

H. Lundbeck

Transcript: Financial statements for the first three months of 2021

Date & time: 11 May 2021 at 13.00 CEST

Operator: [00:00:00] Welcome to the H. Lundbeck Q1 2021 conference call. For the first part of this call all participants will be in listen only mode, and afterwards there will be a question and answer session. Today, I am pleased to present Deborah Dunsire, President and CEO. Please begin your meeting.

Deborah Dunsire: [00:00:19]

Thank you, operator, and thanks to all of you for your interest in Lundbeck. Welcome to our teleconference covering the financial report for the first quarter of 2021. I'm joined today by:

Our CFO, Anders Götzsche,
Head of R&D, Johan Luthmann,
Head of Commercial Operations, Jacob Tolstrup,
Our Head of North America, Peter Anastasiou

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Deborah Dunsire: [00:00:45]

You see our disclaimer, and I know you've see it many times before, so we'll move on to slide 3.

The first quarter of 2021 is one we feel very proud of. It's a continued unprecedented pandemic era, and we know that tradition interaction isn't yet get back to normal. And the promotional activity is still below the pre pandemic times. But we're glad to say there's movement towards a more normal world, and we see this showing up in increased momentum in the brand. We saw growth in our strategic brands of eight percent in local currency, and I'm very pleased with the momentum of Vyepti in the U.S. The Trintellix launch in Japan is accelerating, and we're also

delighted with the strong data from two new studies, Relieve and Reconnect, which further highlights the benefits of Trintellix in major depressive disorder.

Deborah Dunsire: [00:01:41] Important factors influencing in Q1 to comparison are of course the stocking in 2020, which was driven in the pandemic by people being told to refill their prescriptions. We've also seen significant currency headwind and in March we experienced the first impact of Northera loss of exclusivity.

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Deborah Dunsire: [00:02:07] Our market shares remained stable or improved in many markets, and even though we definitely saw an impact on demand from patients not being able to see the physician and also from our field teams being unable to work as normal. Despite those challenges, Trintellix achieved 800 million kroner sales for the quarter, which is growth of seven percent in local currency. Rexulti, shared a growth of four percent in local currency achieving 672 million kroner. Abilify Maintena remained resilient 2020 into 2021. And on the next slide *inaudible*. Can we have that slide, please.

Deborah Dunsire: [00:02:52] There is both strong momentum in vial demand for Vyepti. And we have seen growth around 50 percent two on two, and it's developing as anticipated in the US market, which is still experiencing some obstruction in patient to physician interaction. The payer coverage for why it has remained extremely good, and patients have *inaudible*, even in plans that require brand *inaudible*. The global rollout will get underway in mid-year with launches in the balance of the year for five countries. And we're taking the next steps on building this brand into a decade plus growth driver for Lundbeck.

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Deborah Dunsire: [00:03:38] One of the things that we're most pleased with it's how Vyepti is being received by the patients who take it. We see here a lecturer who gives us permission to share her story. And her life has been transformed as her headache has been controlled when she received Vyepti. We look forward to more and more of these patient testimonials of lives transformed as the Vyepti rollout continues.

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Deborah Dunsire: [00:04:10] We all know that the covid-19 related stay at home restrictions significantly reduced in-person visits, new diagnoses and therapy initiation, and that's impacted new patient throughout for both Rexulti and Trintellix. We're still experiencing some of the impact from the pandemic, but I believe we're seeing the early signs of recovery. In Q4 of 2020, when the US market was more open and we were seeing patients coming back to a degree and we were able to have our sales people interacting to educate physicians, we saw a good momentum pickup. We saw a close down a little bit in the beginning of the year, as you know, those next waves of covid rollout and we saw a concomitant decline in new cases and NRx, and now we're seeing that begin to recover.

So, that close down together with the annual deductible reset drove the dip in the early part of the quarter, but we're very pleased with the momentum as the quarter finishes. At the end of Q1, we're at about 55 percent of pre-covid in person calls and together with the virtual interactions that achieved about 80 percent of the pre-covid calls, and we're expecting that to continue to advance and improve as the months go forward.

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Deborah Dunsire: [00:05:41] There has been really good momentum for Brintellix/Trintellix, in both North America and in international market. In Japan, Trintellix has now reached a volume share of 3,5 percent, which makes it the strongest launch in a developed market among all our markets. We see a good growth inflection driven by the listing of the two week prescription limitation, which is something that's required for the first 12 months of any launch in Japan. The combined sales forces, Lundbeck and Takeda, driving education around the brand has been tremendous in driving uptake. For Canada, that's our third largest market, I'm pleased to say that we've achieved public reimbursement for Trintellix there and we expect that further enhance uptake.

Anders is now going to elaborate on the financial performance in more detail.

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Anders Götzsche: [00:06:45] In this waterfall diagram, we have illustrated the pushes and the pools that have impacted the quarter. Vyepti delivered 76 million in sales. We saw an encouraging growth of 8 percent for the strategic brand despite impact from the pandemic. And Northera was down with 35 percent in the quarter due to a more aggressive or more aggressive launches from multiple generics than... and more generics than anticipated. In Q1 last year, the pandemic led to stocking of our products, which has negatively impacted revenue growth this year, and the negative impact is approximately 2 percentage points. Depreciation of currencies have had a negative impact on the growth of approximately 180 million kroner. And that is, of course, also the reason for having a total decline in revenue for the quarter.

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Anders Götzsche: [00:07:43] When looking at the core gross margin, it was 86,6 percent and it's thereby unchanged compared to the same period last year. The reported gross margin decline due to amortizations of Vyepti. SG&A declined 11 percent, approximately 200 million kroner compared to the same period last year, which is mainly due to less marketing and promotion activities, as a result of the pandemic. If you adjust for the impairment charts we took last year of some 800 million kroner due to the Foliglurax write off, the R&D cost increased by 4 percent, and that is mainly due to the increased clinical activities for Vyepti.

The operating result, EBIT, reached 882 million kroner, corresponding to a EBIT margin of 26 percent. The core EBIT margin faced a modest decline from 29,7 percent to 29,3 percent. Overall, we see the financial performance in the first quarter as very solid.

Please turn to slide 11.

Anders Götzsche: [00:08:56] Basically, this slide does not contain any material... new information compared to when we announced the financial expectations for 21 in February this year. I think it's important to remind you all that Lundbeck's main currencies are USD, Chinese yuan, Canadian dollar, which together constitute about 70 percent of our currency exposure. We have,

as expected, seen depreciation for all the main currencies which impacted the growth negatively in the quarter with approximately 4 percentage points. You should also be aware of that some of the other currencies, such as Korean won and Brazilian real, have also seen sizable depreciations in the quarter.

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Anders Götzsche: [00:09:46] On the left hand side of the slide, you can see the development in our free cash flow. Profit from operations in the quarter has been quite robust, but the cash flow has been negatively impacted by a change in working capital due to timing in payment from partners, but also received shipments of inventory. To the right at the slide, it's shown that we have continued to reduce the net debt since the acquisition of all the pharmaceuticals leading to a healthy net debt to EBITDA ratio of one. We expect net debt to be around 3,5 billion kroner at the end of twenty one.

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Anders Götzsche: [00:10:31] The financial guidance for 2021 is unchanged and we still expect revenue in a range of 16,3 to 16,9 billion kroner. The generic erosion for Northera following the LoE at the end of February 2021 has been faster than we anticipated, and we therefore now expect a decline of approximately 70 percent in sales, corresponding to around 1,7 billion kroner, which is higher than what we communicated when we announced the full year expectation in February, where our expectations were approximately 1,3 billion kroner. This will, of course, put a bit pressure on our financial performance. But the other strategic brands are expected to show high single digit or to show double digit growth in the remaining part of the year and are expected to partly mitigate the erosion of Northera.

The mature brands are expected to decline around 10 percent, and that is due to normal generic erosion, but also BDP in China impacting Ebixa. Included here is also the sales impact from our handing back of Sycrest to Merck late last year. Sycrest realized the sales of 31 million kroner in the first quarter last year.

The growth and revenue for the strategic and the mature brands is expected to be approximately 1,1 billion kroner, which actually is better than we assumed in the beginning of

the year. We assume negative currency impact of approximately 600 million kroner and a hedging effect of approximately 50 million kroner, which will result in a net impact of around 500 million kroner. The explained movements in revenue are expected to lead to an overall decline in revenue for 21. The financial guidance for the earnings figures are unchanged compared to Lundberg's financial guidance provided in February 21, 2021. For the full year, you should expect financial items seems to be a net expense of 250 to 350 million kroner, depending on the currency development. We believe that the rest of the year will still be a year of uncertainties with factors that are beyond our control in relation to the pandemic. But we are, as a company, optimistic that the increasing number of vaccinated people globally will continue to drive the rebound of the growth of our strategic brands in the second half of 2021.

I'll now hand over the microphone to Johan for... going a bit more into the details of R&D.

Johan Luthmann: [00:13:23] Thanks Anders, please turn to slide 14.

Let me start with the resulting agitation Alzheimer's type dementia. As we wrote in the release on April 13th, and the independent interim analysis, in the ongoing phase III clinical trial, study 213, supports progressing the recruitment of patients to the planned full enrolment of 330 patients. Completion of the trial is expected in the first half of 2022. With regards to Vyepti, we are progressing very well with the global expansion and we have regulatory reviews ongoing in 12 markets, including EU and Australia, as well as countries in Asia and the Middle East. The clinical programs on Vyepti are also advancing very well to deliver trial, phase 3b study, that relates the effects of Vyepti for the prevention on migraine in patients with prior unsuccessful preventive treatments is well executed. And in spite of the pandemic, enrollment has been exceeding target. And we are expecting forward to look at the results at the second half of this year.

Additionally, we have initiated the pivotal global program supporting major findings in Asia with the so-called Sunlight study that is China centric, soon to be followed by the Sunrise study that is Japan centric. We also continuing to keep expanding and progressing the early stage pipeline, so programs can be evaluated in humans faster with gatekeeping experimental medicine studies. Overall, we have expanded and built a broader set of Phase one assets, including a couple of magli pace targeted molecules that are evaluated in a number of early exploratory patient

cohort studies. We are also continuing the further advancement of two promising early development programs, the alpha-synuclein and the pick up programs.

We continue to see a fluid situation around the pandemic, with clinical trial sites opening and closing again. This is primarily impacting studies starts, especially the early development stage studies, which are less flexible since they are heavily dependent on few sites and countries. In late development, the effects are more variable, with studies migraine doing very well, while others are more challenged regaining the enrolment momentum.

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Johan Luthmann: [00:15:47] Now I like to turn to interesting new data on Brintellix/Trintellix. Firstly, we are very pleased to share the positive data from the Reconnects study. This study evaluated effects of vortioxetine in patients with primary diagnosis of major depressive disorder, MDD, that had a comorbid diagnosis of generalized anxiety disorder, GAD. This patient category represents the largest subpopulation of patients with MDD, with the prevalence of comorbid anxiety disorder perhaps as high as 60 percent. This is also a patient population generally has a higher severity of illness with consequently greater impairment in functioning and thus more difficult to treat. In line with this, the patients enroll in Reconnects study were severely depressed and anxious, and the majority of the patients had already failed in other antidepressants. Patients were treated open label and flexible doses 10 and 20 mg vortioxetine with an uptitration to 20 mg after one week of treatment.

Vortioxetine effect on symptoms of depression was verified with an improvement on the Montgomery-Åsberg depression rating scale. More importantly, there was also significant improvement in anxiety symptoms, as measured by the Hamilton anxiety rating scale.

The improvement in depression and anxiety symptoms were strongly aligned with improvement in patients overall functioning and health related quality of life measures, which obviously are particularly encouraging giving the poor over a social family work life function in this group of patients.

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Johan Luthmann: [00:17:25] Relief is a real world study in which the ability to expand Trintellix to improve functioning in people living with the MDD was assessed. Leave was a global prospective observational study conducted in patients with MDD that were prescribed Vortioxetine. Data from nine 994 patients were collected at routine clinical visits at baseline three months and six months. The study demonstrated the ability of Vortioxetine to improve the daily life of people working... living with major depression and measured using the Sheehan disability scale. That's a scale that evaluates areas such as family, social life, home work and school. Additionally, the trial met all its secondary endpoints measuring quality of life, measures of depression, as well as reconfirmed Vortioxetine's positive effects on cognitive symptoms, as measured in two very different ways: a questionnaire and the neuropsychological test. As in the Reconnects study, the results released are particularly interesting in that it shows an effect Brintellix/Trintellix on family work and social life functioning. In the relief study, it's also very nice to see that we clearly demonstrated that Vortioxetine can restore brain health in an everyday clinical practice setting. With that, I turn over to Deborah.

Deborah Dunsire: [00:18:53] Thank you, Johan. We also have, as you know, we focus our business on medicines for brain health, but we also do it in a way that builds a sustainable company over the long term. Our sustainability strategy aims to ensure that the business activities are conducted in a way that supports the... as many as possible of the 17 Sustainable Development Goals, mitigate any risks to the business and create a diverse and inclusive organization where the best talent can thrive. And that remains in the top five percent of comparable international workplaces and several parameters. And we've been proud to receive the accolades of top place to work awards in multiple countries in the quarter. We drive diversity, equity and inclusion across our organization and also at our board level with the addition of two the board members. We now have 30 percent of our directors being women and we have seven nationalities within our board. Having achieved our 2006 long term climate goals, Glenn Beck announced in February a new 15 year climate target, which was approved by the science based target initiative. There are three pillars in this new target, and that includes: A commitment to being carbon neutral no later than 2050, which is aligned with the Paris climate agreement. Carbon emissions from our production and fleet will be reduced by two-thirds over the next 15 years and we'll also reduce the so-called scope 3 emissions, as we work with our

suppliers and customers to reduce their carbon emissions by nearly a fifth over the next 50 years.

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Deborah Dunsire: [00:20:42] As we forge ahead in 2021, we'll be working hard to continue to mitigate any effects of covid-19 and driving those strategic brands forward to get to the patients who need them. They'll also be looking to drive forward the pipeline. The regulatory process for Vyepti is continuing with expected approvals in Australia, as Johan said. And we're also expecting the recommendation from the European CHMP towards the end of the year with approval for Europe in the early part of 2022. Two of our early stage projects are also getting ready for phase two testing.

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Deborah Dunsire: [00:21:27] We're off to a good start this year and we aim to keep it moving. Our current top priority is to maximize the value of our brands, and they continue to perform robustly, as you've seen from the financial performance this quarter. The strength of the operating results over the past year, as well as in this quarter, give us that strong financial foundation to continue to drive our expanded investor growth strategy and deliver a sustainably, profitably growing company in the decades to come, as we focus on restoring brain health, so every person can be better.

With that, I thank you for your interest and open the Q&A session.

Operator: [00:22:11] Thank you. If you wish to ask an audio question, please press zero one on your telephone keypad. If you wish to withdraw from your question, you may do so by pressing 02 to cancel. Once again, please press zero one on your telephone keypad if you wish to ask an audio question.

Our first question comes from James Gordon from JP Morgan. Please go ahead.

James Gordon, JP Morgan: [00:22:33] Hello, James Gordon, JP Morgan, thanks for taking the

questions. A couple of questions, please. First one was over Rexulti Alzheimer agitation and the interim and its implications. So, if I remember correctly, I think there had been comments that if the *inaudible* had been in line with what we've been seeing for one week for Rexulti in previous trials, it could be good enough to stop the interim. And so does the fact that it didn't stop the interim, does that suggest that maybe the benefit you're seeing in this trial isn't as good as what you saw for Rexulti one week in previous trials? So, the question is, how does this make us think about or how should we think about the chances of success as a final result, now we know it didn't stop the interim? Any reason why it might not have looked as good? So that's the first question.

Second question, sort of connected to Rexulti and Alzheimer agitation. Business development – so it's a given, maybe some uncertainty around Rexulti and AA, and there isn't that much other late stage pipeline shots on goal – does that make it more urgent to do some of the deals ahead of the final data of Alzheimer agitation? Do you need to have a Plan B in place?

And then third and final question, just on SG&A, I think on the last call there was a comment yesterday could be something like 41 to 46 percent of revenues for the full year, but it seems like it Covid is continuing on longer in terms of delaying people getting back in the office. So should we assume SG&A is going to be on the low end of that 41 to 46 percent range and is it, sort of, Q2 similar to Q1 and then it's really the second half it goes up to.

Deborah Dunsire: [00:24:02] Thanks, James. I'm going to ask Johan to start with the description around the interim analysis, and then Anders will take the SG&A question and then I'll end with the beauty question.

Johan Luthmann: [00:24:14] Yeah, thanks so just a few back-end facts around the resulting agitation, as you recall, we had two previous studies and the strongest data was in the 2 mg group, either with a fixed dose or a subgroup analysis of the flexible dose that we looked at. So the 2 mg was the one that we showed earlier to work and show effects. And this study is looking at 2 and 3 mg in the pooled assessment. So there are sort of two arms here, a placebo arm and a pool group of 2 and 3 mg where we aim to have at least 100 people on the 3 mg dose. The interim was done at 252 subjects and we are now aiming for 330 to full enrolment.

In terms of, I guess what you are asking about are the bars that we set here. Let me first say the study continues – we didn't hit fertility, which was part of the analysis. So we obviously have a drug that is working. The question is how well it's working. And to hit the success, interim criteria, we needed to have pretty strong effects, obviously, with fewer subjects to accommodate for the variability being a little larger with fewer subjects. But we are aiming for a very robust effect to be able to have a solid conversation with the regulators. So now we're looking forward to finish the trial and see what kind of data we get in the ball range of working or working extremely well. That's what basically the design is now moving forward. And I'd like to add also we're doing our best to execute this trial as fast as possible. You may recall we had some issues getting patients into the study last year. We now have a number of activities, so we hopefully can speed up this trial.

Deborah Dunsire: [00:26:03]

Thanks, Johan. Anders?

Anders Götzsche: [00:26:04]

Yeah, the SG&A, you should expect that the ranges that we have given is actually what we still expect, because what we had also built into our estimate was that the promotion and marketing or the promotion of sales activities will be less in the first quarter and hopefully they will ramp up during the year. So the range that we set in Q1 is still applicable also going forward.

Deborah Dunsire: [00:26:36]

Great. And I think that, you know, our expansion of this growth strategy, we're constantly looking at ways to build the future sustainability of the Lundbeck and be active across all stages of the pipeline. So that remains true. And I think we've always said that we are going to be very disciplined about what we do. So we're not rushing in any way to try and do something before the A, the readout. We've always be looking to do the thing that's right for Lundbeck, and that we believe fit and *inaudible* the company. And it would be driven by the finding those assets, not by a specific readout timeline. If that's... I make myself clear.

James Gordon, JP Morgan: [00:27:25]

Thank you.

Operator: [00:27:32]

Our next question comes from Wimal Kapadia from Bernstein. Please go ahead.

Wimal Kapadia, Bernstein: [00:27:40]

OK, great, thank you very much for taking my questions. Wimal Kapadia from Bernstein. So can I just first ask on Vyepti, please. You know, recent trends have stepped up quite nicely in the US, and you say that 1Q was in line with your expectations. So can you just provide a little bit more color on what that looks like for the rest of the year. Maybe you can comment in relation to the consensus expectation of around 530 million DKK.

My second question is on Rexulti and borderline personality disorder. We expect from the phase II in mid-21. But just curious how we should think about this opportunity here, you know, in the US you suggest 1,7 million treated patients but no approved drugs. So how much of an inflection could we actually see from this label expansion? And, just tied to that, how much off label usage do you actually see for the product in BDP at the moment? And this is final question, is this an entree? We've now had four or five quarters producing similar revenue numbers. So I just want to get a sense of how we should think about the trajectory for the product from here – you know, how much downside is there, if less, if any, for this effort. Thank you.

Deborah Dunsire: [00:28:43]

Great, so thanks. I'll ask Peter to start on Vyepti and its performance and how we think about it in the rest of the year. And then, Johan, maybe you can talk about when we'll see the read out of Borderline. And Peter, talk about how you think about it in the marketplace. And then, Anders, would you comment on it.

Anders Götzsche: [00:29:08]

Maybe I can start with *inaudible*, you should expect our best guess it is 5 to 10 percent decline in 21 compared to 2020, and I can start with Vyepti, and then Peter can take over. So the consensus when you look at the trend line and if you just extrapolate that, then we are on the way to the 500 million, which is comparable to the consensus. But then, of course, we need to build in a caveat. And that is, of course, we expect that society is opening more and more up in the US and then Peter can take it from the.

Peter Anastasiou: [00:29:53]

Yeah. Hi Wimal, thanks for the question. Yes, in terms of Vyepti, it certainly was a good quarter and on track with our expectations, and I think it's a combination of a number of things. You're seeing patient volume starting to return, although not anywhere close to full volume. Our reps are able to get in front of our customers. Physician practices are getting closer to being fully operational and back online. And then also there's a number of things, as you know, that are now in place that are very important to create the momentum that we're seeing with ASP being published now for the first time and then will continue to be on a quarterly basis. Market access situation is quite good. We have two 235 million patient lives that have access to Vyepti in the US, which is great. And of course, *inaudible*. So all those things create a runway that we believe will get us where we need to be for the year. Of course, the big outlying uncontrollable factor is Covid. Will there be any future waves, that sort of thing? But we're pleased with the momentum that we have.

Deborah Dunsire: [00:31:05]

Great. And would you like to comment the borderline Rexulti, Peter? Just in terms of the inflection...

Peter Anastasiou: [00:31:15]

Yeah, obviously, I won't give specifics about what kind of a sales increase we would expect, but yes, there is, of course, off label use that we that we hear about. It's tough to quantify the product, of course, in terms of delivering remains to be seen with the phase II readout, but the market opportunity is a meaningful one. There is no approved treatment. It's a sizable population in the US. These patients have a lot of disability and are very challenging patients for physicians to treat. And so they are looking for new therapies. And so we believe this is shaping up to be a meaningful label expansion, when the study results come out and we see those.

Deborah Dunsire: [00:31:08]

Johan, Any comments on the timing?

Johan Luthmann: [00:32:12] Yeah, let me just fill in a little what Peter just said there. This is, you know, of course Rexulti has a great profile, but we're going into an indication that it's extremely hard, and we actually are running a proof of concept study here. It's the phase 2 proof of

concept study, because of several things. First of all, there is no established therapy, and the readouts are also new readouts – they're not established. So we have to pave the way here – a completely new ground. So this is a challenging study and challenging indication. And we're looking forward to see the outcome of the study. It's actually fully enrolled, so we know the timelines pretty well. We'll get it by the shift of the year, medio, and basically then we'll see what data we have and how we'll progress for this asset.

Wimal Kapadia, Bernstein: [00:33:01] Great, thank you very much.

Operator: [00:33:06]

Thank you. Our next question comes from Michael Leuchten from UBS, please go ahead.

Michael Leuchten, UBS: [00:33:13]

Thank you. Three questions, please. Michael Leuchten from UBS. Just a question for Peter. Has there been any stocking going into the year after Q4? Anything that will make the underlying growth less good than the quarter cosmetically looks like.

The second question, Deborah, you commented on your sales force and your... the digital efforts. Is there any way of quantifying the level of effectiveness of the promotional activities now relative to where you would expect it to be if there hadn't been a pandemic? Maybe it's impossible to say, but I just wondered if there is a way of measuring your impact at the moment, given that you're running a dual strategy.

And then the third question is on Vyepti DTC. Can you talk to timing on when you will roll out an initiative, and when would you expect a return on that? On that in terms of quarters, say, if you did it now, would that then be seen in Q2 or what do you think it's going to take a little bit more time to convert that into revenues? Thank you.

Deborah Dunsire: [00:34:26]

Peter, you can maybe start with talking about the Vyepti DTC?

Peter Anastasiou: [00:34:33]

Yeah, Michael, you didn't specify a product, so I assume you mean overall and the short answer

is no, there's no stocking effect beyond normal quarter to quarter swings that would explain in the first quarter performance. There's no one time events, anything like that. This is true momentum. I think, you know, I'll steal a little of the answer from Deborah's second question about promotional activities. And you can see from the slides that that Deborah showed that when we are able to get in front of our customers, the customers respond and the prescriptions go up in terms of new prescriptions. And there have been ebbs and flows in our ability to do that. But we feel confident that as the pandemic recedes, as we can get in front of our customers and right now we're doing a relatively good job of getting back in front of our customers and the brands are responding. And so that explains, I think, the good performance that you saw from the strategic brands in the first quarter.

Deborah Dunsire: [00:35:36]

And then Vyepti DTC?

Peter Anastasiou: [00:35:39]

Yeah, DTC is something that we intend to do with Vyepti. The timing of it is something that, in a little bit, is out of our control for two reasons: One, we we need feedback from the FDA. As you know, for all DTC campaigns, you need to have those precleared. And so feedback from the FDA is critically important. And given all their other priorities with with Covid and approving treatments, it's tough to know exactly when we'd be able to receive that feedback. The other piece is, of course, the timing really does depend on Covid and patient volumes. We certainly want to make sure that we're launching the DTC campaign, when the physician practices are ready for the influx of patients, but also that the patient volumes are getting back to close to normal. So it is in our plans and our armamentarium. The timing remains to be determined.

Deborah Dunsire: [00:36:40]

And just commenting on *inaudible* a little bit more, I think that what we do know is that the person could call converts to a prescription much more frequently than the virtual engagements do. And I think we've seen that in our own interactions, but we also see it with *inaudible*. Physicians interacting virtually with patients also don't initiate scripts. And so the virtual adds something, and I wouldn't put a quantification on it, but it's certainly not as effective in converting to prescription as it is in custom call.

Michael Leuchten, UBS: [00:37:27]

Thank you.

Operator: [00:37:28]

Our next question comes from Martin Parkhøi from Danske Bank. Please go ahead.

Martin Parkhøi, Danske Bank: [00:37:33]

Yeah, hello. Martin Parkhøi, Danske Bank. First question is probably for Jacob. Just if you could elaborate a little bit on the on Japan and Trintellix in absolute terms, how much are we talking about now in sales in Japan? And maybe also a little bit on the combination, because, of course, also Lexapro is still also active in Japan. How are these fairing in combination, combination with respect to market share position?

And then a second question to Anders or maybe Deborah. It was... you were quoted on newspapers today, talking about growth for the next six to eight years. If we look beyond 2021, maybe you can elaborate a bit on that and maybe discuss the growth on on the regional development. And then just finally for US, maybe you could talk a little bit about the net price development you are seeing on your products right now in the US in 2021.

Deborah Dunsire: [00:38:44]

Thanks Martin. Jacob, over to you.

Jacob Tolstrup: [00:38:46] Oh, absolutely. Thanks Martin. As you've seen also from the release and the comments that we have made, I think, probably doing today, but I would it's actually going really well in Japan, and we were hit during the pandemic last year. We have... now we have about 50 percent access to our clinics and university hospitals and so forth in Japan. Last year, that gave us issues in terms of getting started. But as soon as the two week prescription ban was lifted in Japan, market share has climbed very fast. And looking at volume market share, Japan is now our best launch ever for a transgenics, so they have done a super job in Japan for Trintellix.

I don't think we commenting on how much sales that we get specifically for Japan on Trintellix, Martin, so I can't help you with that. But of course, as you know, Takeda takes the line share and we get around 30 percent of that is coming back to us in terms of royalty for the brand. But I don't think we've given specific sales numbers. If we look at new scripts, and we are we are climbing up fast and we are the leading brand in capturing new patients. But of course, we are still a coming from a lower level than the others in terms of the total market share, but changing fast. And I think one dynamic that is about to change is that we will see generics on Cymbalta relatively soon in Japan. So that could change some of the market dynamics there.

Martin Parkhøi: [00:40:39] In which way do you think it will change?

Jacob Tolstrup: [00:40:43] Yes, so right now we are actually climbing on fast. That means that I think we're building up a great reputation for the brand. So difficult to know, but of course that always gives a different pressure in the market that you have one more generic entering. But I would say that that has always been part of our plan. And looking ahead to we, we see no change compared to what we have estimating in terms of growth for the year.

Deborah Dunsire: [00:41:16]

Jacob, Martin also asked about can Lexapro and Trintellix... co-existing?

Jacob Tolstrup: [00:41:22] Hmm, yeah, that's a great question, and I would say Lexapro has done very well, doing the pandemic. One of the benefits of having a bigger portfolio. So how we co-position them hasn't changed, meaning that in many markets, but be able to promote Lexapro, the focus has been on anxiety, whereas for all markets, the focus for Brintellix/Trintellix and has been around recovering your functioning. So sort of complete recovering of the of your function as a patient, not only looking at depressive symptoms, but the total functioning. And that has worked very well. So Lexapro is primarily used in an anxiety setting.

Deborah Dunsire: [00:42:06] And commenting on the growth in the coming years, I think that the major loss of exclusivity are behind us and of course, we have to wash Northera, too, and you'll see that this year. And then we will have a period of relatively uninterrupted growth over the coming years. So that's a good picture for us. And with the robust financial base that we have, it's a great place to grow from.

Anders, would you like to add any comments?

Anders Götzsche: [00:42:38] And of course, we expect that the challenge we will have is of course in Europe, but we still, we will have the pan-European launch of Vyepiti starting in 22, which we expect would fuel the growth there. So we strongly believe that we will see 6 to 8 years of growth in... coming through 21. Then we would see a continuously growing business. And with respect to the net pricing question you had, I assume it was related to US, and if you look at the majority of the products, the gross to net has not changed dramatically. Of course, when you come in the earlier phases like Rexulti, the gross to net has changed slightly. And then you have on top of that, you of course have the price increases taking. So, overall, if you look at the average net price, then it has been increasing, and that is also part of the growth that you're seeing. And then in some of the regions, you would say, but it seems how can you speak about growth for the brands? But if you look at the last, in Q1 last year, you would also see that we had a super growth for some of the products, which was due to the stocking in March pre pandemic. So, overall, the underlying growth is actually pretty nice and also supported by the pricing actions this year and last year.

Martin Parkhøi: [00:44:12] Thank you.

Operator: [00:44:16] Thank you. Our next question comes from Trung Hyunh from Credit Suisse. Please go ahead. The line is now open.

Trung Hyunh, Credit Suisse: [00:44:26] Hi, guys, it's Trung Hyunh from Credit Suisse. Three questions from me. Firstly, on your guidance, just some of the reasoning why you're keeping the guide, given that there is now 70 percent erosion for the year. Is it simply that the expectations for the growth drivers are just going much better than you thought since the start of the year? And is there anything else that's doing much better than you originally thought?

Secondly, just on costs, following up from James's question on SG&A, just to clarify the cadence of spending through the year. So do you think 2Q is going to be a similar quarter as 1Q. And similarly, just on R&D spend, just how that progresses for the year? And then finally, just your

opinion on Lundbeck being taken out the MSCI? I think it's tonight. Do you think that's going to impact the stock indirectly? Any thoughts here would be interesting. Thanks very much.

Deborah Dunsire: [00:45:23]

Anders, maybe you can comment?

Anders Götzsche: [00:45:25] So if I start with the guidance, it goes without saying, you know, it is approximate numbers, so we have... we went from approximately a decline of 50 percent to 70 percent, and we have estimated in our books it's around 400 million down on revenue. That, of course, put a bit pressure on the guidance, but on the other hand, we have seen some of the uncertainties we had when we entered the year, seems that they're a bit less for the for the strategic brands. But of course, and that's due to we see that the vaccination levels are going up. We see that societies are reopening. We also accept that some countries are still suffering dramatically. But in the major countries, we see a good momentum, and that is why we believe that we can be balancing out the faster erosion from Northera. But, of course, that needs to be seen during the year, but we are still confident that we'll be able to deliver the guidance.

From SG&A and R&D perspective, I'm not going... I don't want to go into details for each and every quarter, but it goes without saying that we have been building into our estimate that we had a gradual return to normal, so you would see that in in Q2. We hope that we will have more pressure behind the sales and marketing efforts and then it will... we hope it will be more back to normal in Q3 and Q4. But that needs to, you know, we need to see how it plays out, and then some activities might be moved around the quarters. But for the time being, we expect that the SG&A ratio that we told you in in February is still holding up, and that is around between 41 to 46 percent. So you could say, is it 43-44 percent? That is what we believe in now. And then we need to see how the quarters play out.

And with regards to the share price and inclusion in different indexes, I think you have as much knowledge as we have, and your speculation around the impact on the share price is actually better than ours. So I rely on that. You are more capable of evaluating that than we are.

Deborah Dunsire: [00:47:48] Anything to comment on the R&D cadence on spend?

Anders Götzsche: [00:47:53] Yeah, so I think we have said... I just need to double check so I don't say anything that is out of context, but we have said that the R&D percentage is... should be between 22 and 24 percent for the full year, and that is still what we believe in – That, that is the spending level.

Trung Hyunh, Credit Suisse: [00:48:18] Thank you very much.

Operator: [00:48:24] Thank you. Our next question comes from Karsten Lundborg from SEB. Please go ahead.

Karsten Lundborg, SEB: [00:48:30]

Thank you very much. I only have one left. I was hoping to get a little bit more color on the emerging market performance, because you actually delivered 4 percent year-over-year growth in constant currencies, despite having delivered 17 in Q1 last year. And you have some headwinds from the VBP in China etc. So, I was just wondering, Jacob, could you give us some more color on what's the driver here, because you are up in growth was Q4 and maybe also there's a lot of focus on this VBP in China. Is everything in the numbers now for Ebexa or do you expect anything more in the coming quarters here? Thank you.

Jacob Tolstrup: [00:49:14] To comment on that, there are different pools and pushes for the quarter, Karsten. You are absolutely right on VBP for Ebexa, that that is something that has taken us down in terms of growth for the quarter. On the other hand, also remember that China last year was going through the pandemic earlier than everyone else. And that meant that early on we were actually behind in China in Q1 last year. So that sort of pulls in the other direction. And then for other markets, we had stocking going in. We had a product, Sycrest, that we've handed back to Merck, which also has a smaller impact on some of the international markets. So it goes a little bit in both directions, but that also means that at the end of the day, all of those effects basically equals each other out. And that means that what we're looking at is demand driven. It's performance that is driving the growth for the quarter for many of these markets. And on VBP for Ebexa, we have lost market share after VBP. We are now at a level where we are able to then, you can say, promote and compete again. One of the generic suppliers last year were not able to deliver, that gave us a little boost at the time. And now we are down at a level where we

are promoting again, and we are actually able to grow Ebexa a little bit again, locally, but at a lower level, of course, than what it used to be.

Anders Götzsche: [00:50:56] But I think it's fair to say that our expectation for Ebexa the upcoming quarter is also a bit lower. So that would be a bit more impact on the international markets in Q2 and Q3. So, still it has been rebased to some level, but we believe that we need to see a bit more decline in the upcoming quarters. What we believe, on the other hand, is that the strategic products, they will actually be growing more in the upcoming quarters, but on the other hand, some of the mature products will be dragging a bit down.

Karsten Lundborg, SEB: [00:51:33] Ok, thank you.

Operator: [00:51:36] Our next question comes from Michael Novod from Nordea Market Equities, Please go ahead.

Michael Novod, Nordea: [00:51:45] Yeah, thanks a lot. And three questions from my side. So, first of all, to Trintellix and the Reconnect the Relief data – so how fast and how wide can you start to use the data? And how important is it also to sort of see the rebound in Trintellix, particularly in the in the US?

And the second question is to Vyepti in Europe. Again, how fast do you expect sort of reimbursement to be concluded? We see that CGRPs in generally have good access in in Europe, and do you expect this to also be sort of a fast reimbursement process for Vyepti. And then lastly, on the Trintellix generic court case, do you still expect this to be concluded during June, July?

Deborah Dunsire: [00:52:32] Great. Thanks, Michael. I think on Reconnect and Relief, I'm delighted with the performance of the Trintellix profile in major depressive disorder. All of these things help, they don't change the label. And, as you know, so they'll be presented at scientific meetings, they'll be used in medical education, but they're not promotional in the sense... What it does, it highlights the benefit of Trintellix on function, even in patients who have concomitant *inaudible* disease. And it helps us with payers that we can really talk about how to Trintellix does perform extremely well in the real world, because we *inaudible* questions sometimes, you know,

to see *inaudible* controlled clinical trials. Do they demonstrate what happens in real world? Our Relief really does that. So, I think that they will add to the body of evidence that this brand is an ideal brand for people facing major depressive disorder who need to be able to function normally and, frankly, who doesn't. So I'll stop there and maybe, Peter, do you have any further comment?

Peter Anastasiou: [00:53:52] No, just emphasize your point. These data are extremely helpful to be in the public domain and with key opinion leaders and other scientific exchange venues and well, I completely agree with your point. While we have excellent coverage, payer coverage, with Trintellix, these data just further reaffirm the value that Trintellix brings to patients and the real world and help us on those levels. Yes, that's right.

Deborah Dunsire: [00:54:23] Jacob, perhaps you can comment on Vyepti and approval?

Jacob Tolstrup: [00:54:26] So hopefully the plan is, or not hopefully, the plan is that we expect to have approval of Vyepti early next year and then we will begin the European rollout. There's a couple of things that you have to look for here. First and foremost, this is an infusion product, being a biologic, there're a little bit of a longer lead time for us to have products available in the market. So that's that's one factor from approval. But when it comes to market access, we believe at that time we will have all the tools in place to have that discussion. And actually looking at the other CGRPs and the success that they've had in most markets of getting through and getting good pricing, we believe actually it will help us in the discussion. So I don't expect it to take longer than what has happened for the other CGRPs. In fact, it should actually be more helpful for us that they've sort of established a pathway. And with the *inaudible*-trial that we are coming through with, we believe we have all the data to go in to have a good discussion with authorities around that. So it will be a typical, you can say, European rollout where you begin with a market where you can easily get into and secure a price, and then it will be sort of a phased rollout as soon as you can. But that still means that it takes anywhere between two or three years before you're into all European markets, which is very common and not something to do with Vyepti – also the same that it took for Trintellix, as an example.

Deborah Dunsire: [00:55:58] Anders, perhaps you could comment on the Trintellix generic lawsuit?

Anders Götzsche: [00:56:05] Trintellix lawsuit?

Deborah Dunsire: [00:56:10] I think the measure that is, that we... there's nothing telling us the time line has changed. I know that some times this causes delays, but right now we haven't heard anything different. And it's going to be driven by *inaudible* then.

Michael Novod, Nordea: [00:56:32] Super. Thanks a lot.

Operator: [00:56:33] Thank you. Our next question comes from Casey Arklaka from Goldman Sachs. Please go ahead.

Casey Arklaka: [00:56:40] Hello, thank you for taking my questions. Casey Arklaka from Goldman Sachs. I have two related questions, please. On your guidance, it would be great if you could share your refreshed assumptions behind the top end of the range, especially given the steep decline that you now expect from Northera. And on a similar note, relative to the start of the year. Do you think you're more or less confident about achieving the top end of the state's guidance range? Thank you.

Anders Götzsche: [00:57:08] Yeah, thank you for the question. Thanks for the question. I'm not at this point in time, I'm not willing to go into speculation around if it's a... what kind of level where we are heading into the range. We're still keeping... we believe we will be within the range, and then, you know, we will see in the upcoming quarters where we are ending if it's the top end or the low end – that I don't want to speculate on now.

Casey Arklaka: [00:57:37] Thank you.

Operator: [00:57:41] Thank you. Our next question comes from Peter Welford from Jefferies. Please go ahead.

Peter Welford, Jefferies: [00:57:49] Hi, yeah. Thank you, I've got four quick ones left over. Just firstly on the, with regards the synuclein antibody, I'm curious if you can outline, is the plan only

now to consider orphan indications like MSA or are you still considering moving forward as well with the proof of concept study in Parkinson's?

And secondly, just on the Parp-*inaudible* antibody, anything you can give us with regards to what the phase 1 told you? Were there any conclusions from that or was it just a case of its past and now going into phase 2. Further, then just on contract manufacturing. Revenue is obviously weak in 1Q, is this just phasing and we still sort of see similar for the year, or is there anything that's happened there, contract wise, that means we should be looking at a different number for this year on the contract manufacturing line?

And then finally, just on Vyepti, US coverage. Appreciate that in terms of the number you could access, but wonder if you could talk a little bit about the type of access you have for Vyepti in the US with those 235 million lives and how that's changing at all. Thank you.

Deborah Dunsire: [00:58:52] So I, I'm *inaudible* there, but I think the first indication of MSA, we think it's a great place for *inaudible* to have to go. It can give us a lot of insight into the profile of the molecules. And then we'll be able to see if it's something that we can and should take into a broader indication in Parkinson's disease. But I think we want to see some clinical outcomes there on MSA to guide us in the path forward. And then, Johan, any further comment on *inaudible*... question?

Johan Luthmann: [00:59:29] So just to add a little bit on the alpha synuclein, of course, we're going into the MSA, as you heard, and we'll talk more about that in the fall. We expect to start a study by the end of... before the end of the year. There are obviously many things you can do beyond that, but we like to see some encouragement in the data set. There are many things beyond Parkinson you can do with alpha synuclein, so we're considering several other things on the way. For *inaudible*, we're basically wrapping up phase one. We have good data, so far, it looks fine from a pharmacokinetic perspective. Tolerability etc. is acceptable to progress. We still have to go through some regulatory reviews to progress into phase two, and we're sorting that out with the Europe FDA. We also need to see a little bit more of biomarker data, target engagement data, really to fine-tune the program, phase 2 proof of concept program, that we expect also to start by next half of the year.

Deborah Dunsire: [01:00:33] Great. And, Anders, on the contract manufacturing?

Anders Götzsche: [01:00:37] You should expect a 10 to 15 percent decline compared to 2020. That is our expectation for the time being.

Deborah Dunsire: [01:00:46] And, Peter, on the Vyepti coverage?

Peter Anastasiou: [01:00:54]

Yeah, thanks for the question, Peter. So to give a little bit more insight, about 110 million covered lives have no branded steps that are required. There are generic steps that are required, that's the norm for all the CGRPs. But branded steps, zero required for 110 million patients. There's another 33 million patients that are required to have one branded step. But what we've seen, actually, is that irrespective of having branded steps or not, our market share is quite similar. And I think that that speaks to the fact that there is a high degree of dissatisfaction with current treatments, whether they be the generics or even, quite frankly, some of the more recent launches in the space. That dissatisfaction is the norm, and so our market share is comparable irrespective of whether there's branded steps or not. And then the balance getting up to the 235 million, those are a variety of other restrictions that might be in place, two or three branded steps that are required. But in total, that's what we were trying to describe, that substantive access is available for 235 million. And then hopefully those other details I gave you provide more insights.

Peter Welford, Jefferies: [01:02:12] That's great. Thank you.

Operator: [01:02:15] Our next question comes from Rosie Turner from Barclays. Please go ahead.

Rosie Turner, Barclays: [01:02:22] Hi. Rosie Turner from Barclays here. Thank you so much for taking my question. And this, too, from me, an apology for being to third person to turn back to Northera. But in this prepared remarks *inaudible*... the strategic brands can partly mitigate this increased erosion. And, obviously, kind of, the top line is probably *inaudible*... near the bottom line, given the kind of solid margin profile we expect for Northera historically. So just to clarify, do you expect that this can get banned to mostly offset this increased erosion or that going to be

other movers that are going to have to pull to maintain guidance? It would be fantastic if you could comment on that.

And secondly, in terms of the strategic brand turning to growth and here I mean kind of Rexulti and Brintellix/Trintellix. I mean, historically, before the pandemic, they were growing at the kind of 30 percent range, and I think you said that next year we kind of see a *inaudible* uninterrupted growth, does that mean we can expect getting back towards those levels in 2022 or do you think that's a further *inaudible*... and that's something we can expect to come through at the end of 21. Thank you

Deborah Dunsire: [01:03:45] Great. Anders, do you want to start with the...

Anders Götzsche: [01:03:45] It was a bit difficult to hear the questions in the room, but but if I understood your question right, it was about the Northera decline, or?

Johan Luthmann: [01:03:56] And the strategic brand offset also.

Anders Götzsche: [01:03:57] OK. Yeah, so I'm not, you know, what you know is that, you know, it's we have tried to lay it out in the presentation. What is the equation you should look into from... what is the decline in Northera? What is the growth for the strategic and mature brands? And at top of that, we have also said that we believe that double digit growth for the strategic brands in the second half of the year is pretty realistic. That's no, we do not see any roadblocks in front of us why we shouldn't be able to generate the same kind of growth numbers that we saw before the pandemic. So, you know, that is what you need to take into the equation of looking into to what is kind of the... how should you evaluate the year, and we basically have no more input to that.

Deborah Dunsire: [01:05:02] I think we will have to take the last question.

Operator: [01:05:09] Our last comes from Mark Edmund from SVB Leerink. Please go ahead.

Mark Edmund, SVB: [01:05:16]

Yeah, hi, Peter, I was wondering if you could comment on how you think the oral CGRPs are impacting the migraine market so far, and obviously with prevention indication coming least expected on one product and then have these product, you know, separate product for prevention comes in. Just curious how you think that playing into the market. And then just secondly, just in R&D. Can you give us an update on where the tar antibody is. And the D1/D2 on Parkinson's, are these moving forward? Are we going to see data anytime soon in the same way that you helped us with the alpha synuclein thought process?

Deborah Dunsire: [01:05:58] Great. Peter?

Peter Anastasiou: [01:06:02] Yeah, thanks for the question, Mark. From our perspective, the oral CGRPs, we don't see that as having an interruption to the momentum that we now have with Vyepti. This market, as you know, is an enormous market. There's 14 million patients that qualify for prevention treatment. Only half of those have either been treated in the recent past or are currently being treated. So there are plenty of patients out there. And as you also know, with the whole anti CGRP market, that's only penetrated the market as a class by about 10 percent. So I don't think we're anywhere close to a share battle between either the subcu or the oral CGRPs kind of taking share away from each other. All boats can rise. All of us together can continue to have the greater penetration of the market. And so I don't see the oral CGRPs as being disruptive to Vyepti.

Deborah Dunsire: [01:07:05] Thanks. And on your tar question, the tar antibody, it's a it's a great antibody. We believe it addresses the right *inaudible*, and we believe it's best positioned in Alzheimer's disease. And therefore, we would look for a partner, and we would not take that forward alone in a disease prevention in Alzheimer's disease. So that is progressing, but we will not take it forward into further development unless we partner it. Johan, If you have any further comments and then perhaps you can comment on the D1/D2.

Johan Luthmann: [01:07:38] Yeah. So the tar antibodies are basically through phase 1, and it looks like a good antibody. And you heard the rest of the story. We have actually targeted engagement biomarkers so that they're looked at. So it's a good, good package around that antibody, but it's a little bit too *inaudible* for us to take on to move forward. And, you know, the uncertainty in the field on how antibodies. For alpha-synuclein, data, I think the question was

when we can expect to see data. Obviously, we will come back to that in more detail, but we're going to run a sort of a stage phase 2 or 3 program, which is going to be a biomarker enhanced with the readouts looking at neuroprotective effects and clinical effects. So we're going to gradually in the coming years, I have to say, because it's a disease modifying approach, release data that will be package wise more a proof of concept part and then more clinical, full pivotal data if we continue. So I cannot give more details.

Deborah Dunsire: [01:08:36] When Mark's question also went to the D1/D2

Johan Luthmann: [01:08:42] D1/D2, I didn't hear that. Yeah, that is progressing. It's the dark-to-D program, as we call it, for off time effect in Parkinson's Disease. It's basically on its way out of phase 1 within, sort of, sometime next year. And we have really nothing that could stop us progress with it. It is, of course, a matter of differentiation and getting enough effects. We do look at some patient effects right now and we'll see how that evolves. But it would require the proper proof of concept study, of course.

Deborah Dunsire: [01:09:20] That's the last question, so I think we will wrap. Over to you operator.

Operator: [01:09:26] Thank you very much. There appears to be no further questions. So I will hand back to you for any last remarks.

Deborah Dunsire: [01:09:34] Well, we look forward to the rest of the year evolving, the world opening up and the momentum continuing to build in our strategic brand. And the growth of Vyepti in the US and the roll out of Vyepti globally. So thank you for your interest in Lundbeck. And we look forward to speaking with you at the end of the second quarter. Thank you.