also a follow-up on the previous one on the euro transplant new allocation tier. It seems that it will allow patients that have been in the waiting list for more than 3 years to be candidates, let's say, to receiving live days [ph]. How many patients are these? I mean, is there any way that patients that identity [indiscernible] have been for 3 years in the system to receive in these days? I mean how can we picture these new allocations here?

Søren Tulstrup

kicking transplant is a certain years on average, right? And if you're highly sensitized, it's many years. And again, if you're a highly, highly synthesized then you're more likely to die waiting than actually be transplanted. So this is a very significant number of patients. So that's the fact that there's this -- we talk about this 3-year limit is not a limiting factor. And we're really looking forward to the impact that this change will have -- which essentially will open up, as I said, very important markets like Germany and Netherlands and so on. So that's important.

And in fact, if you just look at what to expect for the remainder of the year, as I said, we do have some nice activity in France. The U.K. is only now getting May [ph] and we can all now really expect that should be an impact from the U.K. I was at the British transplant Society's annual conference a couple of months back, met with all the key players and there is a high degree of excitement. They're really ready to get going. So we expect that there will be a nice impact there. Spain, Italy, we just got reimbursements. So it's very early but towards the second half of this year, hopefully, having them also gone through successful negotiations with the regions in Spain and in Italy. Hopefully, we'll see an impact from these markets. We had a launch effort in Rome in Italy. Very recently, I met with the key players in Italy, very impressed by the level of professionalism and the excitement and so on around this new opportunity to provide equity of access also for Italian patients.

So hopefully, again, as I said, we will see an impact in the second half of the year from Italy. And so we're now seeing some of the necessary kind of infrastructure changes happening that when we were able a growth in the transplant numbers.

Gonzalo Altek

Okay. And second question is on the U.S. confidence trial. I mean it's this translation, let's say, from enrollment to randomization. I mean how predictable is -- I mean, how can we predict that those patients that are enrolled will be randomized in a matter of 6 months or something like that? I mean how can we understand that -- yes, from the 62 patients that you have enrolled now, how many can we assume that you would have randomized in the next month? I mean, is there any way to do that?

randomized, again, because you need to be offered an organ to the U.S. kidney allocation system. And so there is this delay. We have a double digit number of patients that have been randomized. Now going forward, we expect to report the actual number of randomized stations. That is our key focus at this point in time being so close to reaching the target of 64, even though we want to again, over involved so that there is a sufficient number of patients quickly enough that are randomized. So as I said, what I can tell you is that currently, there is a delay of some months from being enrolled to actually being randomized. And there might even be some patients that will not actually be offered an organ within the study period and which is why it's important to over enroll in the study.

Operator

We have our next question comes from Douglas Tsao from H.C. Wainwright.

Douglas Tsao

Just first, in terms of 5487, I'm just curious how far along are you in terms of collecting an indication? I know you said it's going to depend a little bit on the results that you get. So I'm just curious, what exactly are you going to be focused on in terms of figuring out where you want to hurt go? Is it going to be safety? Is it going to be IgG levels? I'm just curious what parameters are you most focused on? And then for Idefirix in terms of -- should we expect always the first quarter to be a little slower from a seasonality standpoint? Or is that not as much of a factor for this product?

Søren Tulstrup

of potential indications, very, very exciting important indications, not just in the autoimmune disease space, where we have previously discussed, obviously, there is a range of IgG driven, more chronic autoimmune diseases where there is really no good options available for the patients if they have flares and so on. That's one opportunity and we're fairly far advanced already. Also looking at some of the diseases that could be relevant in that space but it's also very relevant in the gene therapy space.

Now, as I mentioned earlier in this call. Clearly, with the MiFIDs initiative through our collaboration with Sarepta or AskBio, we are focused on preexisting neutralizing antibodies but there's clearly also a reach to increase the durability response. We've seen that with the gene therapy programs in the clinic, that there are issues there. We expect that our platform and potentially 5487 and other enzymes really be very helpful there. And potentially, we could also expect to be able to enable lower dosing of the AAV, right -- with all the improvements and benefits from a safety perspective there; so that's another broad opportunity for 5487. And there the area of oncology and not least the exciting area of emetogetic stem cell transplantation which we have previously discussed and where there is a clear need to also look at the sensitization issues and so on. This is almost by default kind of multiple dosing setup and where you need flexibility and so on. So that's certainly also something we're looking at. So we will, based on what we get out of the Phase I trial and concurrent parallel work we're doing, we'll be able to make the decision around what should be our part one indication to go for. And it's really a number of different things we're looking at, including, of course, safety, tolerability, efficacy, antidrug antibodies and so on.

The second question you asked was regarding the launch in Europe and whether we expect seasonality. I think it's too early to really predict. I mean but typically, what you do see is that transplants are scheduled outside of holiday period. So the Christmas period is not a peak period for transplantation and likewise, there might be some other holiday areas. But otherwise, it's not really seasonality kind of driven market. That's not the case. But we do expect volatility from quarter-to-quarter.

Douglas Tsao

Operator

We have our next question comes from Ingrid Gafanhao from Bryan Garnier.

Ingird Gafanhao

I have a couple of questions regarding your news flow and pipeline in the second half of this year. So we should see the data for the AMR trial was to data for GPS. And you already commented before, you're starting to look at what you're going to do regarding the repeat dosing program. So I was wondering, can you high level explain what kind of data you're expecting to see for the trial? And how is that going to give your decision on what programs to go forward with? Are you currently wanting to bring them all forward or out? Just trying to understand how you're going to prioritize based on the data that we'll see.

Søren Tulstrup

So I take your last question as pertaining to 5487 specifically. And I'd say, overall, while there are many different opportunities and we're quite excited by the field of opportunities, obviously, we need to prioritize for obvious reasons, especially in a capital restraint environment. So what we will be looking at is, of course, where do we see the biggest degree of unmet medical need and where we think that there is the highest likelihood of success for this particular molecule and that will be based on a number of different factors. Was that reply enough for your question now? Or did you also have questions around the GBS and AMR results?

Ingird Gafanhao

Yes. I think we'll be interesting also to hear how you're thinking about those because what I'm trying to understand is what will be the sequence of events? Do you want to see the data for all these trials first before you make a decision to move forward or do you see an actual opportunity to do further studies in all the indications that you are looking at right now.

continue, right? And we will make a decision there based on the outcome of those decisions or sorry, discussions and associated decisions. As far as the GBS study is concerned, what we will report out. This year is really around safety, tolerability, potentially early effects of treatment in the GBS patients. But really the efficacy comparative data set will only be available once we've done the analysis versus the matched cohort from the IQOS database and that will happen in 2024. So that will be a decision that we'll make in 2024, what to do as a next step there.

Operator

[Operator Instructions] We have our next question comes from Johan Unnerus from Redeye.

Johan Unnerus

Thank you. And yes, a few questions and have been clarifying so far. Clearly, the launch is a bit on the soft side and would be good as a deal for the level of dynamics and visibility ahead. You pointed to some markets where local protocols and reimbursements are in place where it's about to be in place. Could you give us perhaps an indication of how many markets are in a more dynamic stage by mid-second half of '23?

Søren Tulstrup

pushing that to the regions and all the way down potentially to orders at the hospital level. And so we expect that to take place between now and the rest of the year. So that in the second half of this year, we certainly hope to have real access all the way through to patients in the top 5 countries. And that's why we do expect clearly backload of sales this year. So far, I mean, it's been, as I said, we've seen a very nice impact in France which was also one of the countries participating in our Phase II trials. And if we can replicate that in the other countries as they start getting online, that's really very nice. And then obviously, there's a number of smaller countries where there's also some very advanced in leading kidney transplant centers.

Johan Unnerus

That's useful. And also to what extent you can proactively decision and platform on these processes, perhaps local protocol or so or sharing experience. Do you need to add more supporting capabilities?

Søren Tulstrup

I mean, clearly, this is a responsibility of the clinics and the groups claiming we sometimes organized on a national level like in the U.K. But we have certainly very much if you look at what has historically taken place so far, we have certainly been very much consulted and involved and we've been very pleased with the outcome. And as I said, if I look at the U.K., great protocol in place. There is a high degree of interest and conviction and decide to get going. And we expect, again, similar kind of outcome in the other countries. I mentioned Italy before. Spain is one of the leading transplant countries in Europe with probably one of the best organ allocation systems in the world actually and where our high proportion of the transplanted patients if they're working from a disease donor. So we do expect quite some material impact from these countries as they get online. It's impossible to predict specifically at quarter and so on. But clearly, in the second half of this year, we do expect impact from these large countries and some of the smaller ones as well.

Donato Spota

the drug versus those who are just starting with using it.

Johan Unnerus

And also the process from -- it's more about a follow-up or clarification, in the U.S. pivotal study, the process of moving from enrollment to randomization and to get the allocation of kidneys to cope with the ambition and the target to file by '24, when do you need to have sufficient number of patients randomized by the end of '23 or...

Søren Tulstrup

Yes. So that is greatly important obviously to get the 64 patients randomized by the end of this year, right? So there is a clear focus on this. And that will determine, of course, the ability to find a BLA later.

Johan Unnerus

Yes. And finally, deduction, the collaboration of the tariffs, clearly, they have at end of May or the likely to get to signal that the clinical study is starting to announce that?

Søren Tulstrup

Johan, I think -- I don't know, for some reason, you're going in and out here. Can you repeat your question and maybe speak closer to the mic?

Johan Unnerus

Yes. Sorry. Do you hear me better now?

Søren Tulstrup

Yes, a little bit better. Yes.

Johan Unnerus

Okay. [Technical Difficulty].

Operator

[Operator Instructions] We have no further questions on the line.

Søren Tulstrup

Okay. Well, thank you very much, operator and everyone has called in to this conference call. We're very excited about the progress and we look very much forward to keeping you updated so thank you.

Operator

Thank you. Ladies and gentlemen, this concludes today's call.