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Transcript: Financial Statements for the full year 2021

Date & time: 9 February 2021 at 13.00

Operator: [00:00:00] Ladies and gentlemen, welcome to the Lundbeck Financial statements for the full year 2021. For the first part of this call, all participants will be in a listen only mode, and afterwards, there will be a question and answer session.

Today, I'm pleased to present Deborah Dunsire, President & CEO, Anders Götzsche, Executive Vice President & CFO, Johan Luthman, Executive Vice President Research & Development and Markus Kede, Senior Director Treasury. Speakers, Please begin.

Deborah Dunsire, President & CEO: [00:00:31] Hello everyone, and welcome to the full year financial results and business update from Lundbeck. Thanks for joining us. Today, as you've heard, I'm joined with Anders Götzsche, CFO, Johan Luthman, EVP of R&D, Jacob Tolstrup, the Chief Commercial Officer for Lundbeck, and unusually today, Markus Kede, are head of Treasury. Since we have another announcement in addition to the financial release that we will be talking through today.

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Deborah Dunsire, President & CEO: [00:01:01] You've seen our forward-looking statements. I trust you've all read them, so I'm going to move right on.

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Deborah Dunsire, President & CEO: [00:01:09] We had a very solid year, although a difficult year, given the loss of exclusivity in Northera. We're very proud in spite of that loss to achieve revenue of 16.3 billion. And to see our strategic brands up 15 percent with growth across all regions. Core EBIT reached 3.5 billion and the EBIT margin expanded to 21.6. We also made significant progress reducing the debt since we were able to save money given that we were impacted by

the pandemic. We've had some great progress in our pipeline. Notably, in January, Vyepti was fully approved in Europe and the U.K. We also had the supplemental NDA approved for Rexulti for the treatment of schizophrenia in adolescent patients aged 13 to 17 years. We are on track for the headline results from Brexpiprazole agitation in Alzheimer's disease and Johan is going to talk through that a little bit more. And very proud that we now have a replenished phase two pipeline with two novel molecules; our pay cap inhibitor and our alpha synuclein inhibitor. Both those trials initiated in Q4 of 21, and Johan will be commenting further.

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Deborah Dunsire, President & CEO: [00:02:33] Today, we announced a new share structure splitting the Lundbeck share into A- and B-shares. That is done in order to increase financial capacity into the future to account for the growth of Lundbeck. We'll talk through that in more detail, but suffice is it to say that all shares retain equal economic rights, but the A-shares will carry 10 votes, the B-shares will carry 1 vote. This is proposed and will be brought to an Extraordinary General Meeting of the shareholders for approval. We anticipate that the Extraordinary General Meeting will be in June of 22. In the meantime, we work on a prospectus that will be published once it's been through the iterations with the Financial Supervisory Authority. The Lundbeck Foundation did inform us that they intend to offer an exchange offer exchanging their B-shares for A-shares for some investors who may choose to prefer to use B-shares.

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Deborah Dunsire, President & CEO: [00:03:46] So turning to the year. The strategic brands continue to be the major revenue contributors, ups 18 percent in local currency, 15 percent reported. And notably the fourth quarter of 21 improved 23 percent over the fourth quarter of 20. All four strategic brands showed double digit growth in Q2, and they're now 61 percent of our revenue. We're glad to see that the impact of the pandemic is gradually abating, and so we anticipate strong growth momentum going forward for these brands.

Commenting on each of them next slide, please.

Deborah Dunsire, President & CEO: [00:04:28] Vyepti has continued to perform. We introduced it in a couple of new markets in the fourth quarter, UAE and Kuwait, where it's been well received, and as I said, we've achieved the approval in Europe and the UK, so we have 10 launches planned in the coming year. We saw very good momentum continue through the year for Vyepti, subsequent to the US launch. We've also made progress in expanding Vyepti, getting it ready for its global expansion in Asia with the SUNRISE and SUNLIGHT trials. And of course, bringing it to trials in episodic cluster headache to continue to expand that brand's ability to benefit patients. We saw the same strong profile of Vyepti reiterated in the delivered data, which we spoke to you about earlier in the year. But suffice it to say that in the marketplace, we are very satisfied with how Vyepti continues to deliver for patients, giving very powerful relief over a three month period with a single infusion.

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Deborah Dunsire, President & CEO: [00:05:44] Brintellix/Trintellix has also shown double digit growth. Europe and international markets have significantly expanded. We continue to see great growth in Japan, achieving a market share of over five percent. And we've also seen the profile continue to be supported in some of the phase-4-studies. We've had both our real world evidence trial showing the improved functioning of people taking Trintellix in our relief trial and then showing in people who have major depressive disorder and concomitant generalized anxiety disorder, a significant improvement in both depression and anxiety in our reconnect trial. We still have one ongoing trial in the phase-4-suite of vortioxetine vs. desvenlafaxine vaccine. Brintellix grew 14 percent over the year.

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Deborah Dunsire, President & CEO: [00:06:43] Rexulti, another product that's delivering 14 percent growth in local currency over the year, the sNDA was approved for schizophrenia and adolescence, a recent launch in Brazil continues to show strong uptake, and we're on track for the pivotal headline data for Alzheimer's agitation in mid 22. Johan will comment on our PTSD program. Suffice it to say, we're seeking to redesign that program, given the accrual delays based on the pandemic.

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Deborah Dunsire, President & CEO: [00:07:18] Abilify Maintena has continued to perform. It was a brand slightly less impacted by the pandemic, and so the growth continued in 2021, showing eight percent growth in local currency. Health Canada approved an alternative initiation regimen that allows for two injections at the start and a less days of oral coverage required. And we received our clinical pivotal data that will be required for the submission of the two month formulation in the mid of 22 when we consolidate with the manufacturing data that's needed for that submission.

Next slide, please. Handing over to Johan.

Johan Luthman, Executive Vice President Research & Development: [00:08:05] Yeah, thanks, Deborah. Let's talk a little bit about R&D further. Let me start by commenting a bit further on Vyepti. The global rollout of Vyepti is progressing very well thanks to a very aggressive regulatory submission plan. As Deborah already mentioned, we are pleased to have obtained the European Commission approval for marketing authorization in EU and the European Economic Area countries. We got that on January 24th. This was followed shortly thereafter by approval in the UK on January 26 since the MHRA process was adopting the CHRP opinion and followed the timeline of the European Commission decision. The approved indication in those market is identical, with Vyepti indicated for a prophylaxis of migraine in adults who have at least four migraine days per month. The latest we have obtained so far validate the strong data we have on the drug. With these approvals, including the recent EMA centralized procedure approval, Vyepti is now authorized in 39 markets while a review is ongoing with 13 regulatory agencies and we expect five more submissions based on the current data package. I also like to add that the Asia programs are progressing well with the SUNLIGHT, SUNRISE and SUNSET studies. The SUNLIGHT study actually already reached last patient first visit in mid-January, despite escalating COVID situation in China and restrictions posed by the Olympics and ahead of the Chinese New Year. We are therefore on track for the headline results from this study after the summer. So overall, the current progression of the Sun trials are keeping us on the expected timelines for regulatory submissions in China and Japan.

On Rexulti, the supplemental new drug application for treatment of schizophrenia adolescents was approved by FDA on December 28th, as Deborah mentioned. There is a significant unmet need in the treatment adolescent schizophrenia patients and the approval of Rexulti provides a valuable treatment option for this population. The submission was completed a year earlier than planned based on clinical data and an extrapolation and modelling a PK data. Indeed, this represented the first application for treatment of schizophrenia in paediatric patients to be reviewed by FDA's accelerated extrapolation pathway. As you probably recall, the enrolment of patients in agitation Alzheimer's disease trial was extremely affected by the COVID-19 pandemic. But through a very strong efforts across the Woodstock and Olympic teams, we have now been close to concluding the last patients in the trials. Thereby, we can look forward to the headline data of this pivotal trial, as we promised by mid this year.

The two phase three trials of Brexpiprazole in PTSD are extremely affected by the pandemic still. An enrolment of patients are severely affected. Thus, we have an ongoing discussion with FDA, which we are outlining the different risk redesign proposals of the program, and we are looking forward to have a good conclusion of those discussions. Our alpha synuclein program, AF82422 I presented last quarter. The Phase two AMULET study for potential new treatment or multiple system atrophy has now been initiated. It's still too early to judge the trial progression, but we are up running now with several sites. I will comment a little further on Lu AG09 triple 2 program in the upcoming slides.

So next slide, please.

Johan Luthman, Executive Vice President Research & Development: [00:11:46] So 9 triple 2 is an investigational monoclonal antibody designed to bind and inhibit pituitary and light cycles, activating polypeptide, PACAP for short. 9 triple 2 is targeting biological pathways in migraine that are distinct from the CDRP drug class. PACAP in its receptors are broadly expressed in the nervous system, including at sites implicated in migraine pathophysiology. In preclinical and clinical studies in healthy subjects, 9 triple 2 has shown to bind with high affinity to PACAP, thereby preventing PACAP from activating those receptors.

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Johan Luthman, Executive Vice President Research & Development: [00:12:27] Nine triple 2 has indeed gone through a rigorous phase one evaluation on not only its peak safety and tolerability, but also verifying its target engagement and mechanism of action in an elegant experimental medicine study. This paved the way to enter into a proof of concept study. The initiated proof of concept study, the HOPE trial, is an interventional multinational, double blind parallel group study designed to investigate whether 9 triple 2 can be effective for migraine prevention. A total of 230 subjects will be randomized to one or three treatment groups, two doses on line triple two or placebo. We're excited about the potential on 9 triple 2, we are looking forward to expanded the program and looking forward to completion of this HOPE's trial by 2023. By initiation of the HOPE study, we are advancing our neurology pipeline and adding another program into phase two that I've already mentioned, as well as further expanding our investment in biotherapeutics.

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Johan Luthman, Executive Vice President Research & Development: [00:13:36] So this depicts our current status of the development pipeline organized according to our four strategic areas. While we are in full force working to deliver on our late development activities, including Vyepti and supporting the marketed products, we are working in a very determined manner in steadily building a strong and longer term sustainable pipeline. I have already commented on several of the programs, but I like to highlight the few activities from this slide. On Vyepti, alleviate trial, which is an indication expansion study on cluster headache. It's now fully ongoing and enrolment is reasonably well ongoing in spite of initiation in the midst of the pandemic. As we have described earlier, all clinical bridging studies on Aripiprazole 2-month long acting formulation were successfully completed a while back, so we are still progressing according to plan. We are generating the required CMC data, such as the ability and scale up, and document the manufacturing process before submission to FDA that is expected mid this year. Our MAGL program, the 466 program is progressing with a systematic evaluation of the biology through early development studies in patient populations. We are currently learning a lot about the potential of the molecule and the target class. We will be determining the possible path forward during this year.

Last quarter, we announced a partnership with AprilBio on their anti CD40 ligand monoclonal

antibody with a modified FC binding domain property. LU AG22515 is now progressing into first in human studies in the coming weeks. We are thereby opening up our immunology effort with the development program.

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Johan Luthman, Executive Vice President Research & Development: [00:15:31] So we have during the last couple of years systematically worked on transforming our R&D organization. That included a change in our R&D strategic focus to the focus areas outlined in the previous pipeline slide. We selected four areas represent biological clusters that have strong potential to deliver innovative therapies for diseases of the nervous system. Because of this strategy change, we have made several tactical changes that necessitated an extensive retooling our R&D organization and technical platforms, bringing in many new competencies and capabilities. We are now fully active in all strategic biology areas across R&D with the start of the AprilBio partnership. And indeed, two thirds of our development programs are new since 2019. At the general level, we act modality agnostic, meaning that we go for drug candidates needed to target the most promising neuroscience. As a sign of this, we have now established biotherapeutic competencies across the entire R&D value chain, from early research to the market. We have established an experimental medicine capability, aiming at the De-risking program's early in development, as well as integrating the patient voice more extensive extensively throughout R&D. In addition, we have systematically worked on enhancing our operational excellence and streamlining governance and decision making. We see now signs that those efforts are translating into enhanced R&D productivity, both in terms of quality and speed. As one example, we have substantially increased our regulatory interactions, and we also have now many more programs eligible for special designation regulatory pathways. Moreover, we do see great signs of significant reduction in timelines exemplified as by the fast Vyepti rollout, as well as clear reductions in the clinical trial application approval timelines.

I will now turn over to Anders for the financial comments.

Anders Götzsche, Executive Vice President & CFO: [00:17:34] Thank you very much Johan. Next slide, please.

So we as a team believe we delivered a very solid financial performance. During 2021 we had a three percent growth, if we are excluding Northera and as some of you recall, we actually predicted 50 percent decline of Northera due to generics. It ended out with 74 percent. And we actually, despite that, were ending in the high end of the range for core EBIT. So if you exclude the restructuring that we did during the year to also accommodate that, we had lower revenue and creating a more fit organization for the future, then we were actually ending in the upper end of the core EBIT. EBIT of course, were actually impacted by the some 250 million kroner restructuring provision booked in the fourth quarter. But we were also really happy to report that the goal that we said in the beginning of the year to deliver double digit growth for the strategic branch was achieved by a 15 percent growth across the brands.

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Anders Götzsche, Executive Vice President & CFO: [00:18:44] So for 2022, we are now having the down year behind us, and therefore we also expect that we will have a revenue growth of four to five percent. We expect that that will lead into earnings improvements, both from a nominal perspective, but also from a margin expansion perspective. We will see double digit growth again in the strategic brands, but we also anticipate that some of the mature brands, like Cipralex, will see a more normal erosion than we have seen in the pandemic. So anticipating the underlying decline of 5 to 10 percent. So that will of course mute the growth. So we anticipate a total growth of 4 to 5 percent. It is important to highlight that we will see an improvement in our EBIT. If you look at EBIT and look at the mid range, we will have improvement around 400 million in total and the revenue improvement will of course come with higher contributions, gross margin, gross profit contribution. And then we don't have anticipate to have restructuring. But at the same time, we will also invest more behind Vyepti. We will invest a bit more behind the other products because we anticipate that we are getting more into a normal situation where the pandemic is easing out. Of a special note, please see that financial expenses will be higher in 2022 approximately 300 million higher, and that is due to a value adjustment of the CVR that we are going to pay to the Alder former shareholders in Alder BioPharmaceuticals we have to pay in the first quarter 1.5 Billion that was dependent on the approval of Vyepti in Europe, which has actually happened.

With that, I will hand back to Deborah for going through the share split.

Deborah Dunsire, President & CEO: [00:20:47] Thanks Anders. So today we announced that the new share structure for Lundbeck, a split of the Lundbeck share into A- and B-shares with the intent that over the long run, the B-shares could be a new long term funding source, another tool, if you like in the toolbox to be able to pursue our expanded investor growth strategy. The Lundbeck Foundation introduced this, and we have worked up together with the Lundbeck Foundation. This share split and the purpose is to enable a growing Lundbeck to have access to capital and be able to use equity as a tool as Lundbeck grows in the future. Given that Lundbeck will eventually become of a size that the foundation may not be able to match pro-rata in any equity issuance. There is no change implied by this to our existing strategy or to the level of selectivity that will put behind any transactions that we look at. We've also explicitly stated that we do not have anything on the table at this time where we anticipate the use of this financial tool. And we want it to be clear with all of you that this is being put in place for the long term. The foundation also intends to offer eligible shareholders a 1:1 exchange of their A-shares with the Foundation B-shares, if various shareholders would prefer to hold the B-share.

To take you through the technicalities, I'm going to ask Markus Kede to take you through that. Thanks, Markus. Next slide.

Markus Kede, Senior Director Treasury: [00:22:37] Thank you, Deborah. I will provide some more detail on the proposed share split and timing. The proposed split means that each existing share will be replaced with 1 A-share and 4 B-shares. Existing shareholders will not need to take any actions to enact the split of their shares. This will happen automatically when adopted by the General Meeting. Post split, 1 A-share and 1 B-share will have the same economic rights. This means, amongst other things, that each share will be entitled to the same dividend per share. The only difference in the share classes relates to voting rights. Each A-share will be entitled to 10 votes and each B-share will be entitled to one vote. Since each shareholder will get a split of A- and B-shares, each shareholder will hold the same proportion of overall votes after the share split as they do immediately before the split. A-shares and B-shares cannot be converted, one for another. However, as Deborah earlier alluded to, the Lundbeck Foundation has informed us that as a service to shareholders, they expect to offer to eligible shareholders a 1:1 exchange of A-shares with the equivalent number of B-shares held by the foundation. Further details of this exchange and the mechanism will be issued in due course. Further, there will be no lockup or

standstill in relation to the split. This will allow free movement within the share classes.

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Markus Kede, Senior Director Treasury: [00:24:03] With today's announcement, Lundbeck's Board of Directors have asked management to engage with the Danish Financial Supervisory Authority and commence a listing document approval process. The review process with the FSA is expected to take several months. Following this, Lundbeck will issue invites to an Extraordinary General Meeting to facilitate a shareholder vote on the proposed share split. Depending on the listing document process, we expect this EGM to be held in June of 2022. If approved by the General Meeting, the shares split will take effect one to two days after the EGM. With that, I hand it back to you, Deborah, for concluding remarks.

Deborah Dunsire, President & CEO: [00:24:43] Thanks, Marcus. Next slide, please.

So as we go forward, we have good growth visibility into the coming years with no major patent expiries for several years into the future. And so we have a strong suite of strategic brands that will continue to grow. We have a strong brand that developing in Vyepti that will continue its global rollout, and so we look forward to being a sustainable and profitable growing company into the years ahead.

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Deborah Dunsire, President & CEO: [00:25:21] Right now, our focus in 2022 is to maximize those growth drivers that we have in our hands in Abilify Maintena, Rexulti, Brintellix and Vyepti, while we continue to stand on a base of very strong cash generative mature products. Vyepti’s global roll-out will continue to offer substantial growth opportunities. We will launch in 10 markets this year, but I emphasize that those launches will probably be happening towards the second half of the year, given time to get packages into the market. Rexulti has the opportunity to grow substantially with Alzheimer's agitation, data readout and subsequent submission in 2023. And so that gives us good growth visibility from these brands into the next five to seven years. I'm very pleased with the way that we've been transforming in R&D to set us up well for the expanding future in neuroscience, as the biology is becoming better understood with more

targets and more modalities to achieve transformative outcomes for patients. Lundbeck is dedicated to restoring brain health and to do so, we stand on a strong financial foundation, and of course, we'll continue our customary focus on making sure that all our investments are efficient.

So with that, we'll close the presentation and open for questions.

Operator: [00:26:56] Thank you. Ladies and gentlemen, if you have a question for the speakers, please press zero one on your telephone keypad. Once again, it is zero one to register for a question on the telephone keypad.

And our first question comes from the line of James Gordon from J.P. Morgan. Please go ahead. Your line is open.

James Gordon, J.P. Morgan: [00:27:25] Hello, James Gordon, JP Morgan, thanks a lot for taking the questions. One on the share split and then one on Vyepti please. So on the share split, I heard a comment about no change to strategy, but also noted previously talked about not buying anything that require lots of R&D or marketing step up, such as the 2024 margin target, couldn't be at risk. So why have you changed this now and could you consider doing something that would mean you wouldn't get the 30 percent margin? And how much firepower could you have? Would you do something transformational? It could mean lower cost (inaudible) in 2024, but much more pipeline, for instance. So that's the first question, please. The second question was about Vyepti. So we did see quite a sharp sequential slowdown in Q4, only about six percent sequential growth. So how much of that is patients first trial or CGRP for getting Vyepti? And could that be an ongoing issue? Or do you think it's more COVID? How much acceleration should we expect to see moving into 2022. With Q1 also see disruption sequentially, I think you have done in previous years for products like this and how comfortable are you? Could you do consensus, which I think is about 1.2 billion Danish for Vyepti in 2022, please.

Deborah Dunsire, President & CEO: [00:28:34] Ok, so lots of questions there, James. Two categories of questions. So around the share split, this is something that was introduced by that foundation as they think about the long term growth of Lundbeck. And we've said that there's nothing explicitly on the table right now that would require us to use equity. Up until now, we

have been talking about how we would grow principally in thinking about our financial capacity with respect to raising debt and remaining investment grade, which requires us to pay down debt to the two times EBITDA by the two year time frame. So. Yes, having an additional tool in our financial toolbox in the share split does afford this company going forward. And I say, you know, from today and into the years and decades ahead the opportunity to think about equity and think about what type of combination, partnership license, what type of external innovation would be most appropriate to continue to build Lundbeck, both using our internal pipeline and external to deliver sustainable, profitable growth. I think one of the questions you had was why is this being done today? And that's in the instance of being prepared for something before you need it. As you heard from Markus, it takes some time for all of the mechanics of this to be put in place. So at this time when we don't have anything specific that would require equity, we can take the time to go through that process. With respect to talking about the 25 per cent margin by 2024, we've always specified that that would be with the current pipeline. So with the current framework of our business. So we will always look at external innovation and look to what it will deliver in the short, medium and long term for Lundbeck's shareholders and how it will contribute to Lundbeck being a sustainably growing profitable company into the future. So I'll stop there, and I'm going to hand over to Jacob to take the Vyepti question.

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [00:31:10] Thank you very much, and James, good questions, obviously. And I will try to give you an answer and maybe a little bit of a longer one, but try to give you an answer. I think it's difficult sometimes to look at quarters. I think that for all brands, but I think especially for Vyepti, especially also in the beginning of launch. On top of that, you have a Q4 which is impacted by Thanksgiving, US holidays. I think in general, it's sometimes difficult to look at individual quarters to look at an uptake of a drug. I think what's important for me is to look at the overall strategy and positioning of Vyepti. We have a unique drug. We have a very efficacious, powerful drug. And I think with the brand positioning that we have in the U.S., also outside of the US that we will be working on, it sets us apart also in terms of the treatment algorithm and the patients that we are going for. I think when you look into 2022, first quarter will naturally be a little slower compared to the rest of the year. It has to do with the research of the doctor, both also authorization of patients coming in at the beginning of the year. That takes a little bit longer time. I think the real sort of traction with Vyepti will come towards the remaining quarters of 2022. So not to comment anything on sales targets for next year, but I actually feel quite confident and comfortable about Vyepti also

going forward. And as you can tell, I can probably talk a lot more about that, but I think I will end it there and then see if there are further questions coming regarding Vyepti.

Operator: [00:32:49] Thank you. Our next question comes from the line of Michael Leuchten from UBS. Please go ahead. Your line is open.

Michael Leuchten, UBS: [00:33:08] Thank you very much, Michael Leuchten from UBS. Two questions, please. One, thank you for the details on the share split and timing. In terms of the decision processes to allocate capital, if and when. Does that change at all with that structure? So does the foundation get more involved in decisions further down the line? Or is the decision process the same? And it's just another option that you can choose as long as you wish. So in a way, what's in it for the foundation to allow you to have the flexibility. And then a question on Vyepti. If we look back to the older acquisition, what's the level of Vyepti revenues when the deal starts to hit hurdle rates, given that we're still in this lower part of the launch curve and now the delay in Canada?

Deborah Dunsire, President & CEO: [00:34:01] Ok, so, Michael, I'll start on the decision process to allocate capital. The Lundbeck management would propose deals as we always do. We survey the external landscape. We discuss the strategy with our board, the Lundbeck board, on an ongoing basis. And it's the Lundbeck board that will make the decisions, of course, the foundation does have representation on the Lundbeck board, but it is overall the Lundbeck board that governs the decision making on how appropriate any use of capital is to support the strategy and to support the long term profitable and sustainable growth of Lundbeck. So there's really no difference. Then there is today. There is an additional tool within the toolbox to be able to use. And let me be clear, we could use equity today. It is a tool that is available to us. But what the foundation, when it initiated this discussion made clear, is that over the years and decades ahead Lundbeck will grow into a bigger and bigger company and therefore may outstrip the foundation's ability to participate pro-rata in an equity split with an equity use usage or equity issuance. With the share split and the use of the B-shares as the equity issuance, the foundation can continue to give a long term stable stabilization ownership, which is commonly used within Denmark and within the Scandinavia that has allowed companies to grow and thrive in over the very long term. So it is with that that perspective of building a long term, profitably growing company that this is initiated today. So I'll stop there with respect to the thinking about Vyepti

and hurdle rates, I don't know whether, Anders, you would actually comment on that, and Jacob, you comment on the brand.

Anders Götzsche, Executive Vice President & CFO: [00:36:20] So of course, what we have seen due to the pandemic is that there has been a parallel shift in the revenue uptake, but we have also used way lower cost levels, or we have had way lower cost levels than we anticipated, which actually means that Vyepti has been more profitable in the first couple of years than we anticipated in the business case. We have also made some major improvements in the future costs. We have optimized our cog some 30 percent. It has been declined 30 to 40 percent. So there has been a lot of improvements done from a profitability point of view. From a revenue point of view, it's fair to say that we are waiting for, there's pricing discussions ongoing in Canada, so that has been delayed. We have seen a shift in uptake due to that. It has been more difficult to get out there during the pandemic. I don't know if you want to add, Jacob.

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [00:37:23] I think that's absolutely fair. The pandemic has impacted Vyepti, but coming back to also what I said in the beginning, I think we feel quite confident about where we are with Vyepti today with the brand positioning that we have with the plans that we have going forward, also in terms of optionality that we offer in infusion strategies in the US. And we do see traction, also feedback coming back to us, of the benefits of the drug. So we are quite confident that Vyepti will become an important product for Lundbeck over time. And the blockbuster that we had imagined.

Operator: [00:38:12] Thank you. Our next question comes from the line of Michael Novod from Nordea. Please go ahead. Your line is open. Yeah, thanks a lot, it's Michael Novod from Nordea. Just a few follow up questions. Maybe to the US and North America. Is there any risk, given your latest restructuring, that you are actually starving the year, the sort of the market dynamics your marketing in the US? Or is that something that is said to change? You are guiding, I see an increase in sales marketing cost, just worried that you may be starving your sales organization in the US. And then secondly to the new share structure. So it's obviously indicating, as was previously said, some more transformative stuff. Just trying to ,from a management perspective, what would you prefer; is that the fully accretive and immediately accretive commercial acquisition, if you should do an acquisition or is it the more sort of R&D focused? I'm just also trying to understand, and I don't think the answer was so clear earlier, whether you're sort of

walking away from the mid-term target of margin that you put in place, just to get some feelings of what we could expect if you were to do, and what you prefer in terms of acquisitions. Thanks.

Anders Götzsche, Executive Vice President & CFO: [00:39:39] I'm happy to talk to that. I don't see that issue, Michael, so if you look at twenty-two, that will be for us a big Vyepti not only in the US but also outside where we are investing in the buildout of capabilities behind the Vyepti across the world where we are launching, and in the US, we are going to invest quite a bit more into Vyepti. So I think we are targeted in our approach and I think we have the resources available to make our brand a success also in the US. I would say also, if we look a little bit back in time, there's no doubt our profitability in the US was higher than it is today. So we have totally accepted that because we want to invest into our brand, and we're building out. So I don't see a U.S. resource perspective that is underserved in that way.

Deborah Dunsire, President & CEO: [00:40:41] Yeah, no. On your second question I think we have consistently said that we are in a period where we have a pretty high R&D investment as we globalize Vyepti, bring on the (inaudible) cell line, finish up the Rexulti move forward the pipeline at the same time investing behind the launch of Vyepti, both getting back to a more normal level of spend in the US and then gearing up for the launch outside the US. So in 21 and 22, we knew those costs were going to be high, and so the focus was on either early stage R&D deals being absorbed within the R&D budget, or on late stage, more near-term accretive deals that would help us grow the top line and grow the EBIT in that nearest term. So we we want to be a company that expends towards the long term profitable growth and so anything that we look at will really have to be geared in that way. I think in 22, we still are looking at that near-term accretive landscape. We've also always said that we would need to continue to think about how do we supplement the mid stage pipeline? Now we made good progress last year in our own portfolio, bringing two new molecules in, but of course we will need to consider over time, continuing to add to the to the mid stage pipeline also for that growth in the late 20s and early 30s. So as we always do, we look at the landscape near-term accretive early stage and mid stage, with a discipline of saying what's the right timing to do any of those particular deals and timing has to do not only with what we're doing internally, but also what's happening in the external world. There has been a significant change in the valuations of biotech companies. That doesn't mean we're rushing out, you know, doing mid-stage deals, we're still looking for, you know, how

do we bring in near-term accretive assets, but we need to do the right things for Lundbeck, short, medium and long term, and so we keep an eye on the landscape broadly at all times.

Michael Novod, Nordea: [00:43:19] And I still don't really get a clear answer on some of the mid-term margin target. Is it in place or is it not in place. It's just maybe it's just me not hearing clear.

Deborah Dunsire, President & CEO: [00:43:31] What we've said is that we aim to be at 25 per cent in 2024 with the current portfolio. And then we would look at near-term accretive deals. Will they be accretive by that particular date? Ideally, yes. If it's delayed it a year but did better in the long term, we would also think about that. But with what we currently have in place, we would like to be at 25 percent in 2024.

Michael Novod, Nordea: [00:43:59] Ok, thank you very much.

Operator: [00:44:04] Thank you. Our next question comes from Sachin Jaine from Bank of America. Please go ahead. Your line is open.

Sachin Jaine, Bank of America: [00:44:12] This is Sachin Jaine from Bank of America. Two topics, and I'm afraid the same topics you've had. So firstly, on Vyepti - could you just comment to how much you think you're being impacted by aggressive couponing of orals, and where do you expect that to continue into next year and what visibility you have. And then secondly, what metrics you're tracking at the patient level to give you the clear confidence that you're relaying? I mean, I think on the two 2Q call, you mentioned viral demand. But so, what are the metrics that give you confidence given the lack of sequential growth we're seeing? And then on the M&A commentary, Deborah, I just want to follow on. So understand your comments, but there's nothing immediate. But I have seen in doing this, some size criteria were discussed with the board, and given your balance sheet structure and your very attractive cash flow generation, I guess the balance sheet without equity allows a mid single digit billion size deal, but you know, by the end of next year into 24. So two questions; 1, what type of deal is potentially being considered in the mid-term or to have put this equity exchange in place. And then second, just to understand your time frame comments. I understand there's nothing immediate and the commentary is very much off putting in place for the long term, but in the answer to that question, you've talked about current equity valuations. So just wondering, very simple if you're

able to rule out an equity based deal in the next 18 months to 24 months? Or is that a possibility from any point at which the share structure change in the middle of the year? Thank you.

Deborah Dunsire, President & CEO: [00:45:47] Ok, maybe you like to start on Vyepti.

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [00:45:49] I can certainly start on Vyepti. Thank you very much for the question, Sachin. And again, it will be a little bit of a longer answer. I think the U.S. market in general is, I would say, quite impacted by the orals entering the market. And there are, as you've seen, quite aggressive, they are sampling heavy, they also have big sales forces and are doing a lot of promotion in the market. That said, coming back to the positioning of Vyepti, as I said in the beginning. I think it's important that we look at the treatment of migraine. And if you look at the spectrum from acute to entering prevention to episodic, frequent episodic, and then chronic patients where we are focusing Vyepti and where we're going to win is on patients that are in the chronic or high frequent episodic segment. That's also where we believe we are getting the most patients. It's also where the profile of Vyepti is very strong. We have a very powerful drug that is also delivering in terms of the feedback that we are getting. On the orals they are obviously approved for acute is and we also have one that is only approved for early prevention, but they are mostly playing in the field of acute going into prevention or the earlier stage of prevention. And I know, of course, that that also impacts later stage of prevention. But I would expect that what you're going to see over time is a bigger impact on the subcus than on Vyepti when it comes to oral impact. But there is no doubt that what we see now is a market that is heavily impacted by the orals entering the market. I think over time you will see and that's where you're going to judge the success of Vyepti is us to win more focused on chronic high episodic patients. On top of that, we are the only agency anti-CGRP that has medication overuse headache on its label. So that's also something that we will talk about, especially outside of the US, but also in the US talk about the use of acute meds for patients and how Vyepti can benefit that in a potential treatment. So I think we have a good positioning that sets up us aside and is different to the orals. So obviously we look at vial demand growth in the US. We also look at utilization of the 300 mg in the treatment algorithm for Vyepti.

Deborah Dunsire, President & CEO: [00:48:34] And with respect to the many questions around the use of equity. What we have communicated is that if we use the more traditional methods of

raising debt, we had a ticket size depending on the acquisition target and whether it brought revenue and EBIT of the 1-2 billion dollars in order to retain an investment grade rating recovering the net debt to EBITDA within 24 months. With respect to equity, that's not the choice of currency one uses for an acquisition of that type of size. So equity would only be contemplated if it were something that were a larger transaction to be funded, and then it depends on the type of transaction, what type of entity would you be using that capital to invest in. And it could be something that also brings revenue and EBIT as well as pipeline. So there's there's so many different options of how that could be deployed. So I would say that we don't have anything on the table now. Would I guarantee that it would never be used in 18 to 24 months? I cannot see far enough into the future to be able to make that guarantee. All I can say is we don't have anything on the table now.

Sachin Jaine, Bank of America: [00:50:16] Very clear. Thank you.

Operator: [00:50:20] Thank you. Our next question comes from the line of Matt Weston from Credit Suisse. Please go ahead. Your line is open.

Matt Weston, Credit Suisse: [00:50:28] Thank you very much. Two questions, please, and I'm going to stick to the time old theme of the share structure and Vyepti. I do think it is very unusual and certainly the feedback from the market is that it's been very unusual that a shareholder proposes a change in capital structure. And I'm just mindful that the foundation has a goal to double its wealth by 2030 in order to deliver on its commitments to distribute to the causes that it supports. So is this the foundation saying that you don't have enough in house to achieve their goal and so they want you to do more because they need more? And should we therefore expect the foundation is taking more of an activist role than your growth? Or am I just overinterpreting? And then the second question on Vyepti. You obviously have a number of readouts coming in migraine prevention and cluster headache. Can you remind me of how that scales up the current opportunity? So if you see what the current opportunity is with the current label, how much do you add with prevention and then how much do you add again incrementally with cluster headache? Thank you.

Deborah Dunsire, President & CEO: [00:51:38] Ok, so thanks Matt, for the questions. I think the foundation have been very clear that they are a long term owner and they believe that long term

their long term ownership gives the company the stability to continue to prosecute growth in neuroscience. So they sit on the board, they understand where Lundbeck is, they have supported the strategy of building our pipeline both internally, the refocused innovation strategy, the advancement of molecules within the pipeline, the acquisitions of Abide and Alder and they have agreed with the strategy that will continue to build not only internally but through external innovation. So all of those tenets are in place and are supported by the Lundbeck Board, which is the decision making body for Lundbeck. But of course, we have foundation representatives on that board. When we look out into the future, Lundbeck is a company that's 107 years old. It's been operating in neuroscience for 70 years, and the foundation takes a decades long perspective. So they do think about what this company will look like, not just a year or five years, but 10 and 20 and beyond years into the future. And so it is with that in mind that they want to retain that stable long term ownership, but enable the company as it grows to be able to deploy equity as a financial resource. So. Are they an active participant in the board of Lundbeck in that representation? Absolutely. Always have been. Always will be. The use of the word activist has a different quality and I would say that that is not what we're seeing. We're seeing the same active engagement together with management around the strategy to build Lundbeck into a sustainably, profitably growing company. And we've always said that we do need to continue to look externally as well as foster the growth of our internal pipeline. So that's completely consistent with the strategy that we've worked on with the board over the years. So thank you.

Anders Götzsche, Executive Vice President & CFO: [00:54:34] On your question on Vyepti. Of course, as you know, Vyepti is fully approved in prevention. So the studies that we're doing, there is more to sustain our profile. Give us an edge in the field even more than what we have today. So the real sort of label expansion that we're looking at here is the ALLEVIATE trial in cluster headache. And we haven't said what that opportunity brings. And I don't think we comment on that today.

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [00:55:04] What I could add to that is obviously we continuously monitor what beyond the ongoing activities we could do. One thing we already talked about is that we'll do some additional phase 4 activities of medication overuse headache to really build on what we already have in the label that differentiates us, to building a stronger case there. And obviously, we're also looking at other potential line extensions, but we tread very carefully there. It's much higher R&D risk when you go further out, and we already

have a big investment in R&D in Vyepti to deliver the more hardcore Data that we need to deliver right now, including the Asian expansion.

Deborah Dunsire, President & CEO: [00:55:43] And just a last comment from me, Matt, you said, you know, how much do we think the expansion in prevention would bring? We have the label in prevention. We're amplifying it with the, you know, the trial and medication overuse, but that already exists in the label. And so we have prevention in both episodic, frequent episodic and chronic migraine. And we know Vyepti is being used in the most heavily impacted patients, given the powerful efficacy that it demonstrates. And then episodic cluster headache would, of course, be a new indication. But migraine is the major indication, and we are at the beginning of the global rollout and growth in migraine.

Matt Weston, Credit Suisse: [00:56:30] Thanks, Deborah. I should have asked it more differently, I should have asked what if you see any incremental reach from the new data? I guess that's what I was trying to get across. From the new prevention studies, it sounds that you don't. you see that as reinforcement. And then the new reach comes from cluster headache.

Deborah Dunsire, President & CEO: [00:56:49] I would say that's accurate.

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [00:56:51] Yes, obviously, we talked about the delivery study previously where we gave a good dataset to support that. It can work when you failed on 2-4 previous treatments, and that's of course, important also to position the drug. Others have that type of data, but it was very critical for us in, particularly in Europe, but also beyond to build on that case. And we had tremendously good data out of that study. Extraordinarily good data. So we building on what we have a lot.

Matt Weston, Credit Suisse: [00:57:21] Thank you.

Operator: [00:57:24] Thank you. Our next question comes from the line of Emily Field from Barclays. Please go ahead. Your line is open.

Emily Field, Barclays: [00:57:32] Hi, thanks for taking my question. Just a couple of quick ones. Vyepti, how are you thinking about the launch trajectory in Europe, obviously relative to the U.S.

launching at a more favourable time in the pandemic? However, I would imagine it's somewhat offset by the need to obtain reimbursement in the various jurisdictions. Also a non-Vyepti business base of this question, sort of, you know, where we're at in terms of the pandemic on the base MDD market, where do you psychiatry visit stand relative to baseline? Are you still seeing depressed switches or new medication starts due to more telehealth? Just sort of how that trajectory is shaping up. And then just a very mechanical question on the share split. So just for my own understanding, so ordinary shareholders will get their A- and B-shares and then I would imagine an incentive to exchange shares of the foundation is that the super voters are likely in the market will trade at a premium and that is an open ended offer. So I would imagine that, you know, the extent to which those shares change hands will just depend on the premium of the super voting A-shares to the B-shares in the market. Thank you.

Deborah Dunsire, President & CEO: [00:58:48] Okay, great. So Jacob, you will start. And then Markus, you will take the question on the share.

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [00:58:53] Yeah. Thanks very much for the question. So why Vyepti for Europe? Rollout in Europe, not only for Vyepti, but for, I would say every new brand that you introduce, takes time. We have full regulatory approval and now begins the process of obtaining market access and pricing reimbursement. Depending on markets, that can take anywhere between a few months and up to some years. And that's also what you should expect for Vyepti. We will launch in the first markets in Europe before the summer, but then it will start to accelerate as we get into the second half and then into 2023. And there will even be markets that are not launching before 2024. So that is sort of a usual picture for Europe. When it comes to the MDD market. I agree with you, we have seen a contraction of the market, especially for in the US. We've also seen it a few other places, but not nearly to the same degree. And there are slight signs of recovery in the US towards the end of 2021. And hopefully we will see that continue so that the branded MDD market comes back to growth in 2022. So we're building our assumptions on a world that will be even more open in 2022 than what we've seen last year and also providing us more access in terms of coming out and detailing our products.

Deborah Dunsire, President & CEO: [01:00:39] And just adding of it to that. I think we've seen more of an impact in the broad MDD market, including the GP segment more, which obviously is

with Trintellix positioned, versus the adjunct market where Rexulti is positioned. Both were affected by telehealth, where new-to-brand prescriptions are less frequent. We're seeing more of the recovery in the adjunct section and the beginnings of recovery in the broad MDD section. But that market has only now returned in total TRx across brand and generic to where it was in 2019. So we hope that market will return to growth this year. And then Markus, maybe I can ask you to comment on Emily's question on the mechanics.

Markus Kede, Senior Director Treasury: [01:01:34] Yes, absolutely. So it's fully correct that all ordinary shareholders today will get A-shares and B-shares, and the exchange offered by the foundation will be an offer for each shareholder to each eligible shareholder to take into account. Obviously, if the A-shares would trade in the market to a premium, that could be an advisable thing to execute in the market instead of accepting the exchange offer. But yes, it will be an exchange offer that each shareholder can take into account.

Emily Field, Barclays: [01:02:09] Thank you very much.

Operator: [01:02:12] Thank you. Our next question comes from the line of Suzanna Queckbörner from Handelsbanken. Please go ahead. Your line is open.

Suzanna Queckbörner, Handelsbanken: [01:02:21] Hello, thank you for taking my call. I have two questions concerning Vyepti. First of all, given Vyepti hold the share of about four percent of the CGRP market, where do you see this heading post the pandemic. And keeping in mind the oral CGRPs availability in the US now Biohaven seeking approval outside of the US with Pfizer back in. And then the second question. When looking at your typical Vyepti patient, are these patients CGRP-naive patients or have they had previous failures with the orals or the subcutaneous CGRPs?

Deborah Dunsire, President & CEO: [01:03:04] Jacob.

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [01:03:06] Yeah. Thanks very much. Let me try to see if I can answer your question. So if we take the last question first on the typical patients. As I said, our focus is primarily on patients in the higher frequent episodic migraine cases and in chronic patients. And that means naturally, you will have a larger proportion of

patients that have been through other treatments before. It doesn't have to be that way. And I think also we are still early days, so I'm leaning out a little bit here. But what we also start to see is a growing confidence in using Vyepti that over time we also trigger earlier use of Vyepti, but that's still early to speculate in. So naturally, when you have that position, you will see patients coming in that have tried other treatments before. Your other question around the ex-U.S. Pfizer, backing on Biohaven's drug Nurtec, I think we have to await what happens with the regulatory process. Still no outcome there. I know they have filed for both acute and prevention. Let's wait and see what that outcome is. It is perhaps more difficult to imagine a European market that will be acceptable for a price level than what we've seen in the US, but what that means for their plans is anyone's guess at this time. I think you had one more question that I didn't note down, maybe,

Deborah Dunsire, President & CEO: [01:05:01] It was about the patient but I think you sort of answered it.

Deborah Dunsire, President & CEO: [01:05:04] I mean, right now, just to be clear that the patients have typically, as with any new launch, are patients who have tried something else that hasn't worked as well for them. So the initial patients that we saw were often coming off subcu CGRPs and were taken into Vyepti. We also have seen people coming off orals into Vyepti, but because the oils are relatively new, there are fewer of those. But as Jacob said, as people use Vyepti and see its power in those most impacted patients, it can open up for them to use it earlier.

Suzanna Queckbörner, Handelsbanken: [01:05:49] Yeah. Great, thank you.

Operator: [01:05:55] Thank you. Our next question comes from the line of Keyur Parekh from Goldman Sachs. Please go ahead. Your line is open.

Keyur Parekh, Goldman Sachs: [01:06:02] Hi, thank you so much. A couple of kind of broad topics, I suspect. The first one is just coming back to the capital structure. And Deborah, thank you so much for providing all the details so far. I'm just wondering, and maybe I'm sure I'm missing something but can you help me understand why this is a good thing from the perspective of the non foundation shareholder at Lundbeck. You are inherently proposing you

are the foundation to kind of dilute their voting rights in the event you were to do a transaction. And I'm sure kind of you paid enough thought to why that is good for shareholders. Just wondering what I'm missing their. Linked to that, are you expecting any impact from the perspective of inclusion in various indexes kind of across the Danish exchange or kind of the broader European markets as a function of the structural change? And then separately, as I look at the two month formulation for Abilify Maintena, how should I think about your plan to target commercialize that? Should I think about it as moving the existing patients onto the new formulation? Should I think of it as a switch market or think of it as new patient starts? So just any kind of insights there from a commercial perspective would be very helpful. Thank you.

Deborah Dunsire, President & CEO: [01:07:41] Thanks, Keyur. Perhaps we'll start with the third question first, and Jacob will take it away on Abilify Maintena.

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [01:07:49] So Abilify Maintena, two months, I think is a very good addition to our portfolio. Also fits very well into the LIA landscape that we've seen. So we're really pleased to be able to offer that option going forward. I think naturally, you should expect something which we've also seen in the market, which is a conversion from the one month to the two month to a higher level than capturing new patients. So that is the picture that you should expect.

Deborah Dunsire, President & CEO: [01:08:27] Great, and then as we think about the share split, remember that the economic value for every shareholder that currently owns Lundbeck is the same, the day after the split is approved, should that happen at the Extraordinary General Meeting. And then because of the same economic value in each share, the ability to appreciate value from those shares is also equivalent going forward. So we will see the minority shareholders point of view on this, but they also have come into the share knowing that there is a majority shareholder whose stated position is that they are a long term owner of Lundbeck and they wish to remain a long term owner of Lundbeck. They have stated that they want to see their foundation grow. For that, they anticipate Lundbeck will be growing. We anticipate Lundbeck will be growing. And this share structure is put in place to enable the foundation not to limit the possibilities as Lundbeck becomes bigger, and it may be more difficult for them to participate pro-rata. So I think it is with the perspective of enabling Lundbeck to grow, which

benefits all shareholders that this is undertaken. And then I'll ask Markus to answer the question on the listings.

Markus Kede, Senior Director Treasury: [01:09:59] Yes. So in relation to the inclusion indexes, that is, of course, a consequence of the market cap and the trading in the shares. So what we understand is that it will be included both the A- and B-shares in the indexes in Denmark as a starting point and then it will depend on the development and trading and size of the shares going forward.

Keyur Parekh, Goldman Sachs: [01:10:29] Thank you.

Operator: [01:10:33] Thank you. Our next question comes from the line of Rajun Sharmit from Deutsche Bank. Please go ahead. Your line is open.

Rajun Sharmit, Deutsche Bank: [01:10:40] Hi, thanks for the question. It's just one last, actually, it's on Brexpiprazole. Could you just give us an update on the discussions that you're having with the FDA on the PTSD study design? And maybe if you could just kind of talk about your realistic expectations of conclusions of those discussions?

Jacob Tolstrup, the Chief Commercial Officer for Lundbeck: [01:11:03] Ok. That's probably for me. So we have an ongoing conversation with FDA. We actually had meetings with them already and discussed the plan forward for a redesign. I'm not going into the details of the redesign at this time point, but I can say that they have been very productive conversations we had with the regulators. And we're looking forward to be able to come up with some redesign that may help us to conclude these trials. The current rate enrolment rate is basically prohibited, so continue as we're doing it right now. So we need to redesign and obviously see resample sizing of the trials. The prospect of this being positive, whatever design we have, of course, is completely unknown because there were two ongoing phase 3 trials that we expect to support any approved ability. I like to remind you, we had a phase 2 study that we did some years back and even some additional activities within this indication. And they were all supportive of going into this Phase 3 program. This was on top of a standard-of-care or SSRI. So that's the comparator we have. SSRI versus BREX. But the data from phase 2 was encouraging enough for us to initiate this program. That's why we did it. Then obviously, we have to see when and how we finish the trust. But if the

redesign is successful, hopefully we can do that in the foreseeable future and then we can see the data basically.

Deborah Dunsire, President & CEO: [01:12:38] Great. Well, we're well beyond the scheduled time for this meeting, so if there is one last question, we don't see any further questions.

Operator: [01:12:50] We have no more questions.

Deborah Dunsire, President & CEO: [01:12:53] Great. So thank you all for attending. We appreciate your interest.