H. Lundbeck

Transcript: Financial statements for the first three months of 2022

Date & time: 11 May 2022 at 13.00 CEST

Operator: [00:00:00] Ladies and gentlemen, welcome to the financial statements for the first three months of 2022. 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, Johan Luthman, Executive Vice President, Research and Development. Bjørn Mogensen, SVP Group Finance. Speakers. You may begin.

Deborah Dunsire, CEO: [00:00:34] Hello everybody and welcome to the first quarter update from Lundbeck. Thank you for joining us. Next slide, please.

Deborah Dunsire, CEO: [00:00:43] That's looking at our forward looking statements. I know you've all read them before, so we'll move on to talk about the business. First quarter in 2022 has been a strong quarter driven by the momentum behind our strategic brands. Revenue achieved 4.4 billion, up 2%. Up 9% in total, when we adjust for the Northera loss of exclusivity. The strategic brands were up 25% in aggregate and now constitute 61% of the total revenue of Lundbeck. Vyepti continued to grow strongly, achieving 170 million Danish kroner. And we have, of course, seen some benefit from the rising exchange rates. In the first quarter, we saw limited impact from the Russian war. The EBIT reached 1.2 billion and the core EBIT margin reached 27.1%. Vyepti has continued to roll out globally and is now approved in over 40 markets, of course, including the EU, where the approval was achieved back in January. We've also continued to ready ourselves for the global launch, completing the SUNLIGHT trial, which sets us up for a potential submission in China. So we've completed a recruitment there and Johan will talk more about that program. With Brintellix/Trintellix we've continued to deliver on our phase IV program, achieving a positive headline results in the VIVRE phase IV study, which Johan will talk about in more detail also. And we are on track to deliver the headline results from our agitation and Alzheimer's disease with Rexulti trial in the middle of 2022 and also now have a possible path for PTSD headline results within 12 months. We've also continued to make great

progress with the early stage pipeline. Now let's dove into the strategic brands and a bit more detail. Next slide, please.

Deborah Dunsire, CEO: [00:02:39] They are our major revenue contributors, up 25%, 18% in local currency. So all of them showed double digit growth in Q1 2022. And we're growing significantly in all the regions, 24% in the US, 38% in international markets and 18% in Europe. We expect that strong momentum to continue into the balance of the year. Next slide, please.

Deborah Dunsire, CEO: [00:03:09] Vyepti growth is continuing and we're seeing several new markets launching. We've launched several in the first quarter in Australia, Singapore and Switzerland. The two launches that we did in the latter part of last year, UAE and Kuwait are looking very promising. And in total, we've got a plan for around ten launches in 2022. On track, we recently got approval in Brazil. In the US, we're seeing normalization of our commercial engagement. We do, of course, see Q1 impacted by the reset of the high deductible plans in the US. But we're continuing to press forward with both in-person promotion, but also our patient activation campaign, which has been in social media and other more directed media we're piloting now in a broader set of media. Next slide, please.

Deborah Dunsire, CEO: [00:04:06] Brintellix is showing solid double digit growth with good growth in demand. There's strong market uptake in international markets, including China, Brazil and Japan, where we've reached an exceptional 6.4% market share together with our partner Takeda. We do see increased market shares in other countries Australia, Canada, Italy and Spain leading the way. The news flow is continuing with the positive VIVRE trial. Next slide, please.

Deborah Dunsire, CEO: [00:04:37] Rexulti is also continuing to grow strongly up 24%. There's been strong uptake in recent launches in Brazil and Italy and the volume share has reached 3.3% in Canada and exceeds 2% in the US. Now that we're starting to get back to a more normal promotional cadence. And we're on track for those important headline results in the middle of 2022 in Alzheimer's agitation. Next slide, please.

Deborah Dunsire, CEO: [00:05:07] Abilify Maintena is also growing well and we have seen a return to growth in the LAI market in the US. There's been solid market share gains and it's very impressive to see that market shares in the UK have now are now up to 42% and Italy and

Switzerland are well above that one third market share. Abilify Maintena continues to deliver for our patients. Next slide, please.

Deborah Dunsire, CEO: [00:05:38] Over to Johan.

Johan Luthman, EVP Research & Development: [00:05:39] Thanks, Deborah. We are actually making steady progress in R&D with several key events recently and more coming up in the coming year. Last quarter we reported Rexulti sNDA for treatment of schizophrenia in adolescents and it was approved by FDA. However, the big upcoming event for Brexpiprazol is naturally the pivotal trial readout in agitation Alzheimer's disease. As you may recall, the enrolment of patients in the ongoing trial was much affected by the COVID 19 pandemic. But through a very strong effort across the Otsuka and Lundbeck teams, we are now on track for readout in the summer. I will come back to that in some more detail in the coming slides. As you heard from Deborah, we are also now looking forward to finally being able to have a readout in the ongoing pivotal trial in post-traumatic brain disorder with Brexpiprazol. This is a program consisting of two trials that were also substantially impacted by the COVID 19 pandemic. While we have been pleased to see some partial recovery of the randomization in those trials, the more important factor is that we and our partner Otsuka had a very fruitful discussion with the FDA, which allows the change in the design of the program. We now possibilities to conclude the study within 12 months. For Vyepti we have now authorized the drug in 41 markets. And while the review is ongoing with 12 regulatory agencies. As part of the global rollout, we are conducting a clinical trial program to support filings in China and Japan with the SUNLIGHT, SUNRISE and SUNSET studies that Deborah mentioned. The SUNLIGHT study in chronic migraine with medication overuse, we have reached full enrolment. We did that in mid-January. And that despite the escalating COVID situation in China. We are therefore on track for headline results from this study in the early fall. The SUNRISE study, which is a much larger study with target enrolment of 530 patients and a much larger cohort in Japan, in addition to a major proportion from China, is also progressing very well. Thus, the nice execution in those studies is keeping us on the expected timelines for regulatory submissions in China and Japan. The strong profile of Brintellix/Trintellix has been well documented in a serious, well-designed and impactful phase IV studies. Most recently, we had a readout in the VIVRE study, as Debra mentioned, that was a direct head to head comparison of Vortioxetine in versus Desvenlafaxine, described that also in some later slides. Another upcoming event is the submission of Aripiprazole two month

injectable formulation. That will add to our current Abilify Maintena brand for once monthly injections. We are looking forward to submissions to EMA and US during the coming months. From our Phase II pipeline, I like to mention 9222 to our high affinity anti PACAP antibody, which has shown in early clinical studies to bind with high affinity preventing peak up receptor activation. 9222 had a good trial start up in the rather large hope proof of concept study and it's progressing well towards the readout during H1 2023. Next slide, please.

Johan Luthman, EVP Research & Development: [00:08:55] Since the readout is now coming up in our ongoing phase III trial, Brexpiprazol in agitation and Alzheimer's disease. I'd like to remind you about this condition, which has a very common occurrence and includes an extremely troubling set of symptoms. The agitation is triggered by a range of factors, including confusion, anxiety and hallucinations. It constitutes a very high burden on caregivers and families and the health care system. Due to those challenges, it is a major cause of nursing home placements. Current treatment options are very unsatisfactory. While patients are commonly prescribed older antipsychotics that are heavily sedating and causing disturbances in motor functions. Agitation in Alzheimer's disease occurs in well over a million patients, of which the majority are in community or family care. And thus an effective treatment may delay institutionalization and escalating health care costs. Next slide, please.

Johan Luthman, EVP Research & Development: [00:09:49] So, with Brexpiprazol we are now running a third pivotal trial to support eventual registration for this indication. Data from the two previous phase III studies showed, that those are two milligrams per day was efficacious on the Cohen-Mansfield Agitation Inventory scale that systematically assess agitation. This primary endpoint was demonstrated to be significantly improved at the clinically meaningful level in the past, fixed dose study, or in a post hoc analysis of the two milligram cohort in the flexible dose arm of the second study. It's also critical to note that a two mg dose Brexpiprazol was safe and well tolerated. In the ongoing Phase III trial, for which we have a readout in the summer, we're starting two and three mg doses, so the study includes a higher dose range than previously. The study finalized enrolment at a sample size, a bit over target of 330 patients at the beginning of the year. Next slide, please.

Johan Luthman, EVP Research & Development: [00:10:51] As you heard, we had some readouts with Vortioxetine. I like to highlight the very successful set of Phase IV studies we have

conducted on this compound. We have previously reported studies such as the COMPLETE Study that showed improvement of emotional blunting and major depressive disorder. A very interesting study, which has been followed by a set of publications and the RECONNECT Study that showed good effect of the drug in major depressive disorder with comorbid generalized anxiety disorder. We have also, which is not in this outline, reported the relief study. A real world evidence study in major depressive disorder that showed improvements in several functional and quality life outcomes following the use of Vortioxetine in regular clinical practice. The memory study studies for Vortioxetine in patients with depression or early dementia, and that is still ongoing. We had very recently the readout of the VIVRE study. Next slide, please.

Johan Luthman, EVP Research & Development: [00:11:49] The VIVRE study was a randomized comparative study exploring the role of Vortioxetine as a treatment option between SSRIs and serotonin noradrenaline reuptake inhibitors, SNRI's. A rare head to head study on antidepressants. The efficacy of Vortioxetine was directly compared to one of the latest introduced SNRI's, Desvenlafaxine. They were recruiting a total of 605 patients who were suffering from major depressive disorder and had a partial response to the treatment with a SSRI for at least six weeks. Both Vortioxetine and Desvenlafaxine showed significant improvements versus baseline. That's an improvement over the partial response to SSRI as measured by the Montgomery-Åsberg Depression Rating Scale was shown. Moreover, Vortioxetine demonstrated a noninferiority to Desvenlafaxine on MADRS. Importantly, the VIVRE study demonstrated that Vortioxetine provided significant benefits versus Desvenlafaxine on secondary endpoints, including remission, daily and social functioning and also which is very important satisfaction with medication. I'm showing here the outcome on the function assessment shortest (FAST) in the total population where you can see that Vortioxetine has numerically and in some instances also significantly different effects from this Desvenlafaxine. We have also obtained data showing, if anything, a better separation versus Desvenlafaxine in the larger sub cohort of patients that were actively working a very important subgroup. Thus using objective assessment the study shows a significant better efficacy of Brintellix/Trintellix versus desvenlafaxine on remission as well as daily and social functioning. In sum, this study clearly demonstrates that patients suffering from MDD, major depressive disorder, with a partial response to SSRI are offered important clinical benefits treated with Brintellix/Trintellix. Next slide please.

Johan Luthman, EVP Research & Development: [00:13:49] I am excited to report progress with Lu AG22515 our interesting novel antibody like molecule against anti CD40L. We have now started clinical studies for this program. Thereby accelerating our R&D strategy within immunology. One of our four strategic biological focus areas. In preclinical studies 515 has demonstrated in engagement with CD40L, leading to decreased antibody response and circulating inflammatory markers. 515 is differentiated neutralizing and CD40 in a way with innovative molecular design, blocking the essential CO stimulatory interaction between CD40L and its receptor. The company includes an anti serum human albumin binding domain, thereby utilizing albumin for half life extension and avoiding some of the previously observed liabilities with a traditional FC binding domain to neonatal FC receptors. This would potentially allow 515 to show superior clinical features, including on the safety parameters. CD40 signaling is an established and clinically validated immune pathway to its ability to trigger activation, differentiation and proliferation of B-cells, T-cells and several other immune cells. Modulating this pathway therefore holds great promise for treatment of a wide range of immune driven neurological diseases, such as sub indications of myasthenia gravis and multiple sclerosis. Next slide, please.

Johan Luthman, EVP Research & Development: [00:15:25] I'm pleased with what I see here. We have a broad portfolio early, but maturing and very interesting molecules. In 22 and 23, we will see key events coming up in several programs. Naturally, a big R&D effort is going into the Phase III and IV activities on Vyepti a drug that has a very strong feature and is up to date provided very convincing data. In studies like the Pivotal Promise Trials, but also in relief study that shows it's fast, powerful onset of action and the DELIVER study that showed this effect in patients that previously failed on prior treatments. We are now looking forward to the SUN trials in chronic migraine with medication of use as described before, as well as our indication extension activities in episodic and chronic cluster headache our alleviate and chronic studies. We are also seeing good progression in our research and early development transformation, where we now have a number of innovative programs progressing within our strategic areas. With that, I'd like to leave over to Bjørn for the financial updates.

Bjørn Mogensen, SVP Group Finance : [00:16:31] Thanks, Johan. We have seen solid financial performance in Q1 and the quarter is impacted by expected negative effect from the generic erosion on Northera. Beyond that, I see solid performance of the company with a 9% growth

driven by our strategic brands. EBIT reached 875 million corresponding to an EBIT margin of 20%, even though we in R&D sales and distributions are in an investment phase, mainly because of the global rollout of Vyepti and the normalization of activity levels after COVID. The core EBIT margin reached 27%. We continue to have a strict focus on cost spend and also continuously optimizing our organization to match the business we expect. As we communicated in the last quarter the Vyepti EMA approval triggered an increase in the fair value of the contingent consideration of approximately DKK 300 million. This is expensed as financial items in Q1 22 or we see the financial performance in the quarter as satisfactory. Next slide, please.

Bjørn Mogensen, SVP Group Finance : [00:17:51] Lundbeck's guidance for 2022 is maintained. 2022 will be driven by the continued growth of Abilify Maintena, Brintellix/Trintellix, Rexulti and the strong growth of Vyepti. Lundbeck has a foreign currency risk mainly in US dollar, Chinese yen and Canadian dollar. The financial guidance for 2022 is based on the current hedging rates for those currencies and includes an expected hedging loss of approximately 350 million. The fair value adjustment, which I mentioned earlier, brings our expected net financial items to around 500 million. With that, I'll turn the microphone over to Deborah.

Deborah Dunsire, CEO: [00:18:33] Thanks, Bjørn. So Lundbeck has looking out into the future, significant growth opportunities. We also have something that we announced in at our Full Year results that is coming up in the first half, and that is the Extraordinary General Meeting on our dual share structure, which we anticipate there will be in the first half of June 2022. We're looking forward to the submission of the Aripiprazole 2-month LAI formulation in mid 22 in Europe, US and Canada and of course the AAD results in the middle of the year. The Asia program headline results for the SUNLIGHT trial will come in the third quarter of 22, and then we hope, based on finalizing discussions with the FDA, that we would be able to read out the headline results from the Rexulti PTSD trial by the end of the year to the first quarter or the first half of 2023. The PACAP HOPE-Study, we also anticipate the Phase II results in 2023. So important information coming through the pipeline that will drive the growth of Lundbeck into the future. So with that, we'll close the discussion of a strong first quarter and move to your questions.

Operator: [00:19:59] Thank you. Ladies and gentlemen, we will now begin our question and answer session. If you wish to ask the question, please press zero, followed by one on your

telephone keypad and wait for your name to be announced. Again. That's zero one on your telephone keypad now. The first question is from Omar, who's from Bernstein. Your line is now open. Omar, please go ahead.

Wimal Kapadia, Bernstein: [00:20:26] Oh great. Thank you very much for taking my questions. Wimal Kapadia from Bernstein. So I'm just curious. First question. how do Lundbeck think about the deal this week for Pfizer and Biohaven? And now that all is going to be in the hands of a rather aggressive marketing machine. Now, what impact is it having today on Vyepti and how aggressive is the couponing? And how do you think about the change in the hands of Pfizer? And then just tied to that, where are the patients coming from? Are the majority postals? And then my second question is just a little bit more colour on Rexulti and PTSD. And it sounds like there's been some decent progress on that front with the FDA. So if you do get over the line and show good outcomes, just thinking about the growth acceleration, we could see how important is this indication for the Rexulti trajectory? Thank you.

Deborah Dunsire, CEO: [00:21:24] Wow. Lots of questions there, Wimal, but thanks. I'll start and Jacob Tolstrup, Chief Commercial Officer, will also chip in there. So we I guess the first thing we can say about the Pfizer deal is that we were surprised it didn't happen earlier on. The Pfizer did the deal for ex-U.S. rights. We thought that could have been a whole CO-deal. Now the whole CO-deal has happened. And we also know that in the marketplace, Biohaven has already been extremely aggressive. So that aggressive competition is already there. Importantly, remember, this is a market that is going after the entire migraine market, including the acute. So from people who have 1 to 2 migraines a year all the way through that acute setting into the prevention in episodic migraine, that product doesn't have an indication in chronic migraine. So I think we will see continued heavy promotion as there has been up till now. We'll see continued heavy couponing as there has been to now. But overall, we anticipate that the level of discussion of migraine that is happening right now will draw back into the market people who have dropped out of therapy based on not being satisfied, because we know that a large number of migraine patients living with migraine have have stopped coming forward for treatment because they were dissatisfied. And so the overall promotion of the CGR class of therapies will draw those people back into the migraine market. So net net, we think it doesn't change a lot because there's already aggressive promotion in the marketplace. Jacob, I'd like you to comment.

Jacob Tolstrup, Head of Commercial Operations: [00:23:25] Yeah, I mean, not much further to add. Of course, I agree with what you said Deborah. I think it is a very competitive market that we're looking in right now, and it's difficult to see that it can become even more competitive because there is a lot of activity going on in the migraine space already today, not only from Biohaven, but with all the competitors and all the companies that are active in the space. So I don't think I'll add much more to that.

Deborah Dunsire, CEO: [00:23:53] Yeah, I think the one thing that we do see. Vyepti, we're targeting that most impacted patient population, who are the people who are, you know, using more and more acute meds. The migraines are not controlled and Vyepti really delivers in that setting. And anecdotally, we are hearing of people who have tried even a couple of CGRP's, either injectable or oral, who have either not achieved the efficacy they wanted or have had a tolerability issue, who have subsequently been treated on Vyepti and done well. So we know that there is a big unmet need in migraine. There are, yes, it is a competitive market segment, but we do need these different alternatives for people because not everybody is treated in the same way by one product. Going on to PTSD and the commercial opportunity. First of all, we're glad that we'll be able to get to a headline result. As you know, we have had significant difficulty during the COVID period of finalizing the accrual to the two trials. And so we're hopeful that with this strategy, we'll be able to finish, although it probably puts a bit of a higher bar on it. It is a high unmet medical need. So we know that it's an important market. And I think what we've said is that it's not as big as the MDD market for, you know, the supplemental addition of an antipsychotic to an MDD regimen. But it's a bigger market than the schizophrenia market. Johan wanted to comment.

Johan Luthman, EVP Research & Development: [00:25:37] I just may add, of course, we can discuss the eventual growth, but I think Deborah touched upon it. It's of course a very challenging population to treat as a mixed group of patients with very different causes of PTSD. And this study is run on top of Sertraline, which is one of the therapies that are approved for this indication. So there are not only operational challenges for this, but also, of course, scientific and medical challenges to obtain an effect. But we at least are looking forward to see the results of this study.

Wimal Kapadia, Bernstein: [00:26:10] Thank you very much.

Operator: [00:26:17] Thank you. Your next question is from Martin Parkhøj from SEB. Your line is now open market, Martin. Please go ahead.

Martin Parkhøj, SEB: [00:26:26] Thank you very much, Martin Parkhøj from SEB. Also a couple of questions. And to the migraine, firstly, then firstly, on the orals and maybe that is for Johan. but although that Deborah also mentioned it, that tolerability and efficacy of orals, but is it the case that maybe the tolerability issues for the orals has maybe proven to be slightly less of an obstacle? And what you may be saw in the in the clinical data and maybe the same goes for the efficacy side. And then also, maybe that is for Jacob. On Vyepti, we see this very aggressive competitive situation in US. But we also hear from Deborah that the market is probably now is the market opportunity is much bigger now than what you saw when you bought all. What do you think what do you expect outside the US? What kind of competitive situation do you expect to see there on the opportunity for you? And then just maybe a little bit bookkeeping for Bjørn on FX because you also kind of to mention that the hedging laws since your full year result has increased from 200 to 300 million. But if we back that out, could you then also say how much benefit you actually see on the top line from the improved FX situation, which I guess is is quite substantially if you take the current FX rates.

Deborah Dunsire, CEO: [00:28:03] Johan, would you like to start on the orals?

Johan Luthman, EVP Research & Development: [00:28:05] Yeah, I can start. First of all, I think one should look at Nurtec and Qulipta little bit differently. If you look at now primarily in the prevention of migraine space where we are operating and Nurtec had weaker date than Vyepti while, Qulipta has reasonably strong data, but when it comes to reality a strong response rates, we are also stronger there. In terms of what that means on the side effects, Nurtec looks like a slightly, and no one has done head to head, of course, but it looks like a slightly less troublesome side effect profile. While (inaudible) Qulipta has a little more of nausea and the eye problems and it's also hitting a little harder. So it may be that tricky balance. So if you really like to drive efficacy, you may actually build up a little bit more of the side effect issues that you see with receptor blockers.

Jacob Tolstrup, Head of Commercial Operations: [00:29:00] On the competitive situation. So I think the short answer, Martin, is that I expect something that's less competitive. That said. You will see some of the same competitors in markets outside also. But there is a timing aspect of this where we are not coming in after the others, as we've seen in some cases elsewhere. We are coming in maybe even before some of the competitive competitors that will come in after us. And then there is also a question mark around pricing strategy, market access, how that all plays out in the different markets around the world. Obviously, Europe will be different than Latin America, China, so forth. And then there is also a question on, for instance, sampling, which is extremely heavy in the US and depending on pricing strategies outside may also be less. So I think the short answer is we do expect to see some of the same competitors around the world, but we do expect a less competitive situation than what we've seen in the US.

Bjørn Mogensen, SVP Group Finance : [00:30:06] And for your question in relation to currency impact, then of course we are negatively impacted by our lower hedging rate. But if you high level look net at that, we have a positive impact between 50 and 100 million.

Martin Parkhøj, SEB: [00:30:28] 50 and 100 on the top line? Or you mean the EBIT line.

Bjørn Mogensen, SVP Group Finance : [00:30:31] On the top line.

Martin Parkhøj, SEB: [00:30:35] But correct me if I'm wrong, the dollar is up to 10% higher than last year, and you have around 50% of your sales in the U.S. and that only gives you (inaudible) million net.

Bjørn Mogensen, SVP Group Finance : [00:30:45] We are hedging at a very low rate. So next year we will start getting the benefits. But for quarter over quarter, it's not a lot.

Martin Parkhøj, SEB: [00:31:01] Okay. Thank you.

Operator: [00:31:06] Thank you. Your next question is from Michael Novad from Nordea Equities. Your line is now open, Michael. Please go ahead.

Michael Novod, Nordea Equities: [00:31:15] Yeah, thanks a lot. Also, a few questions from my side. So first of all, to the key brand or the strategic brand performance in IO and in Europe, it seems like some very strong momentum going there. Maybe Jacob you can add a bit of more details of what you believe is driving the market. We have been talking about earlier on whether there could be sort of a lack on the sort of the treatment need. Is it that you're starting to see that when patients are getting back there's been a lot of treatment that's been postponed. So is that part of what is driving this very strong momentum? Or is it other reasons to IO and Europe? And then secondly, maybe you could remind us on the potential impact to see. Now we are closer to generic erosion probably in Canada and Brazil. So just to remind us what you actually putting into to guidance for 2022? And then a question for Bjørn. Maybe also you can remind us of what your expectations are for net debt level by the end of 2022. Thanks.

Deborah Dunsire, CEO: [00:32:20] Okay. So Jacob perhaps you'd like to comment on the strategic brands doing so well in IO and Europe. Is that those patients coming in from COVID blues?

Jacob Tolstrup, Head of Commercial Operations: [00:32:30] Thank you very much, Michael. And I do agree it's it's really strong performance that we see and something that we obviously very proud of. There are, of course, markets where we see it's purely driven by uptake and demand in markets like Japan, where Trintellix is doing really, really well, our best launch ever and also measured in market share. Then also in China, we continue to see strong growth from Brintellix in China even though we are not (inaudible). So that's obviously a couple of places where we see strong performance. But then we also see it in many other places around the world. So I have in Europe, across Europe, we see strong momentum for Brintellix specific markets that are doing extremely well. Our markets in like Spain and Italy, but I will say across Europe, we have very strong performance for Brintellix and also in in Latin America. And then we even have a little bit of downside here and there in terms of timing of markets in the Middle East and timing of tenders and so forth. So in some places, it's even a little bit muted compared to what we see. I wish I could say that it's a COVID, or coming out of COVID, that is sort of driving this. Latest data suggest that there is perhaps a little slightly higher growth in the MDD market, what we've seen in the past, but it's too early to say. And then I would also say that often sometimes we see, for instance in the US, that the growth of coming back in goes to generics and doesn't go to brand. That's not exactly what we see ex-US. We actually see also the brands benefiting from the market growth. But I would say most of what we see now is brand performance related

recognizing the great profile on Brintellix. And Abilify Maintena continues to do well and it's been tracking quite well during COVID all the way through. And then the last point I would make is, of course, there is a correlation also our ability to come back to promotional activity. And in markets, we are at the level of pre-COVID and in other markets we are still a little bit below, but we're getting close to where we were in our ability to promote that we were before COVID. And that, of course, also helps performance.

Deborah Dunsire, CEO: [00:35:01] Okay. I think just commenting on what's included in the guidance and the terms of the patent expiries, I think in 22 we're expecting Brazil and if I'm not mistaken, Mexico, and that is factored in to the guidance. Canada (inaudible) is to be in March of 23 considering the pediatric extension.

Michael Novod, Nordea Equities: [00:35:24] All right. Thanks. And for Bjørn.

Bjørn Mogensen, SVP Group Finance : [00:35:28] The question on net debt, we expect to land around 3.5 Billion DKK.

Michael Novod, Nordea Equities: [00:35:36] Okay. super, thanks a lot.

Operator: [00:35:43] Thank you. Your next question is from Harry Swefton from Credit Suisse. Your line is now open, Harry. Please go ahead.

Harry Swefton, Credit Suisse: [00:35:52] Thanks very much. I have a clarification question on the gross margin for the quarter. So we saw an extremely strong gross margin. And even if you adjust for the lower amortization, it is a notable increase year on year. So I was hoping that you could potentially explain what is driving that. You noted the lower royalty payments in the first quarter, but what is specifically driving those lower royalty payments? As I think some of the products which you pay higher royalties on, like Abilify Maintena did very well. Is that just a timing effect? Is there a mix impact that is particularly notable? So any help on the gross margin would be helpful. Thank you.

Bjørn Mogensen, SVP Group Finance : [00:36:35] I would expect that what is triggering you there is the Northera amortization that we don't have included in this quarter, but had in last quarter because it LOE now. So I think that's what is triggering your number.

Harry Swefton, Credit Suisse: [00:36:54] So even if you adjust for the amortization difference year on year, it seems that it is particularly strong. So is there anything else that you could potentially highlight which is driving that?

Deborah Dunsire, CEO: [00:37:08] I think it's the un fee royalty, right? Right.

Deborah Dunsire, CEO: [00:37:33] Next question.

Operator: [00:37:37] Your next question is from Diana Na from Berenberg. Your line is now open, Diana. Please go ahead.

Diana Na, Berenberg: [00:37:45] Hi. Thank you for taking my questions. It's Diana from Berenberg. I have a couple of questions, please. Firstly, just on the M&A. Just wondering what your lead is. Thinking is around sort of like appetite to do a bigger deal, looking to sort of like the second half of this year. You know, what are some of the sort of disease areas, you know, that's currently under your radar? That could be a good addition to your portfolio, please. And then my second question is on sort of Rexulti and AAD. Clearly, the phase III readout is going to be the next big focus. Just wondering if you could just sort of remind us again how big of a commercial opportunity you think this indication can ultimately be? The latest visible alpha consensus that was stating 3 billion Danish kroner, peak incremental sales in a sort of. What are your thoughts around this number, please? And then my third question is just for the the A2422 asset. I noticed that AbbVie has recently dropped its alpha synuclein program. So I just wanted to get your thoughts around your confidence in your sort of phase II program and sort of the science behind it. Thank you.

Deborah Dunsire, CEO: [00:39:01] Thanks, Diana. So firstly, on the M&A appetite, we've always said that M&A is not the only tool in the toolbox. We look externally at licenses, partnerships, regional deals and acquisitions. And we remain focused in brain health and in neuroscience. We focus M&A on near-term accretive deals, looking to continue to drive revenue growth through

the mid and late stages of the decade. And our appetite is really driven by what's going to be a good strategic fit at the right price that returns to Lundbeck shareholders after we've paid for the assets. So it's opportunistic as we go through. But within our strategy to profit from Lundbeck has significant experience in both neurology and psychiatry. All of those aspects are on the table. We've also said that we'd like to be in high unmet medical need where specialists are the the driving prescribers. So that niche neurology, niche psychiatry, rare diseases, neurology. So those are all the areas that remain in scope. I'm going to ask Jacob to comment on the commercial opportunity for Alzheimer's agitation.

Jacob Tolstrup, Head of Commercial Operations: [00:40:30] Thank you very much, Diana. And so we never given guidance on these specific opportunities, but I would say the AAD would obviously be a good benefit to have on the label for Rexulti. And if I were to rank it also compared to what Deborah mentioned before then the adjunctive MDD is obviously the biggest indication and will be also the biggest even if we had AAD on, but is probably a bigger opportunity then PTSD. I would also then just caution that the physician overlap in terms of prescribing here is limited. So it's also going to require additional efforts and cost to launch an indication in AAD, just so you are aware of that.

Deborah Dunsire, CEO: [00:41:17] And then, Johan, do you want to take on the A2422, which is the (inaudible) ?

Johan Luthman, EVP Research & Development: [00:41:24] Yeah, thanks for asking that. I mean, first, generally, phase II studies are by nature our proof of concept studies where we're finding out these things are working the way it should. And the technical risk in this of course is lower because we're working with antibodies. So that's actually the benefit of both our phase II programs that we're working with molecules that are very well designed to do the job. So we have a molecule that we're very confident is doing its job. The execution risk, of course with MSA is a little challenging. It's a new indication for us. We are in the upstart of the trial, just a few subjects in the trial. I have to say it's quite a few US sites that are not taking up. So in terms of delivering the data, it's a little early to say. Timelines are really nailed down. It's still too early in the trial. In terms of the scientific risk. This is of course a high risk, high reward area. It's protein aggregation. It's in the realm of all those amyloid antibodies that you're seeing. But we have great confidence in this because we have quite supportive preclinical data and we have also

decent way of de-risking the trial forward. We are building this on biomarkers where we're going to look at neural filament light early on. So if there is not a promising sign, we can step out early, but with a promising sign we can really invest and ramp up also substantially. It's different from Parkinson's, I'd like to emphasize, this is a more rapidly progressing disease, more aggressive, and that is, of course, bad for patients, but it gives a little bit better chance of detecting a clinical signal. And we have also other biomarker opportunities coming into this field. It's very rapidly moving. So it's as good as you can talk about a phase II really at this stage in this area.

Diana Na, Berenberg: [00:43:19] Great. Thank you very much.

Operator: [00:43:24] Thank you. Your next question is from James D. Gordon from J.P. Morgan. Your line is now open, James. Please go ahead.

James D. Gordon, JP Morgan: [00:43:33] Hello, James D. Gordan, JP Morgan. Thanks for taking the questions. Three questions, please. First one was just about migraine market dynamics and competition. And I know we had a question about Pfizer already. So my question would be, can you see anything that can accelerate the uptake of injectables versus orals or make you gain a lot more share within the injectables? And I know there is potentially through that the Vyepti is the more efficacious or the most efficacious option. But would you actually consider running a trial to show that if that's the case, that you'd have a stronger marketing claim? Or is there anything else that could mean you start making more share gains? Second question. Rexulti. Your latest confidence in success at this final readout based on all the stuff you've seen so far. And we know it didn't work at the interim. Is there a scenario where you are statistically significant but it's not highly clinically meaningful? Or is the power in such that if you go over the line on the stats that it's definitely shown a very clinically meaningful benefit. And then lastly, the M&A plans, the shareholder vote on the share split next month. If approved, it would make it easier to do an equity funded deal. Would you actually consider an equity funded deal with equity trading where it is right now?

Deborah Dunsire, CEO: [00:44:43] Okay. Well, maybe I'll start with the last one on the share split. We anticipate the General Meeting in June and it puts a tool in the toolbox. But what we said from the get go is we didn't have anything on the table that we were looking to use equity for. It is done with a long term perspective in mind. And we also said that we would prefer that the

equity was appropriately valued at the time we used it. So we'll just reiterate those same remarks today. Jacob, would you like to comment on the market dynamics?

Jacob Tolstrup, Head of Commercial Operations: [00:45:18] I'll be happy to. I think it's important also to look at the total market and not only the injectables. So the situation that we have now is a very competitive market, as we talked about. And that also means that the orals have taken their shares. Sometimes blurring the line between what is prevention, sorry, what is episodic and chronic, and also what is acute and prevention. And that has given a lot more sort of treatment options to physicians and patients in the field. You've seen the oral come in and taking a larger market share that has impacted the injectables in a negative direction. So you have a very competitive situation with a lot of different players. And for us, I think it's very important that we differentiate and we have a strong positioning in the market and we are focused on more severely impacted patients that are looking also or perhaps on the way to develop, for instance, medication overuse, headache or experience medication overuse headache where Vyepti is the only product on the market that has those kind of data in its label. So we have a unique positioning of a very efficacious product. That also means that it's not uncommon that you'll see some of the other treatments being used before you get to Vyepti. And that's actually okay because we will offer a product that offers very significant efficacy and relief for patients. So I think the dynamic that you will see going forward is a very competitive market, a lot of sampling, a lot of sales forces that are impacted, the market dynamics and it will probably take some time before you have sort of that washed out and then you become to see a more stabilized situation where the different product profiles will gain the traction that they're supposed to have.

Deborah Dunsire, CEO: [00:47:15] Johan, would you like to comment on the clinical trial, I think also the statistically significant versus clinically meaningful.

Johan Luthman, EVP Research & Development: [00:47:24] So let's start with the I think you asked about eventually head to head trials against various CGRP's. And you may be aware that there is one reasonable one going on right now, Lilly started a Nurtec vs Emgality trial. I'd like to point out a few things here. First, if that trial is showing some superiority or strong effect on Emgality versus Nurtec, that's of course, very encouraging because we have, if anything, even a stronger and more powerful agents. We have not yet contemplated starting a face face to face study against any of the others, but that's obviously something we could do with this powerful and

strong drug. We're not afraid of that. But we also, as Jacob pointed out, playing a slightly different space. We're working with the chronic really hard patients, while the other ones are blurring the pictures, Jacob said. They are more in the acute episodic, and episodic is not really that distinct indication and we're going for really the harder cases. So in that space we could definitely do something eventually to see how they perform against each other. So the question is, would that be against another MAB or (inaudible) And I think it would probably be against Qulipta or Nurtec in that case. Then the question about agitation in Alzheimer, yes, the simple answer is significant on this CMI scale is meaning clinical meaningfulness. Obviously this is a scale that has not been used for years and years very extensively. It's considered a validated scale for the purpose, but you can always have conversations with the regulators, what is clinically meaningful on a scale. But from our perspective and with the past conversations we had and remember, this is a long program we had with two previous phase III trials, we have pretty good understanding what it takes to also hit on clinical meaningfulness, and that's what we're aiming for with the readout. So it's basically significance is the same as clinical meaningfulness here.

Deborah Dunsire, CEO: [00:49:34] Next question.

Operator: [00:49:35] Your next question is from Keyur Parekh from Goldman Sachs. Your line is now open Keyur. Please go ahead.

Keyur Parekh, Goldman Sachs: [00:49:47] Thank you very much. Two separate lines of questions, please. First, coming back to Vyepti. So can you hear me?

Operator: [00:50:00] Yes, please go ahead.

Keyur Parekh, Goldman Sachs: [00:50:03] So just on Vyepti. I'm conscious of the messaging around the increased deductibles in the fourth quarter from a US perspective, but would appreciate any incremental colour you might be able to give what the underlying growth rate was without kind of this deductibles, both kind of either on a US basis or on a global basis. And secondly, as you looked at the full year numbers for consensus for Vyepti, it is close to 1.2 billion Danish. How comfortable are you that consensus is modelling this correctly given the first quarter trends? That's kind of on Vyepti. And then secondly, Deborah, coming back to the questions around kind of M&A and kind of transactions, etc., at the time of the original

announcement, you said kind of you weren't looking at anything in the near term, that it was more to create optionality, which you have kind of reiterated today. As you look at the correction in the pricing for biotech assets over the course of this year, does it put you in a more interested frame of mind to pursue something sooner rather than you might have otherwise done? If not, why so? Thank you.

Deborah Dunsire, CEO: [00:51:31] Great. So Jacob on the deductibles.

Jacob Tolstrup, Head of Commercial Operations: [00:51:33] Yeah, thanks. And I think we also mentioned in the conference call the last time that you're absolutely right, there hasn't been an impact on deductible reset and also reauthorization of insurance in the first quarter. So but we haven't quantified that mean what that exactly means. I think when we look out for the full year, which just makes it difficult, but I don't think we're giving guidance. But if I look at consensus, then I'm I would say that I'm comfortable. But please do remember that you also will be looking into a very competitive market that we have a traction with Vyepti, especially in the chronic segment. We have growth in our market share there. We also see the persistence and usage of Vyepti is growing. We have just launched a patient activation campaign in the US that we are trialling and those factors mean that we do expect to see continued growth of Vyepti. But it also means that some of these factors may be coming in a little later in the year than right now at this quarter. So without saying too much about how we we end the year, I think that's probably the closest I can get at this time point.

Deborah Dunsire, CEO: [00:53:01] I think the US market is the only market where we see this resetting of deductibles and insurance re-authorization. The other markets, obviously we're just coming into the negotiation, but of reimbursement in Europe. But once that's done then patients don't have to reauthorize. To your questions on M&A. There has been a reset in the market for sure. And some companies are much more effective than others. And the ones that are carrying a relatively heavy R&D burden and have some time till their readouts tend to be the most affected. Right. So those are the prices that have come down the most. And what we've been saying is if we were doing M&A, it'd probably be more towards the near term accretive that we're not doing M&A in the mid stage pipeline right at this moment because we want to first get through the investment period in the globalization of Vyepti that has us at a pretty high R&D burn. So some of those other companies, there's been a bit of a downdraft, but they haven't

reset quite as much. And so we keep looking and looking at where is the value? What is the value to our business? And we'll act at the time that we see the alignment of the strategic fit and the appropriate valuation. I wish it were yesterday. But, you know, we'll just be looking forward to the time that those things come into alignment.

Keyur Parekh, Goldman Sachs: [00:54:47] Thank you Deborah. Could I just perhaps clarify a comment you made earlier reference to the Vyepti answer. Should we be thinking of this as maybe a second half kind of pick up in trends and not necessarily a second quarter pickup in trends? Is that kind of a fair implication of your comments?

Jacob Tolstrup, Head of Commercial Operations: [00:55:09] Yeah, it is, I think. Yeah. Let's leave it at that. Yes.

Keyur Parekh, Goldman Sachs: [00:55:15] Thank you.

Operator: [00:55:20] Thank you. Your next question is from Marc Goodman from Leerink Partners. Your line is now open, Marc. Please go ahead.

Marc Goodman, Leerink Partners LLC: [00:55:29] Yeah. Just to continue on with this Vyepti. Can you talk about maybe the numbers of patients that have been on the product in the United States and what types of patients are you getting or these are these naive patients or are these mostly patients who've tried the orals or other injectables? Or maybe you can give us a sense of that. And then back to the comment about the gross margin. Maybe you could give us an idea of how we should be thinking about the gross margin the rest of the year, but also maybe the next couple of years. Just given these changes that you were mentioning with some of the royalties and amortization changes and stuff like that. Thank you.

Deborah Dunsire, CEO: [00:56:08] Great. So Bjørn will take the gross margin question, Jacob you dive in on Vyepti.

Jacob Tolstrup, Head of Commercial Operations: [00:56:15] I can give you a little perspective here. I think it's fair to say also with the patient positioning, the brand strategy that we have that we are, I think Johan also uses the word looking and targeting Vyepti towards patients that are

more severe impacted patients. And that naturally means that many of these patients have tried many different medications before they get to Vyepti. So it's not uncommon that they may also have tried in an (inaudible). So in that flow, that is actually what you should expect that they have tried something else before Vyepti and the most of our patients are in that severe segment of high episodic frequent patients or the chronic patient segment. And that's actually also where we see a lot of benefit and positioning of the brand.

Deborah Dunsire, CEO: [00:57:16] Yeah, I think that we see Vyepti delivering for those patients. So regardless of whether they've come off all the therapies like the topiramates, whether they've had one or even two injectable CGRP's or again anecdotal data people coming off orals for whatever reason, lack of efficacy or tolerability, we do see them responding to Vyepti. So it's a great place that migraine patients now have a number of opportunities, but there is a lot still remaining that don't get benefit from all of those other therapies and that are still getting benefit from Vyepti.

Marc Goodman, Leerink Partners LLC: [00:58:04] Can you give us a sense of how many patients have been on the product?

Jacob Tolstrup, Head of Commercial Operations: [00:58:08] I don't think we've given out that number. And so I will also refrain from doing that today.

Bjørn Mogensen, SVP Group Finance : [00:58:16] And the question on the cross profit. We expect to stay at the level we have shown we don't see significant changes in the business to that. So we still expect in the level of around 78 to 80% and also going forward.

Operator: [00:58:38] Thank you. Your next question is from Jo Walton, who's from Credit Suisse. Your line is now open, Jo. Please go ahead.

Jo Walton, Credit Suisse: [00:59:04] Thank you. Three quick ones. Just a follow up to James's question on the clinical utility in agitation. Can you just give us some idea of what you mean by clinical utility? Is it all the patients who were, I don't know, agitated for 6 hours a day and now agitated for 4 hours a day? So that's clinically meaningful. But hey, the patients are still agitated. Or we are just trying to get a sense of the the speed of pickup by the degree of clinical utility that

you could get from, say, a four point reduction in the CMA scale. My second question is just on the overlap of doctors. So particularly outside of the US, are the same doctors prescribing migraine drugs as a prescribing some of your other drugs? Just trying to think of the level of incremental marketing that you may have to put behind this, particularly as you've said that Biohaven is aggressive in the US and presumably Pfizer is equally aggressive ex the US. And final just one and I'm sure I should know the answer to this. You say that you're doing very well with Trintellix in China without it being on the NRDL. Do you have a possibility of getting getting on the NRDL and if so, when? Thank you.

Deborah Dunsire, CEO: [01:00:28] Okay. Johan, would you like to comment on the Alzheimer's agitation utility?

Johan Luthman, EVP Research & Development: [01:00:34] Yeah. So let's start. First of all, let's see, my scale is a composite scale with several items that we put together and it's given at one time point today. So we're not getting the resolution or the 24 hour time point. This is a visit to the doctor. And you give the scale at that time point and we try to keep that at a certain time of the day. So we don't have that resolution how quickly it works. This is for chronic therapy. So obviously it could be interesting to see if it sets in quickly. But as with most neuroleptic, you expect that it takes a little while before the effect kicks in. So that's not usually the key event here. The key event is to see a more chronic improvement. The scale has many, many sub items and we look at all the different sub items. We have a little special sort of balance in the scale, how we look at this in terms of clinical meaningfulness, utility, that is really the way it's considered. So if you have a certain degree or points on the composite scale, overall combined composite scale, you are considered to be clinically meaningful. But as I emphasized before, this is of course a discussion one needs to have with the regulators because the scales are not that the validation level. So they've been used extensively. It's not an ADAS, COG or CDR, some boxes or anything like that. This is a slightly newer scale, so I'm sure there could be some discussion about the clinical meaningfulness, not really utility, because in the question of utility, I heard your time points and I hope I answer your question properly.

Jo Walton, Credit Suisse: [01:02:13] I wasn't thinking necessarily the speed of action, but I think you've answered it. It's let's say 3:00 in the afternoon, you know, every time you do the measure. I was just thinking in an institutional setting, which is presumably where you'd expect

the fastest ramp up, and this is where outside Alzheimer's patients are just sort of routinely given off label drugs. It was just whether you had a sense of this would make people just easier to manage at certain times in the day, or just some people not have the agitation at all and therefore be able to, you know, function on their own to a greater level. But we'll just have to wait and see the data, I guess.

Johan Luthman, EVP Research & Development: [01:02:56] Yeah, we need to see the data. Just to remind you, we have about 50/50 outpatients in home care of various kinds and institutionalized patients. So we're going to have a look at both sort of categories here. I showed the data that majority of patients with agitation probably are in home care, and this is a major factor to go into nursing home. So it's very important to actually delay that. And that is the rub with the old neuroleptic is they have all these side effects that make them really hard to use in an outpatient setting. That's where we think Rexulti could have a good place because it has clearly a better tolerability profile than other neuroleptic that are used now. So that is so it's kind of a slightly different take on this. You like to delay people to go to the institutions. In the institution care obviously the good old way is to basically sedate the patients. You like to have a calm nursing ward. That is not idea here. We like to treat the symptoms.

Deborah Dunsire, CEO: [01:03:56] Right. Moving on Jacob?

Jacob Tolstrup, Head of Commercial Operations: [01:03:57] Yeah. So Veypti. And the short answer is there is not an overlap to our existing sales force, so it is incremental what we are building for Vyepti when it comes to sales force to launch Vyepti. And that's also why you will see increased cost as we are rolling it out globally. But that being said, remember that this is a specialized product and in many places it will be hospital, some places headache clinics that will administer Vyepti or infusion centers. So it is a more targeted group of physicians that we're going to see with Vyepti around the world. In our deal for China, Brintellix is absolutely correct. We don't have NRDL. We've been negotiating with the Chinese regulators around this a few times, but haven't been able to reach an agreement on price. For now we don't plan to have NRDL for Brintellix.

Jo Walton, Credit Suisse: [01:05:01] Thank you very much.

Operator: [01:05:06] Thank you. There are currently no more questions in queue. I'd like to hand the call back over to our speakers today for their closing remarks. Speakers, please go ahead.

Deborah Dunsire, CEO: [01:05:15] Thanks everyone for joining us today. We're very pleased with the outcome of our first quarter and we look forward to continued growth and momentum in the coming quarters ahead. Enjoy your day.