

H. Lundbeck

Transcript: Financial statements for the full year 2022

Date & Time: 08 February 2023 at 13.00 CET

Operator: [00:00:00] Welcome to the Lundbeck Financial Statements for the full year 2022. If you have dialled into this call by the Danish line, stutter may occur. To avoid this, please dial into the Norwegian line instead. Sorry for the inconvenience, this may have caused. For the first part of this call, all participants are in a listen only mode. And afterwards there'll be a question and answer session. To ask a question, please press five star on a telephone keypad. Today, I'm 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: [00:00:47] Hello everyone, and welcome to the financial update for 2022 for Lundbeck. You see here one of our patients, the people who we serve everyday living with migraine. Next slide, please.

Deborah Dunsire, CEO: [00:01:02] The forward looking statements you've seen before. So, I won't dwell on them, because I'd far prefer to turn the next slide and say we had an outstanding year at Lundbeck and achieved the highest ever revenue for the company in its history.

Deborah Dunsire, CEO: [00:01:17] Revenue was up 12% and our strategic brands, which are really the engine driving that growth, were up in aggregate 31%. Vyepti, the newest of the strategic brands, grew 104%, and the strategic brands are now approximately 67% of the total revenue. The growth came across all regions and it's really gratifying to see the growth of the strategic brands and the momentum developing across all our regions. That, of course, drove profit growth higher, despite the fact that we've been investing behind the launches for nine countries for Vyepti with the EBITDA margin up 25%. The pipeline has made very strong progress and Johan will be talking through that. Of course, key dates for us will be May 10th for the PDUFA date for our agitation in Alzheimer's disease submission for Rexulti and April 27th for the 2-monthly version of Abilify Maintena. Very pleased to say we finished enrolment in

both of our Phase II trials. So, there were a host of other achievements that Johan will touch on. Next slide, please.

Deborah Dunsire, CEO: [00:02:39] So, you can see here the markets growing across the world. The US now 49% of the revenue in 2022, but strong growth coming from all our regions and the strategic brands up 31% reported 20% in local currencies. So, yes, there were tailwinds, particularly from the dollar, but the underlying momentum in the business is extremely strong. Next slide, please.

Deborah Dunsire, CEO: [00:03:11] Vyepti the newest of the strategic brands. You can see on the left, the growth in US demand vials and you see strengthening growth at the back end of the year. We achieved a 5.4% volume share within the prevention market. And this is really driven by the way the brand continues to perform for those heavily impacted patients. And we've seen key opinion leaders and patients speaking out about the effectiveness. We've been working with our sales force and they are doing an outstanding job and we are getting those new patient starts and showing that persistency people who stay on Vyepti for second, third and fourth doses is going up. We've got a growing number of loyalists, people who use Vyepti for their patients and describe its efficacy as transformative. And so we see that continuing traction with the clinical efficacy messaging. You can also see in the middle chart the beginnings of the growth of Vyepti outside of the US as the markets that launched late in '21 and through '22 begin to contribute. And of course, we'll see that grow over time. Next slide, please.

Deborah Dunsire, CEO: [00:04:33] We have had strong adoption across the markets where we did launch nine countries in all in 2022 and then we've had significant penetration. UAE, which launched towards the end of '21, a 13% volume market share, 6% in Switzerland within seven months and already in the third month, 1% in Germany. Canada launched late in the year and have had very strong uptake. The most recent launches in '23 are France and the UK and in total we've got about 15 launches planned during this year. So, a lot of excitement as we roll this brand out globally. Next slide, please.

Deborah Dunsire, CEO: [00:05:16] Brintellix/Trintellix really has continued to grow 13% in local currency. Japan in its third year on the market, 10.1% value market share, which is outstanding as we together with our partner Takeda, build this brand and we can see a movement forward

in the lines of therapy. As we see physicians use Trintellix like its profile and begin to move it earlier and earlier in their treatment paradigm. Europe had a particularly strong year as we've seen growth in that segment. We've spoken about for a while as patients have come back after COVID expressing the need for help with mental health challenges. They've seen their GP's and we've seen GP prescribing pick up, particularly in Spain. We also had a great year in Canada, in China and Italy. The others of our key markets driving the growth. But really everywhere we did see good growth. The US antidepressant market has taken longer to come back to pre-COVID levels, but it's just achieving that towards the end of 2022. And we together with Takeda in the US now have our field force fully in place. You know that there was some disruption during 2022 and beginning to drive new patient starts and seeing that overall demand growth coming back in Trintellix. Next slide please.

Deborah Dunsire, CEO: [00:06:53] Rexulti had a very, very strong year in 2022, with demand rising significantly. That momentum really coming from the MDD market in the US, as physicians have used the adjunctive therapy together with their initial therapy, as we've seen continued use of telemedicine and that willingness to add a therapy rather than change therapies. We've really gotten going with our Alzheimer's agitation launch preparations, which are progressing rapidly. Countries outside the US, Canada notably had great growth with a 30% year on year growth and a volume market share of 3.6%. And Brazil, a more recent launch right in the midst of the pandemic, doubled sales with a volume market share at 1.9%. So, Rexulti really continuing to perform for patients, particularly with major depressive disorder. Next slide, please.

Deborah Dunsire, CEO: [00:07:54] Abilify Maintena also continues to grow well with 16% in local currency. And we see the US, Spain and Canada being the strongest growth drivers for Abilify Maintena. Europe has also had a very strong year exceeding 30% market share in several countries, including Italy, Switzerland, the UK. And in a lot of key markets in Europe, we're seeing Abilify Maintena growing faster than the overall aLAI market. The regulatory process for the 2-month formulation was initiated during the year and the PDUFA dates set to April 27th for the US, and the review is progressing in Canada and Europe. Next slide, please.

Deborah Dunsire, CEO: [00:08:42] I'm going to hand over here to Joerg to take you through the financials in more detail.

Joerg Hornstein, CFO: [00:08:47] Thank you, Deborah. We deliver exceptional revenue and profit growth for 2022. The plus 12% of reported revenue growth can be decomposed as follows. We're delivering an underlying organic growth rate of plus 7% due to the strong performance of our strategic brands. The strength of predominantly the US dollar has led to a positive effects impact of plus 9% that has been backstopped by a negative hedging impact of -4%. Please keep in mind that the negative hedging effect of DKK 640 million for the year is impacting EBITDA 1 to 1. Our gross margin is 0.7 percentage points higher compared to 2021. Despite the provision for Vyepti inventory obsolescence in the amount of DKK 228 million taken in Q4. Which is an important topic to understand and that I will cover in more detail on the next slide. Adjusting the gross margin for this provision, it would be five percentage points higher for Q4 and 1.3 percentage points higher for the full year. SG&A costs grew plus 13% with an underlying organic growth rate of plus 5%. The increase is driven by higher promotion and sales costs, predominantly for Vyepti, but also to an extent due to the return to pre-COVID activity levels that still impact our full year 2021 numbers in comparison. R&D costs declined by -2%, which was impacted by a year over year decline in activities for marketed products. Our core EBIT growth is at plus 18% with an underlying organic growth rate of plus 17% and our EBITDA grew plus 25% overall with an underlying organic growth rate of plus 25%. The positive EBITDA effects impact of plus 17% was fully offset, as mentioned earlier, by the negative hedging effect of -17%. Overall, we improved our EBITDA margin here from 22.8% to 25.6% for 2022. Next slide, please.

Joerg Hornstein, CFO: [00:11:02] Before we go into our reported numbers, allow me to provide you with more background on the shift of the antibody backbone of Vyepti. With the acquisition of Alder BioPharmaceuticals Inc. in 2019, we inherited a fixed batch quantity supply agreement for five years with an external CMO that is effective up to June 30th of this year, producing Vyepti on the back of a pichia cell line. Shortly after closing the acquisition, we started a process on how we could potentially shift the antibody backbone of Vyepti from a pichia cell line to a CHO cell line. The CHO cell line itself is a more modern, high yield and lower cost producer cell line. That transition is actually progressing well, and especially with progress made towards the end of 2022, the likelihood of success transitioning to CHO has significantly increased. As a result, we have built a provision of 228 million in 2022 for inventory obsolescence for Vyepti based on pichia based inventory on hand that has been recognized in

cost of sales in Q4 2022. Further, we have reflected an additional provision in the amount of DKK 300 million in our guidance for 2023. Next slide, please.

Joerg Hornstein, CFO: [00:12:29] Let's focus on our reported numbers. Our EBIT grew plus 42% overall with an underlying organic growth rate of plus 43%. The positive effects impact of plus 21% was more than offset by a negative hedging impact of 22%. Overall, we improved our margin here from 12.3% to 15.6% in 2022. Our net financial expenses decreased for the year by -12%. The low expenses are driven by a mix of lower net interest costs due to higher deposit rates and the gain from other financial assets. The lower expenses were partially offset by the fair value adjustment of the contingent consideration for EMA approval of Vyepti, which amounted to DKK 331 million in 2022 compared to DKK 110 million in 2021. The effective tax rate has increased significantly, but as expected 22.6% compared to last year's 16.6%. The increase is due to 2021 having been positively impacted by the recognition of tax credits, whereas 2022 is negatively impacted by the non-deductible CVR payment for EMAs approval of Vyepti mentioned before, which is partially offset by the Danish R&D incentive. The reported net profit corresponds to an EPS of 1.93 versus an EPS of 1.33 in 2021. Next slide, please.

Joerg Hornstein, CFO: [00:14:09] The cash flow from operating activities is landing at DKK 4.1 billion in 2022, compared to DKK 2.9 billion in 2021. This is, of course, a reflection of the stronger EBIT performance, partially benefitted by adjustments for non-cash items of around DKK 1.6 billion, deriving from higher amortization and depreciation in 2022, and a net change in other provisions of the DKK 0.3 billion. This is partially offset by higher net change in working capital, driven by higher receivables due to higher sales, net increases in inventory and timing of accruals for short term liabilities. From the total CVR payment of DKK 1.6 billion in Q1 2022, DKK 0.5 billion are reflected in other changes in operating activities, the remaining DKK 1.1 billion are reflected in the cash flow from investing activities. In case we would have not incurred the CVR payment, our free cash flow would amount to DKK 3.2 billion, which would constitute an increase of more than 100%. The changes in the cash flow from financing activities are driven by loan repayments in 2021 and loans obtained in 2022. Our net debt position decrease to DKK 2 billion, leading to a net debt EBITDA ratio of 0.5 for the rolling four quarters. And we are making our plan progress on further deleveraging the company. Next slide, please.

Joerg Hornstein, CFO: [00:15:43] For the financial guidance for 2023. Lundbeck will focus on revenue performance and from first quarter 2023 onwards on adjusted EBITDA. This will provide an improved and more consistent assessment of the underlying business performance. The adjusted EBITDA information for comparative periods will be made available no later than May 10th, 2023. When we release our interim financial statements for the first three months of 2023. For this interim period, we provide EBITDA guidance. Our guidance for 2023 is as follows: we target revenues of DKK 19.4 billion to DKK 20 billion and an EBITDA of DKK 4.8 billion to DKK 5.2 billion. At the same time, allow me to put our guidance into the following context. The exchange rates from the end of November 2022 when we started our budgeting process form the basis for this guidance. We have set off energy inflation well in 2022, but merit and non-energy related inflation is impacting us significantly in this year. We will continue the rollout of Vyepti in around 15 additional markets this year. We plan to launch the 2-month version of Abilify Maintena and we plan to launch Rexulti in Alzheimer's agitation requiring significant launch spending, together with our partner Otsuka in fully utilizing this blockbuster opportunity over the coming years. Last, an additional provision is mentioned earlier of approximately DKK 300 million for Vyepti inventory obsolescence is reflected in the guidance for 2023. Next slide, please.

Joerg Hornstein, CFO: [00:17:34] Our mid-term financial targets are based on organic development of our business, pointing towards a solid growth in both revenue and EBITDA. We foresee a continued double digit growth for our strategic brands in aggregate, partially offset by slight erosion of sales of our mature brands, leading to a mid-single digit CAGR for our mid-term revenue aspiration overall. We're planning for investments for Vyepti, Rexulti and AAD and the 2-month version of Abilify Maintena. Also, we see further investments in life changing medicines. We foresee R&D costs to remain broadly stable from an absolute R&D spend perspective. This leads us to a mid-term target for an EBITDA margin of around 30 to 32% to be reached in the next 3 to 4 years. With that said, I hand over to Johan.

Johan Luthman, R&D: [00:18:29] Thanks a lot, Joerg. Let us turn page for the R&D update. During 2022 we had a very strong year for the R&D pipeline with several submissions and regulatory approvals among our key brands. In addition, we had a solid progression in our innovation pipeline. Of course, a major R&D event in the year was to read out of the Brexpiprazole papers all indication expansion, trial and Agitation in Alzheimer's disease

Dementia, a program that we're running together with our partner Otsuka. I will get back to this program a bit more in the next slide. However, I like to highlight that the sNDA submission was done at the end of last year, and by the beginning of this year we obtained information that the review will be under priority and an ADCOM is expected in the spring. The priority review means now an expected PDUFA date on May 10th. The clinical and CMC development of the new Aripiprazole 2-monthly ready to use, RTU, injectable formulation was completed during the spring of last year. Subsequently, during mid '22, we and our partner Otsuka submitted for market authorization in the US, Canada and EU. The submission is based on an innovative development approach, including a large PK-study providing robust data demonstrating bridging to Abilify Maintena. The FDA decision for Aripiprazole 2-monthly RTU is expected first, we had PDUFA date on April 27th. That means that important regulatory decisions for two key brands are expected during the spring. The Vyepti regulatory path in '22 included, of course, the granting on marketing authorization by the European Commission on January 24th. Subsequently, during the year, several additional market authorizations were obtained for Vyepti, including some Asian countries like Hong Kong. Overall, '22 was an important year for the global rollout of Vyepti, obtaining market authorization in 37 countries. The program aiming to replace the current pichia based manufacturing of Vyepti to a much higher yield CHO platform. Our critical relevance for the possibility of such a switch, we completed a PK-study during the year that demonstrated the clinical comparability between the drug products generated from the two different manufacturing platforms. As you heard me report several times during the last years, we have had really great data generated in various supported trials and Brintellix/Trintellix. That really clearly demonstrates the strong and unique profile of this product. Last year, we successfully concluded the brand's LCM program with a strong home run in a row of positive studies such as the Viver study and head to head study on Vortioxetine versus Venlafaxine in patients with major depressive disorder. We also concluded a (inaudible) study showing real life effectiveness in Japan for MDD patients. A study that was very well received by the SNP conference. And Memory that showed reduced depressive symptoms and improved cognition performance in patients with MDD that have comorbid dementia. This set of studies nicely complements earlier reported studies such as complete study on emotional blunting and reconnect, which showed effects in patients with MDD and comorbid generalized anxiety disorder. So, really nice wrapping up of that program. In our innovation pipeline. as Deborah mentioned, we progress well on our two PoC studies, achieving last patient included. I will come back to both of those programs in subsequent slides. Also,

during '22, we managed to enter clinical development with two very exciting programs. One was early in the year with the start of the CD40L inhibitor, 515, program we obtained from APRILBIO. By that, we initiated our first ever step into development of an immunology mechanism action molecule. This program offers a broad repertoire of indication opportunities. Also, very late in the year, we managed to squeeze in initial clinical development with our ACTH antibody, 909, that has the potential to address various critical neurohormonal dysfunctions, even possibly into the psychiatry space. Finally, we saw tremendous advancement in our early research pipeline with well over ten programs of highly attractive target biologies initiated or progressing. Among those, I'd like to highlight that we now are addressing RNA as drug targets, utilizing small organic molecules. Next slide, please.

Johan Luthman, R&D: [00:23:28] As promised, I will now move over to some more details on the Brexpiprazole program in Agitation Alzheimer's Disease. In the third phase III trial called 213, that had a readout in end-June last year, we explored a broader dose range 2 to 3 milligram as requested by the FDA, and that was a higher dose than in the two prior phase III trials. The trial showed a very clear cut and highly significant effect versus placebo on the primary outcome measure, the Cohen Mansfield's Agitation Inventory, and also on key secondary outcome measures the Clinical Global Impression Subscale severity of illness. In addition, we saw effects on several other supportive measures. I'd like to remind you that there is yet no drug approved on the US market to address behavioural and psychological symptoms or dementia of which agitation behaviours are critical. The medical need is substantial to address those symptoms, which are a common reason for the need to transition from home care to nursing care and agitation remains a clinical challenging problem, even under professional care. In the US. There is currently an estimated 6.5 million patients with AD, but those numbers are growing. Most of the AD patients experience periods of agitation during the course of the disease. And over 30% of patients are prescribed antipsychotics off label at some time point. Unfortunately, there are severe limitations in their use due to the tolerability issues primarily. It's therefore very comforting to see that Brexpiprazole across the AD program has showed very good tolerability and safety reporting. This is in line with what we already know from the established on current label patient populations. The data from the 213 trial were very well received when presented at key conferences in major sessions during the year, such as AIC in the summer and (inaudible) at the end of the year. Next slide, please.

Johan Luthman, R&D: [00:25:28] I'm also happy to note that during the end of '22, the Brexpiprazole program on post-traumatic stress disorder, PTSD, that is run entirely in the US, regained some momentum when the pandemic abated. Thus, the two ongoing trials of the program have been seeing some recovery of the randomization. After various interactions with FDA, we have decided to keep the two trial analysis as they are with an accelerated path for completion. We're now looking forward to finally have a readout for Brexpiprazole in PTSD during the second half of 2023. The unmet need in PTSD is also very high, with over 8 million people assumed to be affected in the US and the condition is highly underdiagnosed, however, so the exact number is unknown. PTSD is sad enough, growing societal burden and current approved therapies that SSRIs provide inadequate treatment responses. The initiation of the two pivotal trials were based on findings from an exploratory PoC trial, where the combination of Brexpiprazole and Sertraline showed an improvement on the primary endpoint, a clinician administered PTSD scale. While neither Brexpiprazole nor Sertraline showed an effect versus placebo. The two ongoing phase III trials are thus studying a flexible and fixed dose regiment of Brexpiprazole in combination with 150 milligrams per day Sertraline against either Sertraline or placebo. Next slide, please.

Johan Luthman, R&D: [00:26:56] I like to start to provide some more details on 222, our anti-PACAP monoclonal antibody. The molecule is being evaluated in the migraine prevention trial in people that fail to respond to 2 to 4 prior treatments. The PoC trial, which we call HOPE, achieved last participant included by the end of '22. And we can therefore look forward to phase II readout during this year. It is important to note that 222 binds to PACAP peptides, the ligands and not the various receptors that can bind PACAP peptides. And that is also an IGG1 isotype antibody, meaning that the antibody is blocking upstream in the signalling cascade with an efficient clearing mechanism of PACAP. The blocking of PACAP signalling is an interesting approach, given that it's differentiated from CRP class of drugs and provide a different and broader set of biological effects. In this program. We very recently obtained PK Data Bridge, which is a bridging study where we established the possibility to transition from the current IV formulation to subQ administration, if the program continues past PoC. In addition, I'd like to remind you that we have previously shown that 222 inhibits PACAP induced vasodilation, which is a proof of target engagement study. Next slide, please.

Johan Luthman, R&D: [00:28:21] 422 is a monoclonal antibody targeting an assumed pathological form of the Alpha-synuclein protein and Multiple System Atrophy. 422 is a biomarker supported trial that we call AMULET, that has raised considerable interest from investigators and patients. With this tailwind, our team managed to do a great job in fast enrolment, finishing the randomization during last year. We are very much looking forward to the patients completing the up to 72 week treatment period to get a readout by next year from this innovative trial. A trial readout that is also supported by a natural progression study called TALISMAN, which lends the possibility to strengthen the placebo arm analysis. Next slide, please.

Johan Luthman, R&D: [00:29:10] So, this is the status of our R&D pipeline. I mentioned most of the programs here. I'd like to highlight a few things, though. First, I like to highlight our Cluster headache program on Vyepiti, which is part of an indication expansion effort of that franchise. Cluster headache is, as you probably know, a very devastating headache disorder, a very intense one sided frontal headache which affects mainly men. Our main pathway is a randomized controlled trial called ALLEVIATE in episodic cluster headache. This is, I have to say, operationally a very challenging population to study given that the randomization is event driven and therefore it's hard to really predict timelines for the trial completion. I'd also like to draw your attention to our dual dopamine agonist. 996. This program is progressing during the year towards completing phase 1B that includes a dose escalation in Parkinson's patients. We have already some encouraging observations on its pharmacokinetics and safety, but also on eventual efficacy. Therefore, this might be an entrance into phase II within a year's time. To summarize the activities during 2022, we saw really good achievements, much thanks to our transformed and streamlined R&D organization. We are now in a clinical development across all our four strategic biological cluster areas. We are also able to further apply our tactics for the really best molecules, investing in programs with better understood pathophysiology and use stringent biomarker driven development, striving for very early and clear cut decision making. We have seen a strong progress in both late LCM as well and the early as well as in the early and late mid-stage pipeline. This means that with our current brand support, innovative development pipeline assets reinforced with further clinical entrants from our exciting preclinical pipeline and hopefully match with careful additions from BD, we are in a good position moving forward. Next slide, please.

Johan Luthman, R&D: [00:31:14] To recap what key deliverables you can expect in 2023. We have the back to back almost PDUFA dates for AD of Brexpiprazole and of course Aripiprazole 2-monthly RTU during the spring. We continue our strong efforts to progress the geographical and education expansion of Vyepti. Also, we have the exciting readout in phase II, our HOPE PACAP trial. And finally, we have the eagerly awaited readout for Brexpiprazole in PTSD during the latter part of the year. With that, I'd like to leave over to Deborah again.

Deborah Dunsire, CEO: [00:31:53] Thanks, Johan. Important to comment that while we drive to bring new medicines to patients, we also have a clear focus on how we do that business, and sustainability is integral to how we do everything at Lundbeck. So, we have made continued progress towards our ambition of being net zero by no later than 2050. We achieved our eighth consecutive year achieving a carbon disclosure project Leadership score. 100% of the electricity from our Lundbeck sites in Denmark is now covered by electricity produced in a solar plant south in Denmark, and we reduced the emissions from all our sites by 29%. We updated our climate targets, according to the new SBTi guidance, and made progress on that low carbon transition plan. So, I'm very proud of the progress that we have made as we think about our planet. Our business is about people and we reach over 8 million people a day with the products in our portfolio, changing their health, their brain health for the better. We increased donations in low and middle income countries, and we also moved the agenda on diversity and inclusion forward, making sure that we are a neurodiverse workplace and that we enable neurodiverse people to be able to work effectively. We additionally made progress of the share of women in senior management, up from 31.5% to 33.8%. The governance side, we're making progress around the world, making sure the selection of third parties and suppliers are based on good governance, compliance and appropriate and ethical treatment of employees around the world. So, next slide, please.

Deborah Dunsire, CEO: [00:34:00] When we go forward into 2023, we are building on an incredibly strong momentum coming out of 2022 with a great engine driving our strategic brands, being able to deliver a robust cash generative business. As Joerg pointed out, we've got a very strong balance sheet and so we have that financial capacity for long term growth. We remain focused on sustainability and everything that we do, and we're progressing towards CSRD readiness, which all of you are probably aware is a big lift. Importantly, we're advancing the progress in our R&D pipeline, the molecules are already in the house, and you've seen that

with progression towards what we hope to have be approval of AAD and the 2-monthly Abilify. And it's exciting to see the pipeline maturing with that promising science coming through from our early stage programs and from our internal research. There are a number of data readouts over the next 12 to 15 months. Of course, as Johan frequently points out, we build the business internally and externally, always bringing in ideas from the outside, even into the earliest target discovery, but also when we do deals with other companies. You know that we're focused on niche or specialty neurology and psychiatry and rare diseases. And there has been somewhat of a renaissance in that area with new neuroscience companies forming approvals coming through in the area of neuroscience. We are focused in our access to external innovation on how do we replace the product growth that we need into the mid and late decade. And we also focus on expanding that early and mid-stage pipeline that will yield the growth on a continuous basis. Lundbeck is a strong and growing business and will remain so long into the future. And so we look forward to an exciting year in 2023. With that, I'll stop for all of us to take questions. And of course, Jacob Tolstrup, Executive Vice President of Commercial Operations, is here with us to assist with all of your detailed questions.

Operator: [00:36:38] If you have a question for the speakers, please press five star on a telephone keypad. To withdraw your question, please press five star again. We will have a brief pause while questions are being registered. The first question will be from the line of James Gordon from JPMorgan. Please go ahead. Your line will be unmuted.

James Gordon, JP Morgan: [00:37:08] Hello, James Gordon from JP Morgan. Thanks for taking the questions. A couple of quick questions, please. One was on pricing pressure and gross margins. I think there was a reference to pricing pressure in the release. So, how much pricing pressure do you think we might see? Is that just in Europe and what does that mean for the gross margin in the three or four year time period you're talking about? Once we get past the Vyepti impairment, is Lundbeck going to be an 80% plus gross margin company? But the second one was also on guidance. Just I think the guidance doesn't include business development. The fact that you've given this long term guidance, not including that, does that mean you're now not thinking that there would be big business development that might maybe even get there? Or could we see you're not doing quite so well on the EBITDA margin because you might need to leave room for a big step up in R&D if you do some pipeline deals. And then just the final question was on Vyepti. The comment about the impairment on Vyepti inventory, which I think

is just over 500 Danish and total, could we read it that the product's selling a little bit less than what order had planned when they entered into that manufacturing agreement? And is there any risk that you might have to write down the value of all the products not doing what their original projections were?

Deborah Dunsire, CEO: [00:38:18] Okay. Thanks for the questions. I'll ask Joerg to take the question on pricing pressure and the gross margins.

Joerg Hornstein, CFO: [00:38:25] I think if you if you look in 2022, we fought off energy inflation quite well. We see an uptick specifically in '23 from direct material, but also basically services across our business. We see these effects and expect these effects to be moderating going forward.

Deborah Dunsire, CEO: [00:38:52] Any comments on the gross margin?

Joerg Hornstein, CFO: [00:38:54] I don't think we give specific guidance on the gross margin. I try to provide some transparency on the impact of Vyepti, but I believe the gross margin is contributing as well to achieve our overall profitability aspiration.

Deborah Dunsire, CEO: [00:39:11] Thank you. And then you asked about the guidance, not including BD. I think within our hands, we have a great business to drive forward and we know what we need to do in internal R&D for the things that we know about. BD is something that we actively look for and we will do the right deals that come across at the time that they're available and make sense for Lundbeck shareholders. And it's for that reason that we don't try to create an envelope that includes all eventualities because we can't plan for that. So, we want you to know what does this business organically deliver? And then I don't know whether you'd add anything Joerg?

Joerg Hornstein, CFO: [00:40:04] Not on this one, but I would take the other one regarding the question on the Vyepti impairment and the sales forecast. I think it's fair to say that there are always different parameters that factor into how we build provisions for inventory, sales volume, transition timelines, approval dates for transitioning to CHO. All of these are numerous of the factors we take into consideration. But I think I can only reiterate we finished '22

extremely strong, growing Vyepti 104%. And we also are intending to roll this out in more than 15 countries this year.

Deborah Dunsire, CEO: [00:40:46] I think it's important to say that the reason that this is coming now is because of a good thing, and that is that the level of certainty increased during the year as we found we would be able to scientifically, we believe, transition to the CHO backbone. And for that reason, we know that this technology shift is potentially possible. Now, of course, there's still a lot of unknowns and we still have to go through all kinds of taking it through regulators. But it's that increase in certainty that makes us consider this at this time. And it's also important to know that no single gram or ounce of Vyepti has been moved out. We'll continue to use this product into the future for as long as possible.

James Gordon, JP Morgan: [00:41:54] Thank you.

[00:41:59] Thank you, James. The next question will be from the line of Charles Pittman from Barclays. Please go ahead. Your line will be unmuted.

Charles Pittman, Barclays: [00:42:08] Hi. Thank you very much for taking my questions. Charles Pittman from Barclays. I have a couple of questions. Just firstly, to Joerg, since becoming CFO in August, I was just wondering what takeaways you've got over the past eight months you've been in the job now and on in terms of how the company is run and how you yourself plan to kind of make changes going forward. I think we've already seen some of that with the change in guidance. And then secondly, on Vyepti, currently you say that it has a 5.4% prevention share of the migraine market. I was wondering if you could give us any details on how you expect that to develop going forward and what your strategy is for competing in the increasingly competitive anti-CGRP market as large cap US player, and specifically how the launch of (inaudible) has impacted the Vyepti launch. Thank you.

Deborah Dunsire, CEO: [00:43:00] Great questions. Take it away, Joerg.

Joerg Hornstein, CFO: [00:43:02] Charles, maybe I start. First of all, thank you very much for your question. Eight months passed by very quickly, and I'm incredibly proud, happy, honoured and humbled to be CFO at Lundbeck. I've experienced a great management team, terrific

collaboration, a strong competence across all levels, and I only have very positive impressions so far. I think in terms of focus areas, I think there are couple. We, of course, are very diligent and laser sharp, focused on costs. I think you've also seen especially a strong Q4 that demonstrates that. I think we are very focused on what exactly is needed for the 2-months Abilify Maintena version to be launched successfully. What we require to achieve the desired uptake in AAD and also to clearly have a very strong and detailed tracking of the individual business cases around the Vyepti rollouts. So, these are probably some of the first impression and focus areas. But I'm sure over the next months there will be numerous coming on top.

Deborah Dunsire, CEO: [00:44:23] And then perhaps, Jacob, you'd like to take the Vyepti question.

Jacob Tolstrup, CCO: [00:44:27] Also, thank you, Joerg, for the great comments on your colleagues. So, thank you. On Vyepti a little bit mixed comment here. The 5.4% market share I think is quite impressive, and in that light you have to look also on (inaudible) coming in at the same time. And (inaudible) has made a, I would say, rather significant impact in the market. So, there's no doubt about that. What's important to note is around Vyepti is that we are the one that has also managed to keep and growing our market share during that entrance period. So, the strategy continues to be the same going forward. We focus on severely impacted patients and also patients that are in risk of or having medication overuse, headache. And that strategy seems to be working. And you've seen, I would say, accelerated growth, especially over the last three quarters in the US. And what we also see from our physicians that we survey is that we have increasingly number of what we call loyalist and the loyalist not only prescribe Vyepti for the target positioned patients, but also try to use Vyepti earlier in the line. So, I think what you'll see over time is that Vyepti will continue to grow and also grow not only in the segment where we focus first, but also in the more episodic segment going forward.

Deborah Dunsire, CEO: [00:45:53] Thanks, Jakob.

Charles Pittman, Barclays: [00:45:55] Thank you so much.

Operator: [00:45:59] Thank you, Charles. The next question will be from the line of Joe Walton from Credit Suisse. Please go ahead. You'll be unmuted.

Joe Walton, Credit Suisse: [00:46:10] Thank you. Just a few, please. You talk about your ambition now as a margin at the EBITDA level and assuming that there isn't too much adjustment there because we know your core EBIT. So, it's presumably core EBIT plus depreciation. That's taking us from around about 26% operating margin today to the 30 to 32% in, let's say 2026. I wonder if you could just help us with your sort of fresh eyes from a finance director's point of view where we should see the majority of that leverage come? You say that R&D is stable. Is that stable as a percentage of sales or stable as an absolute number? And if you could, also for the net interest charge and tax rate, give us a little bit of help for modeling in the coming years. You had a positive net interest charge at the core level in the fourth quarter of the year. So, some idea of what the net finance charge at the core level might be in '23 would be helpful. You mentioned the one time distortions on the tax. Presumably the tax rate should go back on a sustainable level to roughly the level it was in 2021. Thank you.

Joerg Hornstein, CFO: [00:47:36] Okay. Well, let's start probably with the R&D question. The guidance we've given was not as a percentage of revenue, but from an absolute spend perspective. And the first comment here is that you've seen already in 2022 that we more or less kept R&D flat because we had less spend compared to the previous year and marketed products. We still have a significant spend in marketed products also in '23, but already now we can at the same time with the relief versus the history, invest more in innovation. I think that's the question on R&D. I think focus for the margin expansion is mostly around continuing the global rollout of Vyepiti, keeping R&D expenses stable, seeing also a bit of I would say if we exclude the spend required for AAD a bit more of a normalization level on other SG&A related investments. And we also predict continued strong growth in our strategic brands and hopefully with the positive approval on AAD receive the desired uplift as well. I think you had a question on core EBIT versus adjusted EBITDA. Like I said, in Q1, we will provide a reconciliation of comparative numbers for the history as well as the guidance on this KPI going forward. I would say in generally the categories very much align, but we probably are a bit more consistent here in terms of using less of materiality thresholds. You had a question on the tax rate. The tax guidance we gave going forward is more around 22 to 24%. The main reason for the slightly higher guidance of the tax rate is basically a reduction of the R&D incentive in Denmark, which goes from 130% up to 22, now down to 108%. That is driving the higher tax rate. And I think in terms of net finance, the guidance we give is roughly around 100 million.

Joe Walton, Credit Suisse: [00:50:17] Thank you very much. That's very helpful.

Operator: [00:50:23] Thank you, Joe. The next question will be from the line of Keyur Parekh from Goldman Sachs. Please go ahead. Your line of the unmuted.

Keyur Parekh, Goldman Sachs: [00:50:33] Thank you for taking my questions. Please, if I may. One. What do you expect to be the main focus of the upcoming advisory committee for the AAD indication based on your conversations with the FDA so far? Where do you expect that focus to be? And then separately, coming back to Joe's question, if you're going to guide to and measure the business on adjusted EBITDA going forward, is there a reason you can't guide to that today? I mean, you're kind of telling us you guided to an EBITDA margin for the year or long term and you're telling us you're going to change the build of that guidance in three months time. So, I'm kind of just confused on why you can't give us adjusted EBITDA guidance today.

Deborah Dunsire, CEO: [00:51:27] Thanks, Keyur. Johan will take the first question.

Johan Luthman, R&D: [00:51:29] Yeah, thanks a lot. Of course, I don't want to second guess so much what they're going to say because it's up to the FDA how they formulate the key questions to the ADCOM committee and what other questions that will come up. But there are some obvious ones that we can expect here, and I can speculate a little bit about it. It will be the traditional ones. Efficacy, clinical meaningfulness, the strength of the readout and the primary readout is a scale that has not been used for approval. So, there will be probably little discussion around that efficacy data. If we look at the efficacy data we have, we have presented this at scientific meetings. We have very consistent effect across the different sub items of the Cohen Mansfield Scale. So, it's a very robust readout across the different subcomponents of it, which is a good sign that the scale was not driven by one sub parameter. We also have consistency across the trials, which is very important. So, I'm pretty confident about the efficacy discussion. Obviously there will always be some subgroup analysis they like to discuss, but I think the bigger conversation will probably be around the tolerability because this is really the key factor against the off label use of antipsychotics. And as you may be aware of this black box warning for the use of neuroleptic there. And obviously, we have data that are remarkably

strong here, I have to emphasize that. Across this program and from the previous use and other indications. So, I think one could be a discussion is this an applicable black box warning across into this product, which has a little different mechanism of action. This is a partial dopamine agonist with rich pharmacology. So, there could be a rationale to discuss with whether it's applicable. At least we're looking forward to that tolerability discussion because we have that strong data. So, those are the key questions that I think will emerge. But in terms of the medical impact, there is always some discussion about how important could a therapy like this be? I'm looking forward to that with great confidence because the medical need is enormous and this is a key symptom, as I outlined. So, that aspect I think, would be great to converse about. I'm actually looking forward to this outcome. If it happens, it can be always cancelled. But since there's a new indication in the field, I think it would be great to have an outcome and discuss these things with regulators and other people in the group.

Deborah Dunsire, CEO: [00:53:58] And Joerg.

Joerg Hornstein, CFO: [00:53:59] We're taking your question on the adjusted EBITDA. It is, in my opinion, good practice that if you introduce a new KPI, you make historical numbers available. And that is something we're currently looking at. And that's purely the only reason that we don't use it now. But I think as early as said, the categories of adjusting are very similar to core EBIT. And please rest assured we will always provide a full reconciliation and full transparency in case any adjustments would have been made.

Deborah Dunsire, CEO: [00:54:36] Thank you.

Keyur Parekh, Goldman Sachs: [00:54:37] Thank you. Could I perhaps just sneak in a quick third one. On the studies for kind of PTSD. You're going to give us data from the two kind of phase III trials, headline data, second half of this year. So, could I perhaps just check kind of where you are with the FDA on that end? Do you need both of them to be positive for you to be able to file or are you still planning to do the meta-analysis? And if so, have you reached an agreement with the FDA on the statistical plan for that? Thank you.

Johan Luthman, R&D: [00:55:14] Yeah. Thank you for that question. I guess it's for me. So, I start. As you heard from us earlier, we have had some quite some discussions with FDA during

the journey here. Obviously, we had an alignment before we went into this program. They expected the classical replication across two studies. That's a very traditional approach, particularly in behavioural neuropsychiatric indications. So, we're not surprised about that. Some of the conversation we had was can we pool data? And I think they're really still very eager to see the prime analysis being across the two different studies. And relating to your question, if one misses and one hits, yeah, it remains to be seen how the data looks across. But in this very, very high medical need area where there is no drug from this type of class approved, I think there is a really worthwhile having a conversation. Whatever data we get at, unless it's flat negative. So, any positive sign in a trial like this you would like to discuss with the regulators? Obviously, we're hoping for the best that we have two clear cut studies and there would really be no conversation about it.

Operator: [00:56:26] The next question will be from the line of Michael Novod from Nordea. Please go ahead. Your line will be unmuted.

Michael Novod, Nordea: [00:56:34] Thank you very much. Three questions from my side. First of all, maybe you could detail a bit on the sort of the step change in gross margin relating to Vyepiti from changing the production method. I am aware you can't give exact numbers, but just give a bit of feeling of what is actually the magnitude of improvements here. And then secondly, maybe Jacob for you what are sort of the top priorities for the new head of the US? It's sort of not been discussed. You changed head of the US business, is it reinvigorate the franchise together with Takeda, preparing for the launch of AAD, what are sort of the top priorities for you the US? And then lastly, regarding firepower. So, you've always been quoted for in media saying that you don't see any sort of big things perhaps coming up more in licensing smaller Hold ons. But if that's the case and you are so highly cash generative, have you then considered to do a share buyback also in light of where your stock is trading for the time being?

Joerg Hornstein, CFO: [00:57:49] Maybe I'll start in the end, and then we work our way up, Michael. First of all, thank you for your question.

Michael Novod, Nordea: [00:57:54] Sure.

Joerg Hornstein, CFO: [00:57:56] Share buyback is currently not something we have been contemplating or communicated to the market. We stick to our existing policy of a dividend payout of roughly 30 to 60%. So, that is that topic. I think, in terms of gross margin step change of Vyepiti, we don't provide individual numbers, but what is, of course, fair to say, and Johan can fill in here, is of course a significant improvement in the yield.

Johan Luthman, R&D: [00:58:32] Yeah, that's of course, one of the key things. And it's substantial. It's manyfold, increase in yield. And that's really the secret of the sauce here. That's what we're aiming for. But you should also know the PACAP platform is actually, quite frankly, becoming an obsolete platform. So, it's really hard to get providers for the platform. So, we buy CHO, we buy ourself also flexibility in terms of where we can manufacture. And that's very, very critical because the mainstream is CHO, now. Back in the days PACAP was an attempt to get alternative platform, which didn't pay out, when it when it came to yield. And the volume as you saw that big container in that graph, you basically go down substantially in the volume you need in the reactor size.

Deborah Dunsire, CEO: [00:59:21] Great. And then you've asked for the priorities for the US. Well, I never in my career have I had two PDUFA dates within a matter of a couple of weeks of each other. So, any time an organization's launching, there's a laser focus needed on making sure those launches are well prepared and really ready to roll. Additionally, of course, we're still in that growth phase for Vyepiti. So, there's a tremendous amount of work to be done in the US organization. We have been working with our partner Takeda. As you know, there was substantial realignment and restructuring of that Trintellix field force. We did some downsizing at the end of '21. Takeda downsized very significantly given the Vyvanse expected patent expiry coming up now, I believe in this first quarter. And that disruption lasted far longer during 2022. So, we work very closely together with Takeda, making sure that we're aligned on our field force execution and aligned on our messaging around Trintellix. The profile of Trintellix is an extraordinary tool in addressing depression and in a way that people are able to be at work. So, I know that we can get great utilization. The market has significantly changed. And maybe, Jakob, you want to amplify on that?

Jacob Tolstrup, CCO: [01:01:02] Yeah, no, absolutely. So, you can say finally we see the US market coming back to growth rates that sort of resembles what we had before the pandemic.

But it is clear that the rate of remote consultation by psychiatrists are still relatively high in the US compared to what we see elsewhere. We also see fewer patients that are being diagnosed and most of them are getting a first line treatment and not progressing to a third and fourth line. So, whether this is related to sort of an understaffed situation in the US, that question still remains. But it's clear that the US antidepressant market hasn't recovered. You can say to what we knew of before the pandemic began, which is contrary to what we see outside of the US.

Operator: [01:01:58] Thank you, Michael. The next question will be from the line of Mark Goodman from SEB. Please go ahead. Your line now be unmuted.

Mark Goodman, SEB: [01:02:06] Thank you. So, a couple of questions. First, the gross margin, the \$300 million hit, is that going to be any one particular quarter or is that just spread across 2023? Second of all, the operating margin was supposed to be over 30%, I believe, next year previously, but now we're moving it to 30 to 32% in 2026. Is that accurate? And I'm just kind of curious just what has changed there. And then lastly, on the Neurohormonal, it seems to be a new area. I'm just curious, did the science lead you there or is this a new area of focus? I think you said you were going to take it into psychiatry. So, does that mean like depression? I'm just curious what you meant there. Thanks.

Deborah Dunsire, CEO: [01:02:52] Great. So, I think the first two questions go to Joerg, but I'm going to start with Johan on the Neurohormonal.

Johan Luthman, R&D: [01:02:58] Yeah. Thank you for asking about this. Obviously, this is a program that just is going into man and being tested. So, it's very, very early days. And we have a number one is we like to see that we deliver on the pharmacokinetics that we really need to fine tune here. We like a very homeostatic sort of response on the ACTH levels and of course safety and tolerability. That works fine. This is a very validated biology, which is an interesting way for us to work. A really good sign where we like to be, where we can very, very early have very clear cut biomarker readouts that it's working. And obviously here one of the key things we like to see is an effect on different steroids, cortisol levels, etc., in the blood. And we take it into congenital adrenal hyperplasia as the first population. It's a mechanism of action, primarily a pathway to see that the drug is delivering in a population where you really have pathological changes of the levels. Where we take this can be multiple pathways. There are obvious

indications here in the neurohormonal space, the hormonal space, Cushing's congenital adrenal hyperplasia is of course something we could contemplate. All these diseases come with CNS symptoms, so it's definitely within our frame, but it's on the outer limb of our frame. I could say, being a neuroscience company. But there's been a long, long story about the so called HPA axis and psychiatry and you mentioned depression. People have tried this before. Our approach to this is that we're again going to be very strongly biomarker driven. We're going to look for populations where you have an abnormal HPA axis using biomarkers to guide us. Exactly which indications is still a discussion, we are early days, as I said, but there are way beyond depression where you can go over this. There are excited disorders, panic disorders, are some areas of where you can take it.

Deborah Dunsire, CEO: [01:04:52] And I think just a reminder that this antibody came to us out of the Alder BioPharmaceuticals acquisition. So, it's the third of of the molecules coming out of that acquisition Vyepti, our cap inhibitor, and ACTH. So, great exploration of this biology. And it's early days, but it's great to be able to explore it. So, I'm going to hand over to you.

Joerg Hornstein, CFO: [01:05:21] I think phasing for the Vyepti provision. I consider this more of an event for H1 this year. In terms of specific guidance. The guidance we gave before was on EBIT. The guidance we give now is on EBITDA because we have a significant amount of amortization. And even the earlier question I got on gross margin, keep in mind about a third of our cost of sales are basically amortization of product rights and 50% are denominated in dollars. So, you can see quite some swings here that somewhat cloud the underlying, let's say, strong operational performance we have. The EBITA target or range we communicate for the mid-term guidance rests on the, I would say, predominantly strengthen our strategic brands and also the aforementioned key significant launches we are undertaking.

Deborah Dunsire, CEO: [01:06:24] Next question.

Operator: [01:06:30] Thank you, Mark. The next question will be from the line of Michael Leuchten from UBS. Please go ahead. Your line will be unmuted.

Michael Leuchten, UBS: [01:06:39] Thank you. Thank you for taking my questions. Could I please go back to the Vyepti inventory obsolescence? And two questions for that one. Why

does it come into provisions? Why not one? And then looking at the size of revenues that Vyepti has delivered so far, the size of the provision is quite meaningful. So, I guess it's not just inventory recalculations. What else is booked that makes that provision so large. And then a question about the guidance. Now that you're focusing on EBITDA, does that have any implications on KPIs or management incentives going forward? Or is it just a different way of looking at the underlying performance of the business? Thank you.

Joerg Hornstein, CFO: [01:07:28] I think the first question, why not one provision instead of two? Of course, we can only build provisions for inventory on hand. And I think as I said earlier, the external CMOs stops producing during the course of '23 and that also is one of the reasons that only then we can basically build that provision and. The other question was on the.

Deborah Dunsire, CEO: [01:07:58] The size of the provision.

Joerg Hornstein, CFO: [01:08:00] The size of the provision. No, there is nothing else. This is purely value for inventory we received from our (inaudible).

Deborah Dunsire, CEO: [01:08:10] I think the one comment and we did mention this in the release, there was a fixed batch quantity supply agreement written by Alder BioPharmaceuticals. And then during the years the yields even from pichia went up from what had been expected. So, actually there were two levels of I'd say growth in the size of that inventory. But it's very important to remember that the timing of bringing it in now is based on our increased certainty of being able to transition the backbone. And it's a financial provision, not an action on the drug. Coming back to your question on EBITDA guidance, does it change management incentives? And the answer is not in 2023. That's it for today. We really appreciate your attendance and it's great to be celebrating Lundbeck's highest revenue year ever and great performance across our business. Thank you for joining us.