**H. Lundbeck**

**Transcript: Financial statements for the first six months of 2022**

**Date & time: 17 August 2022 at 13.00 CEST**

**Operator:** [00:00:00] Welcome to the Lundbeck financial statements for the first six months 2022. For the first part of the call, all participants will be in listen only mode, and afterwards there'll be a question and answer session. Today, I am pleased to present Deborah Dunsire, President and CEO, Joerg Hornstein, Executive Vice President and CFO, and Johan Luthman, Executive Vice President of Research and Development. Speakers, please begin.

**Deborah Dunsire, CEO:** [00:00:27] Good afternoon, everyone, and welcome to our first half Financial Results and Business Update. I'm joined by Joerg Hornstein and I'm so glad to welcome him as our new CFO and you'll be hearing a little bit from him in the call. Bjørn Mogensen, our SVP Finance, is also here with us today. Johan Luthman is going to be taking us through some of our important results. And Jacob Tolstrup is here to answer all your difficult questions on the commercial operations. With that, let's get started. You've seen our forward-looking statements before, so I won't go through them in detail, but draw them to your attention.

**Deborah Dunsire, CEO:** [00:01:06] Next slide, please. We're going to go through the group performance and then Joerg will take you through some very good first half financial results. We've got strong headline data to talk you through in a bit more detail than we did on our last call. And Johan will take that and then we'll look forward to a balance of the year with good and strong momentum.

**Deborah Dunsire, CEO:** [00:01:27] Next slide, please. So in the first half, we see revenue up in reported rates, 7% to 8.8 billion. And as you are aware, we have raised our revenue guidance. The strategic brand momentum is really driving here with a reported rates of 27% growth across those strategic brands. Vyepti achieved 390 million DKK in the first half, up 120%. We are seeing normalized activity levels both with our promotional activities and with in most countries, patients returning to in-office visits. And so our costs reflect that normalization as

well as the investments in our Vyepti rollout. The EBIT margin reached 16.9% and our core EBIT margin 23.4. Very excitingly, we were delighted to let you know the positive outcome of our AAD trials with Brexpiprazole, and I look forward to Johan taking you through that in more detail. We had said that we would submit Aripiprazole 2-month long acting injectable formulation and that has been submitted in the EU, US and now most recently Canada. So we have been progressing our pipeline.

**Deborah Dunsire, CEO:** [00:02:50] Next slide, please. So I've said that the strategic brands are really the growth power behind the portfolio and they make up 63% of our revenue in the first half of 22, up from 54% last year. And there's double digit growth across all regions and an important 19% increase in local currencies, again coming from all regions. The mature products are still very important from us and I'd urge you to remember that you're comparing the first half, 2022 versus 2021, where in our first half we still had two months of exclusivity on Northera. So we're very happy to see this growth. And in the balance of the year, we'll see the wash out of that Northera impact. Our tried and true Lexapro continue to deliver, being up 2% in reported currency.

**Deborah Dunsire, CEO:** [00:03:46] Next slide, please. We've seen increasing momentum across the strategic brand portfolio. Trintellix up 17% in local performance currency. Rexulti also 17%. Abilify Maintena 11% and Vyepti 100% in local currency. So we're extremely pleased with the performance of all these brands.

**Deborah Dunsire, CEO:** [00:04:10] Next slide, please. Vyepti is seeing strong growth and we're at the beginning of the global rollout with three new markets launching in the first half and another eight expected in the second half of 2022. And in those markets, we're seeing great performance of Vyepti for patients really delivering on its profile. US demand is increasing as Vyepti really does continue to deliver for those most impacted patients. Within the prevention market our share has reached 4.7% and the persistency, the number of patients receiving a second and third and ultimately fourth dose of Vyepti, is also on the rise. Our patient activation campaign got underway also in this first half.

**Deborah Dunsire, CEO:** [00:05:01] Next slide, please. Brintellix/Trintellix growth. Again, that tremendous efficacy profile for Trintellix delivering for patients who want to be at their most

functional, particularly as people are returning to work and there are people in offices all over the world. Our growth has been a lot driven with Europe and international markets, which are performing extremely strongly and of course you know that Japan has been a great performer for us. 8% value share of the market and up 2.2 points in the last six months. So we're really very proud of the combined effort between us and our partner Takeda in the Japanese market. We're also seeing some important beginnings of first line use of Trintellix in Japan.

**Deborah Dunsire, CEO:** [00:05:51] Next slide, please. Rexulti has really been a bright spot of performance in the US. We're seeing very strong demand and this is the use of adjunct therapy in MDD and we're seeing a strong willingness for people to add Rexulti on to things like the SSRIs and SNRIs. We're also seeing growth outside the US. Canada's contributing strongly and the recent launches in Brazil where we also have an MDD approval as well as Italy, where of course it's just schizophrenia are adding to the growth momentum.

**Deborah Dunsire, CEO:** [00:06:28] Next slide, please. Abilify Maintena continues to deliver both in North America and Europe. The growth in the first half, mainly coming out of the US, Canada and Spain and we've got a number of countries exceeding 30% market share. Countries such as Switzerland, Italy, the UK. And in many key markets, Abilify Maintena is growing faster than the aLAI market.

**Deborah Dunsire, CEO:** [00:06:56] Next slide, please. I've said that we're seeing double digit growth in all regions and that's what we like. The commercial organization continues to perform, continues to deliver. Vyepti is an increasing contributor to growth as the global rollout is ramping up.

**Deborah Dunsire, CEO:** [00:07:14] Next slide, please. I'd like to introduce Joerg Hornstein. He's been with us since August 4th. So go easy on him, everybody. He's just here a few days, but he's dived right in and it's a pleasure to welcome him. He has responsibility, of course, for finance, as you know, and IR, Legal, IT Procurement and Shared Services. So a big portfolio. Immediately prior to joining Lundbeck, he was Executive Vice President and Chief Financial Officer at AC Immune, who, you know, is based near Lausanne and prior to that SVP and Head of Group Financial Controlling at the Unternehmensgruppe Theo Mueller. A lot of his formative career was spent at Merck KGaA in many different functions and across many different countries. So

that international experience is incredibly valuable to us. So with that, Joerg, I'm going to welcome you and potentially throw you to the lions.

**Joerg Hornstein, CFO :** [00:08:13] Thank you, Deborah. I'm really pleased to be joining Lundbeck and thank you and everybody at Lundbeck for the very warm welcome. I think there are a couple of important messages to make. I think overall revenues grew 7%. If we look at reported currencies, if we look purely at local currencies by actually coming up to plus 3%. And as Deborah said before, the continued solid growth comes predominantly from our strategic brands, which more than offsets the decline of our mature brands. And again, H1 2021, our portfolio basically strategic brands comprised 54%. If we look at it now, then basically 63% of our revenues are coming from these strategic and strongly performing grants. They grew themselves 27% in reported currencies and 19% in local currencies. Second thing we see is actually a very strong currency tailwind, which, of course, in our specific situation, is mitigated to a certain degree by negative hedging effects. If we shift our focus now to the EBIT waterfall, we see again the solid improvement on our gross profit, which is more than compensating the expected and planned increase in our SG&A costs, as well as again impacted negatively by the net effects and hedging effect. And the increase in SG&A, as alluded earlier to, is levelling and mostly behind the launch of Vyepti and targeted increases in promotion.

**Joerg Hornstein, CFO :** [00:10:04] If we go to the next slide, please. What you see here is the performance for both the half year and the second quarter. And again, I think it's worth noting that revenues were up 8% in local currencies in the second quarter. If we take out the negative impact from the loss of exclusivity of Northera and keep in mind, we will continue to keep an eye on cost disciplines and our margins. But we also understand that 2022 is an investment year where we are now going more back to a normal activity level as previously stated, to support significant investments behind Vyepti.

**Joerg Hornstein, CFO :** [00:10:47] Next slide, please. Lundbeck is a very cash generative and cash flow strong operations. It increased by 6% if we compare H1 2022 versus H1 2021. Keep in mind that our free cash flow was quite significantly impacted by the payment of the CVR in March following the European approval of Vyepti, which has basically an impact in two positions. In the statement, it has about 1.1 billion DKK on net investments. Another impact of

half a billion DKK on financial expenses. I think it's fair to say that Lundbeck has a strong balance sheet and remains in a strong financial position.

**Joerg Hornstein, CFO :** [00:11:36] Next slide, please. You remember we raised our 2022 guidance pretty much a week ago. And what are some of the drivers for that? First thing is basically the continued growth of our strategic brands like Abilify Maintena, Brintellix/Trintellix, Rexulti and the strong growth of Vyepti. Some specific reasons besides the strategic brands is clearly driven again by currency. The main appreciation of the US dollar we've seen in the second half of this year. You will also see that we have increased the bottom line to the same extent as the top line, because again, the positive currency upside is nearly, you can say, fully offset or backstopped by a hedging effect and further other reasons of the, let's say, acceleration and global launch of Vyepti. Just as a reminder for you, again, Lundbeck's main foreign currency risk is predominantly in US dollars, Chinese yuan and Canadian dollars. And the financial guidance we're giving here now, updated for 2022, includes an expecting hedging loss of approximately 500 million DKK. With that, I turn the microphone over to Deborah.

**Deborah Dunsire, CEO:** [00:13:01] Actually, the microphone's going from me to Johan.

**Johan Luthman, Research and Development:** [00:13:04] Thank you, Joerg. It's a really great to have you on board. Let us start to go into a little more details on the R&D progression. So naturally, our biggest R&D event last quarter was the readout of the much awaited Brexpiprazole trial in agitation and Alzheimer's disease, AD for short. However, let me start by giving some background information on the condition. There is an estimated 6.5 million people living with Alzheimer's dementia in the US, with continued growth in the prevalence expected due to the relative increase of the aging population. Current treatments indicated for Alzheimer Dementia are still cognitive directed therapies, so there is no drug approved that address the non cognitive, behavioural and psychological symptoms of dementia. The key non-cognitive symptoms include agitation, aggression, psychosis, depression and sleep problems. Of course, agitation is a dominating medical challenge, causing impairment in daily living activities and accelerating other symptoms such as cognitive decline and sleep problems. And it's also closely associated with and commonly triggered by psychosis. Agitation is especially concerning for caregivers of Alzheimer's patients being a substantial reason for caregiver stress and representing the main reason for nursing home replacements. Although there is some

uncertainty in the epidemiological data, it is clear that agitation symptoms and Alzheimer's disease are extremely common. Agitation symptoms start already in the mild dementia stages of the disease, and they become worse as the disease progresses and remain a critical medical problem until the end stage of the disease. In the graph to the right here, you see the data from a contemporary electronic health record study on prevalence of agitation in community dwelling Alzheimer's patients with dementia in the US. And it shows that well over 50% of dementia patients are affected by agitation throughout the disease process. Currently, at least 30% of patients with Agitation Alzheimer's disease are treated off label with antipsychotics, but those are clearly limited by the tolerability profiles of which sedation, Extrapyramidal side effects and falls are particularly troublesome.

**Johan Luthman, Research and Development:** [00:15:34] Next slide, please. So it's against this background with a very high medical need in agitation in Alzheimer's dementia, that it's really very pleasing to see the outcome. Our third pivotal clinical trial with Brexpiprazole. This is called trial 213. We have actually already presented a headline data in early August, August at the Alzheimer's Association International Conference in San Diego, where the data were very well received. Trial 213 was designed to assess the safety and tolerability and efficacy of two fixed doses of Brexpiprazole, two mg and three mg per day. The trial consisted of a continuous 12 week double blind period, followed with a 30 day follow up period. The trial ended up including 345 patients from the US and Europe, with a diagnosis of probable Alzheimer's disease and meeting criteria of having agitation. The study included both patients who were living at home and those living in nursing home settings with about an equal split. As expected, a clear majority of patients were women, but interestingly, a rather large group from the US was of Hispanic Latino ethnicity. So a relatively diverse population was actually studied. On the primary outcome measures and the Cohen Mansfield Agitation Inventory, CMAI for short, and the key secondary endpoint the Clinical Global Impression - Severity of illness score. Brexpiprazole showed a very clear cut and highly significant effect versus placebo. Brexpiprazole also showed an action starting to kick at the end of the titration period. About four weeks. To see effects on both these very different end points are actually important since it demonstrates the impact of the drug on a more direct agitation related measure, as well as a more general performance of the patients as reported by caregivers and judged by clinicians.

**Johan Luthman, Research and Development:** [00:17:31] Next slide, please. As shown in the previous slide for the poll analysis, two and three mg doses, both the primary and secondary readouts where statistically greater than placebo. However, naturally, it's very interesting to see how the two different doses performed, which is illustrated here on the CMAI end point with the graphs on the two mg and three mg doses in presented in the Italy versus placebo. And as you can see, both the two and three mg dose level showed significant effects versus placebo, even though the two mg dose cohort was smaller. This is particularly interesting to note when comparing the data from this trial versus our two previous trials in Brexpiprazole in Agitation, Alzheimer's disease.

**Johan Luthman, Research and Development:** [00:18:15] So next slide, please. So here you can see in the left and middle graph the outcomes from previous pivotal trials with Brexpiprazole in Agitation Alzheimer Dementia. Started 283 was a fixed dose study with one and two mg doses were improvements from baseline on CMAI for patients receiving two mg, were statistically greater than for those receiving placebo at week 12. Study 284 was a flexible dose trial 1 to 2 mg, of which the primary analysis in combined doses did not meet significance. However, post-hoc analysis of the two mg dose did show a significant effect. Thus, the data from trial 213, together with the two and three mg doses, are highly consistent with the two prior trials that went up to two mg doses and consequently the overall data set Brexpiprazole in Agitation Alzheimer's Dementia is establishing an efficacy at doses of two mg at least.

**Johan Luthman, Research and Development:** [00:19:15] Next slide, please. So given the background on the current therapies used for treatment of behavioural symptoms and AAD, it's really very important to see that Brexpiprazole was generally extremely well tolerated and had no safety signals that have not been observed before. The only Treatment Emergent Adverse Events with more than 5% incident in patients treated with Brexpiprazole was headache, but that did not really separate from placebo. The Treatment Emergent Adverse Events that occur at an incidence of at least 2% included somnolence, so pharyngitis, dizziness, Diarrhea, urinary tract infection as well as asthenia. But frequently those AEs did not separate from placebo. It is particularly important to note that extrapyramidal symptoms events forced sedation all occurred at an incidence less than 2% for both the Brexpiprazole doses.

**Johan Luthman, Research and Development:** [00:20:11] So next slide, please. So now with the third trial on Brexpiprazole completed successfully, we are progressing with the regulatory plans aiming for submission of an sNDA with FDA in Q4. The program has already fast track designation, but obviously we explore potential for expedited pathway. I'd like to mention that there being a continuing interest from the academic clinical community to learn more about the data. As one example, we have now been accepted for an exclusive phase III readout session at the clinical trials in Alzheimer's Disease Conference ICADD 2022 in early December, with the largest session on Brexpiprazole and Agitation and Alzheimer's Dementia. So we are now moving over to the Post-Traumatic Stress Disorder trial. We are actually now looking forward to have a readout in that ongoing trial. As you heard before, we have two ongoing, very similar trials that have been struggling quite a bit with the enrolment during the height of the pandemic. We have been seeing some recovery of the randomization of those trials. But the more important factor is that we and our partner, Otsuka, as we reported before, had fruitful discussions with FDA, which allows a change in design of the analysis of the data with now the ability to finally wrap up the trials to obtain hopefully headline results by H1 next year at the latest. For Aripiprazole 2-month Injectable formulation that will add to our current once monthly Abilify Maintena brand. We have progressed into regulatory process with not only US and EU as previously announced. We have also since a couple of days, submission in with Canada. Also, there have been several R&D activities on Vyepti during the last quarter. First, I'd like to highlight that the regulatory activities are progressing very well with current approvals now in 43 countries, including a very recent approval in Mexico. While review is still ongoing in ten regulatory agencies. We have in a period initiated a phase IV trial called RESOLUTION that aims to broaden and deepen our understanding of the drugs previously described effect in patients with migraine and medication overuse headache. In the Asia directed studies, we have the largest SUNRISE registration trial ongoing, that evaluates the efficacy of Denosumab in prevention of migraine and headache in patients with chronic migraine. It's also SUNSET extension part. For a smaller trial called SUNLIGHT in patients with a combined diagnosis of chronic migraine and medication overuse headache. We obtained data in July for the placebo controlled period. It was designed as a spearheading trial to explore the potential for an accelerated pathway in China based on the very strong data we have prior in for the molecule in the US and Europe. On the primary end point monthly migraine days, the data numerically favoured Denosumab arm, but the trial did unfortunately not reach statistically significant separation from placebo. We are looking currently into the reasons for this outcome, but

among the main reasons are the small size of the trial, combined with a much more pronounced placebo effect versus all prior Denosumab studies, in the Chinese population in this case. Further analysis are ongoing and open label and safety follow up portions of the trial continue. Our main strategy for Asia approval is based on this SUNRISE study. That trial, together with the follow up trial SUNSET, are progressing and recruiting well in spite of some continued challenges in China due to the pandemic. In the indication expansion trial alleviate the enrolment continues steadily. But since the randomization is based on cluster headache events, it makes it a little harder to predict its timelines.

**Johan Luthman, Research and Development:** [00:24:15] Next slide, please. So from our phase II pipeline, I'd like to mention that both our alpha-synuclein and PACAP programs are progressing well. 42 is our monoclonal antibody, targeting an assumed pathological form of alpha-synuclein protein and multiple system atrophy. It is in a biomarker supported phase II proof of concept trial called AMULET. There is a high interest in this trial from participating investigators, given the total lack of therapeutic options for this very severe progressing neurodegenerative condition. 222 our high affinity anti-PACAP monoclonal antibody is continuing according to timelines in the rather large hope proof of concept study in prevention of migraine. We expect a readout during mid 2023. From our phase I pipeline activities, I'd like to highlight a few programs. From our MAGLi program, we are learning a lot in this exciting mechanism in the ongoing phase I studies that include small patient cohorts. We are both seeking good dose regimens and proper indication pathways and we are now obtaining sites that allow us to substantially refine the pathway further for both the leading molecule and also for follow up molecules in the clinical development stage. I'd also like to mention that our dual dopamine agonist in 996 is progressing well in a small dose escalation study in Parkinson patients and we start to obtain an encouraging, although very early findings. Finally, a few words on 515 are interesting differentiated novel antibody like molecule ligand, CD40 ligand. That is accelerating our R&D strategy with the new immunology. CD40 signalling is an established and clinically validated immune pathway with broad potential by its action on several immune cells. There are, however, some known liabilities with this approach that we are believe we have engineered out of the molecule. Thus, we're happy to see that the initial clinical studies are progressing well. With that, I'd like to hand over to Deborah again.

**Deborah Dunsire, CEO:** [00:26:21] Thank you, Johan. So of course we do our business in a context of being an organization that wants to impact our people, our planet, our world positively. And so we keep a continued focus on environmental, social and governance parameters. We're very pleased to say that 39% reduction in energy emission from our Danish facilities, given that we transferred all our energy utilization to electric from powered by solar as of the beginning of this year, it was pretty timely, I have to say, given the energy price crisis that we've seen. We also are proud to say that we're doing important work on managing and bringing down our Scope 3 emissions. That's with all our suppliers and vendors and partners that work with us on our business but are not part of Lundbeck. And we have a 4% reduction in Scope 3 emissions compared to the first half of 2021. We did make a donation of financial support to Ukraine and also in this half donated medicines to support hospitals in Ukraine that were significantly affected and also are helping refugees through jobs programs and providing needed supplies. We also put in place a policy to establish equity in access to reproductive health care in the United States during this half. We continue our diligence on everybody who works with us as a supplier in Lundbeck, so that we are certain that all the parties that we do business with do business in a way that meets our code of conduct. So we continue to assess and we made 67 of those assessments in this half. And we've also added sustainability reporting to the audit committee charter at our board level.

**Deborah Dunsire, CEO:** [00:28:27] Next slide, please. So here at Lundbeck, we're focused on creating value to drive long term sustainable growth. And what does that mean? It means we actively manage our business to drive growth, the pillar of that growth in our hands right now, our strategic brands, so we're continuing to accelerate and globalize Vyepti to make that into a very significant product as we go through to its loss of exclusivity in 2034. Rexulti in Agitation in Alzheimer's, Dementia gives us another very, very important opportunity to address an unmet medical need in brain diseases, that is agitation in this dementia population. It will require investment. But we believe that this can be a very strong growth driver for Lundbeck all the way through to the loss of exclusivity at the end of 2029. We also foresee continued strong growth with Brintellix/Trintellix and Abilify Maintena as we capitalize on these years ahead of us with no significant loss of exclusivity. We've made great steps under Johan's leadership in our transformation of R&D to build that mid and long term sustainable innovation for Lundbeck, as we focus in four biological clusters for our innovation and discovery in-house, as well as for anchoring what we look at externally and drive that biomarker driven development

with active portfolio managing, say, you know, these molecules have to move up or out. So we try to make decisions earlier and faster on our portfolio. And then, of course, we do need to think about what will we bring in that is a good strategic fit with our capabilities in commercial and R&D. We've focused on niche neuroscience in our frame and we would obviously prefer we've said we'd do partnerships, licenses or acquisitions, but our preference is for targeted in-licensing or bolt-on M&A. And through that, we are committed to deliver a rich pipeline that will drive sustainable performance into the future. With that, I think we're at the end of our presentation and we'll turn to your questions.

**Operator:** [00:30:54] Thank you. If you wish to ask a question, please dial zero one on your telephone keypad to join the queue. Once your name has been announced, you can ask your question. If you find your questions answered before it's your turn to speak, you can dial at zero two to cancel. So once again, that's zero one to ask a question or zero two if you need to cancel. And our first question comes from the line of Charlie Mabbat, Bernstein. Please go ahead. Your line is open.

**Charlie Mabbat, Bernstein:** [00:31:24] Great. Thanks for taking my questions. Charlie Mabbat from Bernstein. So firstly, please, could you give us some further colour on the level of step up in SG&A expected over the coming quarters? What level of infrastructure is already in place of Vyepti and what needs to be added, and how sustainable is this spend? Will it come down in absolute terms once the launches are fully underway, or will the Alzheimer's Agitation potential launch take over? And then secondly, on the SUNLIGHT trial. I was wondering if you'd still expect to disclose significant benefit to result over the full trial period based on the initial trends and if there is any read across to the other Asia focused studies. Thanks very much.

**Deborah Dunsire, CEO:** [00:32:05] Charlie. Could you repeat that second question? We lost you a bit in the beginning, so I'm not sure we heard correctly.

**Charlie Mabbat, Bernstein:** [00:32:13] So, say on the SUNLIGHT trial, would you still expect the statistical significant benefit to result over the full trial period? And is there any read across to the other Asia focused studies?

**Deborah Dunsire, CEO:** [00:32:24] Great. So, Johan, perhaps you can start with that and then Jacob will comment.

**Johan Luthman, Research and Development:** [00:32:31] Yeah, maybe I can just give a little personal reflection on this. You know, Vyepti, I spent many years in this business and Vyepti is extremely strong molecule and we have really really remarkable data from the prior trials in the US and Europe. So obviously we are building on that very strong profile and we built a very aggressive trial for exploring what is possible for China particularly. We are still looking through the data and I think you asked about if there was some other signals in the trial. If I got you right. And obviously we have a lot of readouts and there is a mixed bag of readouts here. There are timepoints that look more promising than others. But overall, we did see an unexpected, of course, effect on placebo. And given that this was a very small trial, we didn't really see the separation we'd like to have. I'd like to remind you that in pain indications, like in some of the psychiatry indications, you often see big placebo responses now and then. And this is one of the sort of shadows that always are about those kind of indications. In terms of read across the trials. Yes, we are learning from every trial. Our job is to run experiments and understand and analyse what we're doing. We are very committed to the SUNRISE trial and that is our base strategy for regulatory pathway across Asia, including now also in China. So we took some aggressive path and now we're going back to the more today base strategy. So we have learnings all the time and we will apply that in moving forward with our Asia strategy. I cannot go into more details, but you may have noted also from other trials in China that they have experienced fairly high placebo responses. We did not know that and that was not public at the start of our trial and we did not have any prior data in Chinese population.

**Deborah Dunsire, CEO:** [00:34:24] And I think the question was, is there likely to be a difference in any later time point in this trial? And I think it's fair to say that we have we've read the primary endpoint.

**Johan Luthman, Research and Development:** [00:34:34] Yeah, sorry, I misunderstood just a little bit. Yeah. We have a follow up period with additional dosing, etc.. This was course, of course, the primary endpoint we talked about here is always the crown, you will have a study. And as I indicated, there are other interesting data in this study and the follow up we will look at and see how that responds. So we're getting back to that. We don't have that data yet.

**Deborah Dunsire, CEO:** [00:34:56] Great. Jacob, would you like to dive in on that?

**Jacob Tolstrup, CCO :** [00:34:58] So not to go too much into detail, Charlie, on the different quarters, but just to give you a little bit colour of what's driving the sales and distribution cost. I think first and foremost, it's important to say that the increase you see in sales and distribution in the first half, the majority of that is driven by currency. So you have to take that out. So about 200 million out of the increase you'll see in the first half is due to currency. So you have to dial that out before you look at the additional spend that we are having. I think going forward, you have a US spend level which will be similar going forward. The increase you will see behind Vyepti from a sales and promotion spend will be on the markets that are about to launch. So we have markets, some eight markets launching in the second half of this year and then you have more markets next year. But I would say the spending level in those markets will still be significantly less than what you see in the US, partly also because of a patient activation or DTC campaign that we're running in the US that you can't do elsewhere. So I hope that gives you a little bit of colour of what you should look for in the future.

**Deborah Dunsire, CEO:** [00:36:14] And the question was asked around Rexulti AAD and what do we anticipate for spending there? And this is a great opportunity ahead of us, and so we will invest behind it. Would you like to comment?

**Jacob Tolstrup, CCO :** [00:36:27] I was commenting on Vyepti, and absolutely Rexulti AAD we see as a very very significant opportunity for us. And I don't think we ever give peak sales estimations on brands. But let me just say, you know that Rexulti is already a blockbuster. This indication alone in gross sales will clearly also be a blockbuster. What that means in net sales, we will not go into. But that also means that we will need to build resources into a market where considering where the inline business is for Rexulti, there is limited overlap. So that means that we have to add the sales forces and we also expect that we will be running DTC behind the launch of AAD. So that will certainly going into 23 add more sales and promotion spend behind the launch of AAD. But it is a great opportunity.

**Deborah Dunsire, CEO:** [00:37:23] And we will continually look to streamline and manage our costs across the business so that we can appropriately invest behind the growth drivers that are going to build our future.

**Operator:** [00:37:43] Thank you. Our next question comes from the line of Harry Sephton at Credit Suisse. Please go ahead. Your line is open.

**Harry Sephton, Credit Suisse:** [00:37:51] Brilliant, thank you very much. I have two questions on the Rexulti AAD data. So firstly, the baseline CMAI score was relatively high for the studies, even though you saw a 22 point reduction. I think the literature states that a score of over 45 is still clinically meaningful agitation. So I just wanted to get to your thoughts on how you think about the clinical utility of this product for prescribers, given there's still meaningful levels of agitation in these patients. And then my second question was on the improving reduction of the CMAI score over the 12 weeks of the study, could you look to show any longer term data from the study that could emphasize the benefit of staying on therapy for longer? Thank you very.

**Deborah Dunsire, CEO:** [00:38:46] Great, Johan.

**Johan Luthman, Research and Development:** [00:38:47] Yeah, two great questions. Yeah, this is always the question about validation of an outcome measure and how you use it. This trial was really seeking out the most agitated patients, so that's why you see a fairly high CMAI score. We'll come back to that in more detail in further scientific presentations. But obviously you like to treat those that have agitation. So it's probably a good thing that you have a high score going in and we see a good effect on it. So in terms of the extent of the effect and how much it is, this is an outcome issue that of course has not been to a regulatory approved drug yet. But we have had extensive discussions with the regulators, primarily FDA, of course, throughout the journey of this program. And this is the readout to use. In terms of the extent of the effect, we see effects that can be considered to be clinically meaningful and have been considered. And I know there are a lot of academic work going on to further validate what is constituting clinical meaningfulness here. But the utility is no doubt here, and I don't want to go into the details that we'll discuss at CIAAD in December, but there are very, very consistent effects across the readouts.

**Deborah Dunsire, CEO:** [00:40:06] Great.

**Johan Luthman, Research and Development:** [00:40:07] And then you asked about the longer term data.

**Johan Luthman, Research and Development:** [00:40:14] Obviously, the main readout is 12 weeks and the rest is gathering open label information, which of course, is still very critical. So we get the chance to look at longer term data. Patients have been enrolled over. So will generate more longer term data. We don't have that in our hands yet. But this is going to be a very interesting question moving forward with this brand, how long will people stay on the treatment? How long they benefit? But you saw it and we saw it. We're quite encouraged by the sustainability across the treatment period. It kicks in and if anything expands during the treatment period we observed. So there is nothing to suggest that it all of a sudden would drop after 12 weeks. So there is of course the potential for much longer treatment. But we need to come back with open label data to support that.

**Deborah Dunsire, CEO:** [00:41:03] And just as a as a reference in MDD, our trials were also 12 weeks and patients stay on for as long as the drug benefits them in a safe and tolerable way. So we don't anticipate there's some cut-off at 12 weeks. That's typically not how medicines are used. Hypertension trials are also done over a shorter period of time. But patients stay on it for for as long as the benefit is there. So, you know, we don't see that that is going to be determinant to the length of time patients are treated.

**Harry Sephton, Credit Suisse:** [00:41:47] Brilliant, thank you.

**Operator:** [00:41:54] Our next question comes from the line of Suzanna Queckbörner of Handelsbanken. Please go ahead. Your line is open.

**Suzanna Queckbörner, Handelsbanken:** [00:42:02] Hello. Suzanna Queckbörner from Handelsbanken. Thank you for taking my question. I have three. So one, to just clarify again on the SUNLIGHT trial, what kind of consequences does this have for the regulatory process? I assume this trial specifically was part of the accelerated path for a launch in China. And then my

second question is, the upgraded guidance is driven by dollar and performance strategic brands. It seems as if the dollar effect is larger than the component that is the strategic brand. Would you be able and willing to quantify the ballpark size of the two contributions? And then lastly, I'm curious about the PACAP antibody for migraine. I noted the phase I Subcu trial you initiated in March 2022, as well as the phase II IV, which was already initiated in November 21. Do you think both routes of administration are viable commercial options, or is this a reflection of you leaning more toward the Subcu formulation? Thank you.

**Deborah Dunsire, CEO:** [00:43:17] Great. Thank you for your questions. Johan maybe you'd start with SUNLIGHT and take the PACAP question and then Joerg will take the breakup of the guidance.

**Johan Luthman, Research and Development:** [00:43:27] Yeah. Thanks a lot, Suzanna. That's two really good questions. Well, obviously, we were building the SUNLIGHT trial, which was a small one as an accelerated pathway, as we said. So that means that we were looking forward, if it would have been strongly supportive to try out whether the regulators in China were willing to consider it. It was always an aggressive strategy, both in terms of the size of the study. And also, of course, we were pushing the indication here we were moving more into chronic medication o-use in a completely new arena for us Chinese population. So we were pushing this and it didn't pay out entirely. We are back to our base case. So of course we're now going with the SUNRISE trial, which you heard we are enrolling well in it. We hope to wrap it up within the planned timeframe. So that is the timelines now we're looking forward to. Of course, we have to see the results of that trial as well. It's a quite different trial. It's much bigger, as I indicated. It also includes much more Japanese people and also some European people. So that trial will serve a broader purpose and it's essential for our Japan strategy. So I think you got it. But our Japan strategy is not influenced by SUNLIGHT. In terms of the PACAP every antibody you like to see Subcu, so obviously that's your preferred pathway. However, as you see with Vyepti, there are great opportunity also for IV with fast onset of action, very powerful mechanism of action. So we like to play in both those spaces. Vyepti was not taken as a Subcu pathway, which I think is some benefit for the drug really. Definitely. We see that in the data fast onset, etc.. For PACAP. We have plenty of time to consider this and we are considering both pathway and this is very traditional. You start with some Subcu, exploratory pharmacokinetic studies while you continue. Yes. To show that the drug works before you do too much investment in Subcu

formulation and device development, you need to know that the drug is working to some degree, but there are a lot of opportunities here for Subcu, and I see no reason in the molecule that that would not be possible.

**Deborah Dunsire, CEO:** [00:45:40] Great. So Joerg the contribution of.

**Joerg Hornstein, CFO :** [00:45:43] I think contribution. Just to remember, again, I think the midpoint of our revenue guidance was brought up by 500 million and the EBIT core EBIT etc. guidance was brought up by 150 million. I think it's fair to say that we would say roughly 50/50 between FX and organic.

**Deborah Dunsire, CEO:** [00:46:09] Okay. Next question.

**Operator:** [00:46:12] Thank you. The next question comes from the line of James Gordon at JP Morgan. Please go ahead. Your line is open.

**James Gordon, JP Morgan:** [00:46:20] Hello. James Gordon, JP Morgan. Thanks for taking the question. The question was about M&A plans now, so lets say Rexulti. What's the latest thinking on M&A? Is the thinking more to do a near-term accretive deal or and then maybe follow that with a bigger pipeline deal further out? Or are you now thinking more about doing a pipeline deal and less about near-term accretion? And what's navigating factor on doing a significant deal because we've had the share done, etc.? And maybe just sort of to involve Joerg, what will be the basis on which you're going to help assess acquisition candidates? How do you think the company should look at what to buy?

**Deborah Dunsire, CEO:** [00:46:58] Great. So thanks for the for the question, James. We know that as we look forward, we've got some great growth drivers in our strategic brands. We do face some mid-decade loss of exclusivity. And then, of course, we need to consider the future of Lundbeck. We've got important phase two molecules. Yes, definitely. That can potentially help us in that mid to late decade. But we do want to bring things in from the outside to support the mid and late decade growth and we're prepared to do that. We've had some very good partnerships with Otsuka and Takeda. If other partnerships should deliver the opportunity to bring in growth drivers, we would certainly look at those. Licenses or single product licenses

for regions are definitely part of the remit of things that we look at. So M&A is not the only tool in the toolbox. Of course, it is an important tool. And I think when we did the share split, we said it was a long term preparation tool, that wasn't something we had anything on the table for right now. And we also want our equity to be at a good valuation when we use it. So we do have a preference to look at deals that we can finance potentially with debt. And that puts us in a frame if we're looking for near-term sort of more or less even accretive deals that will drive that mid and late decade growth at the sort of 1 to 2 billion. We are cash generative as Joerg pointed out. So that's really the frame. What is also coming into view as we've gone through the major bulk of the Vyepti investment, as we're finishing up some of the pediatric commitments that we've had on both Brintellix/Trintellix and Rexulti, that frees up some space in the R&D budget and we definitely want to be looking at opportunities that will come into that mid stage pipeline, also with the purpose of driving that sustainable growth into the thirties and beyond. So both of those look in frame and of course as any of us, as individuals, as companies, as nations, we need to look at how do we balance all of the needs for capital. We're going to be investing behind building the AAD indication and continuing to build Vyepti. And so we'll need to look at all of that in context and make sure we're also managing our costs appropriately to meet those big strategic objectives of growth and securing the future.

**Joerg Hornstein, CFO :** [00:49:59] Well, I think, James, a few things. The first thing is, I think being 14 days in the company, it would be a bit premature jumping to conclusions what I think should be a target frame or criteria. I think what is fair to say is, being 14 days in the company, that you shouldn't underestimate the expertise and the discipline in which we potentially look at targets or at in-licensing opportunities. And I think my job will be first to fully understand the focus areas in our R&D, understand our positioning in these areas, and let's say the factors for being successful in that space.

**Deborah Dunsire, CEO:** [00:50:55] Next question.

**Operator:** [00:50:57] That comes from the line of Michael Leuchten of UBS. Please go ahead. Your line is open.

**Michael Leuchten, UBS:** [00:51:04] Thank you very much. Two questions, please. One, just going back to the SCNA phasing and step ups or not. Your guidance seems to imply the stable

OPEX block second half over the first half, which I presume is what you mean by talking to efficiencies. But you probably want to spend money on agitation ahead of approval doing pre-launch activities. So I'm trying to get my head around how that OPEX line can actually stay flat in the second half when you out there, had an impact on going away in the second half. So where is the efficiency coming from that allows you to absorb that incremental expenditure around Vyepti and Rexulti in agitation? And then the question for Johan, I guess I was wondering if you could put the (inaudible) phase III data that we saw recently, the success of phase III and schizophrenia into perspective, how that may or may not feature and from a competitive perspective. Thank you.

**Deborah Dunsire, CEO:** [00:52:13] Okay. Jacobs going to start.

**Jacob Tolstrup, CCO :** [00:52:15] Happy to start. So without commenting on what is our OPEX spend in the second half, I will say that for AAD, we do have some cost built into our plans so that we will be starting to do certain things to prepare for further promotion and marketing of the AAD indication. Already now both Otsuka and Lundbeck is talking about disease stage and AAD from our medical side. But towards the fourth quarter of this year, there is more spend built-in to build up for preparing for the launch more than we have now. At this stage it is, I would call it, not limited, but it's not a significant upgrade. But then coming into 23, that's where you will start to see much bigger spend going into AAD. So I will not go into what is our exact SG&A or OPEX spending for the second half.

**Deborah Dunsire, CEO:** [00:53:28] Next question.

**Operator:** [00:53:30] Next in the line of Michael Novad at Nordea. Please go ahead. Your line is open.

**Michael Novod, Nordea:** [00:53:36] Yeah. Thanks a lot. A couple of questions. So first of all, maybe to Jacob around the geographical differences between Brintellix/Trintellix. You're growing significant double digits outside the US and then you grow a mere 1% local currency in the US. So what the heck is actually going on? Why are you successful in IO and EU and then really can't get it going in the US? And what does that take to see that potentially rebound in growth? And then the second thing regarding costs, I know we've been talking a lot about this

already, but if we do see a significant ramp up in cost also going into to 2023, and if you expect that the AAD indications of Blockbuster, should we then sort of disregard the the old margin guidance of 25% in 2024 or what are sort of the pushes and pulls in terms of this? And maybe also to Joerg in terms of the overall notion around having midterm guidances, what is your view on that, especially in a situation where Lundbeck is right now, where it may take a lot of investments in order to drive additional top line growth? Thanks a lot.

**Deborah Dunsire, CEO:** [00:54:52] Thanks, Michael. So Jacob's going to start, and then I'll amplify. And Joerg will be at the end.

**Jacob Tolstrup, CCO :** [00:54:58] I will try to do it brief, Michael. I think it's a very good question, and I'm very, very proud of what we see in international markets and Europe. So give you a brief background of what we see. We do see rising growth rates coming out of the COVID situation, not in all markets, but in some markets, also important markets. So that's one factor. An other factor is that our promotional abilities and the total promotional spend, not only from us but also in the whole market, is coming up close to what we saw pre-COVID. And in certain markets, we are back to where we were, our pre-COVID levels. I think also one other thing that's very important and I think a couple of years ago or three years ago, we started certain growth projects where we added individuals or sales reps into certain territories, especially focused on GPs. And what we see in this situation is probably also coming out of the pandemic is that we have a rise in the scripts going out of the GP offices and that is especially taking place in, for instance in southern Europe where we have a few forces that are dedicated to GP's and we do see very high growth for Brintellix in some of these markets. But on top of that of course we have the launch in in Japan that's going well. We have very strong growth in Canada, in Brazil and in many markets around the world. So I think that's just some of the factors. Last point I want to make also is that we have found a very good balance between Lexapro and Brintellix and how we promote them. So we can sort of keep Lexapro at a certain level. And then we are growing Brintellix strongly on top. In the US it's quite different. Total new patients coming on to a script in the MDD market has still not recovered back to what we saw pre-COVID. So that's the total market. We do see the NRX and CRX back to pre-COVID levels, but a lot of that has gone to generic scripts. We still see a situation where psychiatrists are doing a lot of virtual consultations and that is making it less likely that they put patients onto a branded product like Trintellix. So that explains some of the factors. That also means that we are

working very closely with Takeda in optimizing our efforts and we will try to do certain things so that we can see growth where we do think that there is growth and that we can improve what Trintellix's demand is looking like now in the US.

**Deborah Dunsire, CEO:** [00:57:52] I think it's fair to say we've had some disruption of promotional.

**Jacob Tolstrup, CCO :** [00:57:55] That's also very fair to say that there has been changeover primarily among our partners, Salesforce in the US, that has given a disruption and also means that the total salesforce in the alliance is not backfilled and fully staffed at this time point. So it will take some time before you see an effect of that coming back where you have a full Salesforce detailing Trintellix again.

**Deborah Dunsire, CEO:** [00:58:24] Great.

**Joerg Hornstein, CFO :** [00:58:25] Maybe coming back to your question, Michael. A couple of things, and I probably respond how I dealt with these things in the past. I strongly believe you need to have a medium term guidance as you have a medium term plan for a company, and you have to have clear aspirations on where you want to go from a I would say growth and profitability expectation. So that's for me a given. On the other hand, it doesn't make any sense to just religiously focus on existing corridors if suddenly tremendously interesting growth cases come up, like in our case AAD that we have to quantify and basically compare and contrast against other investment initiatives we have and we know we can't fund all of them. But then basically the most compelling and interesting ones, we will find opportunities to fund them.

**Deborah Dunsire, CEO:** [00:59:28] Yeah. I think that's a great point. I think our aspiration as a company is always to get ourselves to the point where we're delivering benchmark and above returns. So we remain strongly focused on how do we build a Lundbeck that will deliver those kind of benchmark and above returns and EBIT. We are going to go into a period where we will invest behind Rexulti AAD and we have still the growth case for Vyepti. And I just point out that there's been some delay actually in both those products. Vyepti a lot due to COVID. Rexulti AAD also readout later than we expected because enrolment was delayed in that. So both of those are impacting us a bit later into that midterm than we had initially anticipated. But rest assured,

this management team will focus on driving growth with an eye on how do we deliver the profitable and sustainable profitable growth into the future.

**Michael Novod, Nordea:** [01:00:39] Maybe it's just one short follow up, if I may. Is it fair to assume that we will also then see you going sort of more aggressively on DTC for Rexulti in AAD in the US? As I recall, you've had success early on doing that with Otsuka as early as possible.

**Joerg Hornstein, CFO :** [01:00:57] Yeah. I would say we do that today and it's very optimized and it's also a quite high spend that we have in the alliance between Rexulti already today. And I agree with you, it's been it's been a good success for us to do it that way. We haven't decided exactly on the level of spend for AAD, but I would assume that it will be quite significant also.

**Deborah Dunsire, CEO:** [01:01:23] Yeah. And particularly in this market because these patients are a lot in the community. So and it's going to be very important to reach families and and patients out in the community as well as community prescribers. So DTC will be a critical component, as will the sales force promotion.

**Deborah Dunsire, CEO:** [01:01:43] I think we're up at time right now. So unfortunately, we won't be able to take any further questions. But we do thank you for your participation today and look forward to speaking with you in various different other forums in the days ahead. Thank you.