

H. Lundbeck

Transcript: Financial statements for the first nine months of 2022

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Operator: [00:00:00] Ladies and gentlemen, welcome to the Lundbeck Financial Statements for the first nine months of 2022. For the first part of this call, all participants will be in listen only mode. And afterwards, there will be a question and answer session. Today, I am pleased to present Deborah Dunsire, President and CEO, Joerg Hornstein, Executive Vice President and CFO. And Johan Luthman, Executive Vice President of Research and Development. Speakers, Please begin.

Deborah Dunsire, President and CEO: [00:00:33] Good afternoon, everybody, and welcome to Lundbeck's third quarter earnings call. You've seen our disclaimers before. We will be making forward looking statements. So I'm going to leave it there and move on to describing what we believe is a great quarter. The nine month performance highlights is that we have revenue growth in reported rates, up 11%, supported by very strong demand for our strategic brands. Altogether, the strategic brands are up 30% in reported currency. Vyepti, the newest member or the newest kid on the block of our strategic brands, is up 105% through the first nine months. All of that has helped contribute to robust growth in profitability as well. EBIT up 22% and the EBIT margin reaching 18.1%. We've also progressed in our pipeline. Johan's going to take you through some very, very nice results from Trintellix in our MEMORY study for people with MDD who also have dementia. And we're happy to say that we finished the enrollment to our AMULET trial in multiple system atrophy. Johan will update you on the PTSD trials which are progressing towards a headline result in the second half of 2023.

Deborah Dunsire, President and CEO: [00:01:57] Next slide, please. The strategic brands are really the powerhouse behind the portfolio, reaching 65% of our sales for the nine months. And what's most pleasing about them is growth across all the brands and also across all the regions. The mature brands continue to be very stable and good contributors to both revenue and profitability for Lundbeck.

Deborah Dunsire, President and CEO: [00:02:23] Next slide, please. So touching on each of the strategic brands, you see the growth numbers that are really remarkable and a testament to the execution in the field across our various different countries. And so we'll talk about each of those in a bit more detail. Trintelli, obviously our biggest brand to date, really stand out in Japan, but we'll come to those on each of the slides independently.

Deborah Dunsire, President and CEO: [00:02:53] Next slide, please. Vyepti growing well and we see the brand reach 5% market share in the prevention market for migraine in the US, one of three brands that continue to grow during the third quarter and the persistency continues to exceed that of competition. One of the big stories, of course, is that the global rollout for Vyepti is continuing. Some of the markets that were first to launch after the US towards the end of last year, UAE and Switzerland, have really achieved some great market shares, 13% of the prevention market in UAE and 4% in Switzerland. And of course, the global rollout has continued with Australia, Canada, Estonia, Finland, Germany, Singapore, Sweden and Switzerland in 22. Germany, one of our more recent launches is seeing very nice uptake in the first weeks and some great reports back from people who are receiving Vyepti and being significantly helped. And that's what we've seen in every market where Vyepti has launched. We've got another couple of markets to go in 2023 and then of course the balance of the European rollout into 2023.

Deborah Dunsire, President and CEO: [00:04:09] Next slide, please. Brintellix/Trintelli, it's been a long time on the market in many countries, but it is still continuing to grow. We've had particularly strong growth in Europe, international markets with Canada, Spain, China and Italy being the growth leaders, and we've seen some very strong growth in prescribing from GPs, particularly in Spain. Japan is a standout achieving a 9.1% value market share together with our partner Takeda, up 3.3 percentage points in 2022. And of course, as we've seen in other markets, Trintellix grows as it is accepted by physicians tried in their in their more refractory patients. They try it, they like it, and then they move it forward in the adoption, and we're seeing some first line usage now in Japan.

Deborah Dunsire, President and CEO: [00:05:08] Next slide, please. Rexulti extremely strong. And of course, the US is the driver there with share at an all time high and increased number of prescriptions. And we believe this is due to both strong in-person promotion as well as a very

strong DTC campaign. Our launch preparations for agitation and Alzheimer's disease are underway, but the growth here is really being driven by the MDD indication, MDD indications also on the label for Canada and Brazil, and we do see dynamic growth in Canada with a close to 30% year-on-year volume share with the volume share now at 3.2% and Brazil's more than doubled the sales and it has a volume share of 1.8%. So, good and dynamic growth even beyond the US.

Deborah Dunsire, President and CEO: [00:06:07] Next slide, please. Abilify Maintena has been extremely solid across the markets. The big growth drivers here are the US, Spain and Canada. Market share in Europe has continued to grow and we now exceed 30% market share in countries like Italy, Switzerland and the UK and in some in a lot of instances, we're growing faster than the overall LAI market. Speaking to the strong profile and acceptability of Abilify Maintena for physicians and patients. As you know, we've submitted for regulatory approval for the two month version of aripiprazole, which will be called (inaudible) in Europe. And the FDA has given us a PDUFA date of April 27th, 2023. The review of those filings is progressing on track.

Deborah Dunsire, President and CEO: [00:07:00] Next slide, please. I'm going to hand over here to George Hornstein to take you through the financials in more detail.

Joerg Hornstein, Executive VP and CFO: [00:07:08] Thank you, Deborah. We're delivering very strong year to date numbers and even stronger Q3 numbers. There were certain onetime effects that benefited our top and bottom line performance, especially in Q3, but allow me to come to this in a minute. From a revenue bridge perspective, the plus 11% of reported revenue growth can be decomposed as follows. We're delivering an underlying organic growth rate of 6% due to the strong performance of our strategic brands. The strengths of predominantly the US dollar has led to an additional positive FX impact of 8% that has been backstopped by a negative hedging impact of -4%. Please keep in mind that the negative hedging effect of 410 million DKK for the first nine months of this year is impacting EBIT negatively 1 to 1. From an EBIT bridge perspective. Our EBIT grew by 22% overall with an underlying growth rate also of 22%, so you can see that the positive EBIT effects impact of plus 24% was fully offset by the net negative hedging effect of -24%. If we shift our attention to the key figures, again, the effects impact on our cost items therefore should be looked at as follows. As SSG&A costs grew plus

15% with an underlying organic growth rate of 8%. Reasons for the increase are higher promotion and sales costs, predominantly in Vyepti, but also to an extent the return in comparison to pre-COVID levels that still impact our year to date 2021 numbers in comparison.

Joerg Hornstein, Executive VP and CFO: [00:08:51] R&D costs grew 1%, which was impacted by timing, which makes actually Q3 this year in comparison to last year look a bit lower than what we have seen year to date. Another aspect in the year to date numbers are reversal of a provision of approximately 100 million DKK as well. Our core EBIT growth plus 13% with an underlying organic growth rate of 11%. Our EBITDA growth is plus 14% reported with an underlying organic growth rate of plus 13%, improving our margin to 27.7% compared to 26% 0.8% to last year year. Overall, we see a margin increase across EBIT, core EBIT and EBITDA growing faster than our organic revenue growth. Q3, this year was a particularly strong quarter that benefit, first and foremost from the strong performance of our strategic brands and to a lesser extent, certain one time effects in the magnitude of about 2-3% of our EBIT margin in Q3 and 1-2% year to date.

Joerg Hornstein, Executive VP and CFO: [00:09:59] Next slide, please. Let's have a look at our reported numbers. Lundbeck increased its net financial expenses for the first nine months of this year by plus 26% or 81 million DKK. The most relevant part of this increase comes from the fair value adjustment for the contingent consideration for EMA's approval of Vyepti amounting to 331 million DKK in 2022 compared to 110 million in 2021. This overall increase was offset by the effect of interest costs driven by the 21 repayment of our term loan and the close of IRS contracts and other financial asset gains in the amount of 23 million DKK. The effective tax rate remains unchanged at 22% compared to last year. The reported net profit corresponds to an EPS of 1.62 DKK and an EPS of 1.33 in 2021.

Joerg Hornstein, Executive VP and CFO: [00:11:04] Next slide, please. The stronger EBIT performance is the starting point for higher operating cash flow, but there are few offsetting factors. If you look at adjustments for non-cash items, then the most part of the amount relates to depreciation and amortization of around 1.2 billion and the reversal of other provisions of - 148 million. Changes in net working capital are driven by higher receivables due to higher sales, increases in inventory and timing of accruals. From the total CVR payment of 1.6 billion in Q1 2022, about half a billion are reflected in other changes in operating activities, and the

remaining 1.1 billion are reflecting the cash flow from investing activities. So please note in case we would have not secured the CVR payment, our free cash flow would have amounted to 2.4 billion, which would constitute an increase of plus 56%. The changes in the cash flow from financial activities are driven by loan repayment in 2021 and loans obtained in 2022. Our net debt decreased to 3 billion, leading to a net debt to EBITDA ratio of 0.7 for the rolling four quarters. And we're making our plan progress on further deleveraging the company.

Joerg Hornstein, Executive VP and CFO: [00:12:28] Next slide, please. Our financial guidance for this year was raised on the 8th of November. We've increased our top line guidance to 17.9 to 18.2 billion due to the strong growth momentum in our strategic brands and a further appreciation in the US dollar. Q4 has been historically a lower quarter for Lundbeck, both from a revenue and profitability perspective. R&D costs are higher towards the end due to higher project activity, and SG&A costs are driven by the support of the international rollout of Vyepti. As a result, we have adjusted our bottom line guidance to an EBITDA of 4.4 to 4.6 billion, aore EBIT of 3.9 to 4.1 billion and then EBIT of 2.6 to 2.8 billion. Please keep in mind that the positive impact on EBIT is nearly fully offset by the hedging effect. Consequently we increase our expectation for the full year hedging effect from 500 million negative to 600 million negative accordingly, the core EBIT guidance was only narrowed in range due to the potential reversal of a restructuring related provision that has not been considered a core adjustment to start with that we're currently working through. With that, I'll turn the microphone over to Johan.

Johan Luthman, Executive VP of Research and Development: [00:13:54] Thanks a lot, Eric. So let me start by talking a little bit about how we continue to build our brands through various critical lifecycle management activities. Naturally, one, our biggest R&D events during the summer was the positive readout in the brexpiprazole trial in agitation Alzheimer's dementia. As you may recall, this was the third pivotal trial study 213 on brexpiprazole in the condition, a trial that was designed to evaluate a broader range of doses two and three milligram during a 12 week double blind treatment period. In early August, the headline data were presented at the Alzheimer's Association International conference, AAIC in San Diego, and they were well received. And we are now looking forward to a deeper presentation and the panel discussion of the data on December 1st at the upcoming clinical trials in Alzheimer's Disease conference, the CTAD conference in San Francisco. The Otsuka and Lundbeck Alliance on brexpiprazole working hard together in the submission team in close collaboration on the submission package, and we

are now looking forward to the submission of the sNDA within shortly. The program has already fast track designation with FDA. We are also now looking forward to finally be able to have a readout in ongoing post-traumatic stress disorder trial that Deborah mentioned. While the two ongoing trials of the program are struggling severely with enrollment during the pandemic and still have challenges in enrollment, we have been seeing some recovery of the randomization. Also, as we reported earlier, our joint Otsuka Lundbeck product team has had very good discussions with FDA on those trials and its sample size and data analysis approach.

Johan Luthman, Executive VP of Research and Development: [00:15:43] After final feedback from the agency on this program, we have decided to keep the two trial analysis as they are, but with an accelerated path for completion. For aripiprazole two month injectable formulation that will add to our current once monthly Abilify Maintena brand. We are progressing very well with the regulatory process across agencies in the US, EU and Canada. The end of review and decision date is coming up first in the US with a PDUFA date in April next year. While the EMA and Health Canada decisions are expected during the late summer. For Vyepiti. We are continuing our major R&D activities. Regulatory activities are still progressing very well, with current approvals now in 45 countries, with recent approvals including Hong Kong and Saudi Arabia. Review is currently ongoing with ten additional agencies. In our Asia directed studies, we have the SUNRISE registration trial ongoing that evaluates the efficacy of eptinezumab to prevent migraine and headache in patients with chronic migraine, which also has a sunset extension part. This study is progressing well and is aiming as main markets for China and Japan. However, following the readout of the spearheading small sunlight trial during the summer that focus on Chinese patients with a combined diagnosis of chronic migraine and medication overuse headache, we have been able to obtain invaluable learnings on the Chinese migraine population and expected outcomes. These learnings are now fully harvested into the ongoing SUNRISE trials, where we now have decided to substantially increase the sample size and balance carefully the different patient populations. This will lead to a very robust study to fully establish the drug potential in key Asian geographies. Just a day ago we obtained very interesting results from the dose blinded extension, part of the previously reported delivery study. As you may recall, this study evaluated 100 and 300 milligram doses of Vyepiti versus placebo in Europe that have failed on previously two to four previous migraine prevention treatments. Following switching to active doses, we saw a very rapid treatment effect in the previously placebo treated patients. More importantly, over 60% of the patients saw at least a

50% reduction in their monthly migraine days for up to 18 months. This really confirms not only the very powerful effect of the drug, but also the very long term sustained effects.

Johan Luthman, Executive VP of Research and Development: [00:18:34] Next slide, please.

Yeah, Deborah already indicated that I'm very pleased to present a very interesting study on vortioxetine. The MEMORY study is the last of a set of great Phase IV studies conducted on the molecules such as the complete study on emotional blunting, reconnect in patients with MDD and comorbid general anxiety disorder, and the VIVRE study that compared comparative efficacy of vortioxetine in against decision desvenlafaxine. In the MEMORY study, we evaluated the effect of MDD patients that have developed mild to moderate dementia. Not only did the drug have a rapid onset anti depressive effect as measured and measured by MADRS, but it also improved cognitive performance on two separate measures, the digit symbol substitution, the DSST, and the race short and delayed memory recall test. This effect on cognition is particularly interesting given the different pathophysiological substrate for cognitive dysfunction in patients with dementia. Also note is that effect on those tests were observed already after four weeks of treatment. Also on quality of life measures, the bath assessment of subjective quality of life and dementia measure, there was a strong and very early onset of positive effects.

Johan Luthman, Executive VP of Research and Development: [00:19:59] The next slide, please.

From our Phase II Pipeline. I like to mention our alpha-synuclein and PACAP programs. Both are progressing well. 42 is a monoclonal antibody targeting the assumed pathological form of alpha-synuclein in multiple system atrophy. It is in a biomarker supported Phase II proof of concept trial called AMULET. While this trial had raised a lot of interest from investigators and patient organizations, the team had also done a great job in accruing the patients with the faster-than-expected enrollment. We are also much looking forward to the patients completing the treatment period that lasts up to a maximum of 72 weeks to see if this drug can affect biomarkers of clinical measures.

Johan Luthman, Executive VP of Research and Development: [00:20:49] And I would come back to our second Phase II program 222 in the next slide. That is our PACAP monoclonal antibody that is looking at prevention of migraine. In the Phase I portfolio, I'd like to highlight a few programs. We have a dual dopamine agonist, 996, that is completing a dose escalation study in Parkinson's patients. We have obtained very encouraging observations on its safety

and also potential efficacy actions. 515, our interesting differentiated novel antibody like molecule against anti-CD40 ligand is accelerating our R&D strategy within neuroimmunology. And that program is also progressing well towards completion of Phase I activities. As you may recall, CD40 signaling is an established and clinically validated immune pathway in several non neuro indications, but it has a broad potential. The mechanism of action acts on several immune cells and we're going to explore the program in areas of interest within Lundbeck strategy.

Johan Luthman, Executive VP of Research and Development: [00:22:00] Next slide, please. So back to 222 program in high-affinity anti PACAP monoclonal antibody. It's continuing in its Phase II HOPE trial. It's a proof of concept study in about 230 patients. And we expect to finish randomization within very shortly. That program is built on a very interesting molecule, the PACAP binding antibody. It's an IgG1 antibody that works with very efficient clearance of the targeted ligand for the receptors. In preclinical data, we have shown that it's highly differentiated mechanism of action delivers in different what we believe are migraine-related associated symptoms. We also done a very solid Phase Ib study to look at its target engagement and we demonstrated proof of mechanism before we progressed into this HOPE study. So far, our safety data look encouraging. We have no flags on safety readouts in the trial. I also like to mention that we have a smaller study that may be a little confusing for people because it's in subjects for allergic rhinitis, but it's a mechanism of action study that explores also this mechanism in terms of broader potential mast cells and neurogenic inflammation, which of course potentially could be of interest for our indication areas. With that, I'd like to leave over to Deborah.

Deborah Dunsire, President and CEO: [00:23:27] Thanks, Johan. Next slide, please. So Lundbeck remains committed to our purpose of restoring brain health so everybody can be their best to drive that long-term sustainable growth. We're going to be continuing to maximize the strategic brands we have in our hands, investing behind their growth, bringing new indications and new formulations to the market, capitalizing on the years ahead of us with no significant LOEs. Johan has made great progress with his team in our R&D transformation towards the mid and long term, bringing forward a new innovation into our pipeline focused in those four biological clusters and really driving our development with biomarkers wherever possible. So that we can actively manage the portfolio, making decisions to move projects forward if they succeed or

move them out of the portfolio if they don't measure up. We're also looking to secure the mid and late decade growth that's going to be coming largely through BD. And we remain focused as a neuroscience company, really leveraging the great commercial capabilities and R&D capabilities that we have within Lundbeck focused in this area. We've said that we would be active across all levers to build the company, partnerships where we've been very successful in the past and are currently together with Takeda and Otsuka. We would do targeted in-licensing potentially to get regional rights or access to a molecule, as we did with the CD40 that is now anchoring our neuroinflammation cluster in Phase I or do bolt-on M&A. We've also said that we don't anticipate using equity in the near term in spite of the fact that the share split was put in place to give flexibility in the long term. With all of that, we will be actively managing this company for sustainable growth into the long term future. I'll finish up there and we can move to your questions. We'll be joined for the Q&A also by Jacob Tolstrup, our EVP of Commercial Operations.

Operator: [00:25:41] Ladies and gentlemen, if you have a question for the speakers, please press zero one on your telephone keypad. Our first question comes from the line of Charlie Mabbutt of Bernstein. Please go ahead.

Charlie Mabbut, Bernstein: [00:25:57] Great. Thanks for taking my questions. Charlie Mabbut from Bernstein. So firstly, I appreciate that the R&D spend in the quarter was favorably impacted by timing of payments, but given some of the larger late-stage programs are winding down, how should we think about the development of this cost line in absolute terms over Q4 next year and beyond? And then secondly, on Trintellix, absolute volumes in the US have been flat for around six quarters now. So is there really any reason that we should expect this to change? Thanks very much.

Deborah Dunsire, President and CEO: [00:26:31] Thanks for your questions, Charlie. Maybe I'll start on the on the R&D. We certainly saw a slightly lower Q3, given that there are payments that are falling into the fourth quarter and overall for the year, I think we've said we'd be slightly ahead of 2021. Yes, there are some of the late-stage programs that are rolling off, but there are also some we thought might be done where we're continuing. You heard Johan talk about the PTSD program, the two trials continuing, and then also expansion of SUNRISE. So

there's puts and takes. But we're certainly overall for the year, slightly up on 2021. And right now we're not guiding for 2023. So I'll stop there and turn it over to you, Jacob.

Jacob Tolstrup, Executive VP, Commercial Operations, CCO: [00:27:26] Yeah, absolutely. So I think we talked about it the last quarter or so. The US market has dramatically changed coming out of COVID, which means that we have a psychiatrist to a very large degree continuing to use telehealth in their practice. At the same time, the total NBRx in the US is still at a lower level than it was before COVID. But that doesn't mean that we have sort of or that we expect it to be continue to be flat. We are actively working to change our messaging. We're actually working to optimize physicians that we approach and promote Trintellix too. And so there is a number of activities ongoing so that we can, over time bring Trintellix back to a growing trajectory. That said, I do not anticipate Trintellix US to become close to anything like what we see outside the US for the time being.

Charlie Mabbut, Bernstein: [00:28:32] Thank you very much.

Operator: [00:28:36] Our next question comes from the line of Dominic Lunn of Credit Suisse. Please go ahead.

Dominic Lunn, Credit Suisse: [00:28:43] Hi. Thank you. So my first question is on pricing expectations for next year. So you have historically taken higher price rises than CPI, which we assume are largely rebated away. And clearly next year we have the implementation of the IRA inflation price cap. But there shouldn't be too much of an issue given the current high rate of inflation. So could we assume even higher prices next year than you have taken historically? And if so, to what degree do you think this can offset cost inflation pressures? And then my second question is on Vyepti competition. So I was wondering if you could update us on your plans on how you plan to differentiate Vyepti versus other CGRPs. And clearly, you have the buy and sell angle. I was thinking more in terms of the clinical perspective. So we saw that you've now started a real-world study versus BOTOX and other injectables CGRPs. But what was the reason to not include the orals in this study? Nurtec has really kicked on since Pfizer started promoting it in August. And at their results, they talked about further enhancing that commercial effort. So, you know, does this have an influence on how you plan to carve out a clinical niche for Vyepti.

Deborah Dunsire, President and CEO: [00:29:53] Great questions. Jacob's going to jump in with those.

Jacob Tolstrup, Executive VP, Commercial Operations, CCO: [00:29:56] Yeah, absolutely. So we can start with the price. We do not anticipate any change to our pricing policies next year. On Vyepti. I think it's very important to highlight the positioning that we see for Vyepti at least to begin with, is targeted toward more severely impacted patients that would typically more chronic impacted patients and patients that are in risk over time to develop medication overuse headache. But that also means that Vyepti is targeted different than what you will see for the other anti-CGRPs, just the subcutaneous versions in the US. And I think that's the main differentiator. And when we look at both the preventive market but also specifically into the chronic market share, we also see growth of Vyepti in the market share. And we see the chronic market share also growing well for Vyepti. So I don't know if that answered your question, but that's typically how we see Vyepti more focus towards those patient groups. Also going forward.

Deborah Dunsire, President and CEO: [00:31:12] Johan will comment.

Johan Luthman, Executive VP of Research and Development: [00:31:14] Maybe I can add a little bit on the differentiation. So first of all, before answering directly your question, I'd just like to remind you about the data we have. I talked about the delivery extension study right now, and that really shows remarkable effect over a very long time. 18 months on, more than 60% of the subjects getting more than 50% relief. So we do have a very strong and sustained effect of this drug, and that's what we're building on in a number of activities. We have also the medication overuse headache started going on the resolution study that will add to that profile. So we're building very much on the broader profile. We have. The real-world evidence study that we have will not include the orals as it's designed. Right now, it's BOTOX and others, and that is not really a differentiation study per se. It's one that looks at how it sort of behaves in real life situation, real world situation where the switching and comparison. There are others that do direct head to head studies against Japan. That's not what we're contemplating right now. We think we have a strong set of data here that not yet requires any of those activities. Of course, Japan are also in a different space. They're primarily for the more episodic, weaker kind

of patients in the prevention space. And we are really looking for the chronic patients, the more severe patients.

Dominic Lunn, Credit Suisse: [00:32:47] Thank you.

Operator: [00:32:50] Our next question comes from the line of Emily Field of Barclays. Please go ahead.

Emily Field, Barclays: [00:32:56] Hi. Thanks for taking my questions. Just a couple on the guidance to start. I know obviously you've talked about increasing spending going into Q4. But the guidance update from yesterday contrasted with the strong nine months results so far, would imply a very significant margin compression in Q4. So just wanting to give some thoughts behind that. And then just in terms of the impact of FX on EBIT, if you could just quantify how much of the guidance change was operational versus FX-driven? And that was very helpful on slide ten, getting the organic growth. And if you would consider getting organic EBIT growth going forward, I think that would really help us from a modeling perspective. And then maybe just a question on OpEx spend specifically for Vyepti. Obviously, the launch was heavily impacted by COVID and you talked about investing in the launch here. But I'm just kind of wondering how long should we consider Vyepti in launch mode? And does the competitiveness of the migraine market, as addressed on a prior question, necessitate that this product would have a higher level of maintenance promotional spend? Thank you.

Deborah Dunsire, President and CEO: [00:34:09] Great questions, Emily. Joerg going to dive in.

Joerg Hornstein, Executive VP and CFO: [00:34:11] I think your question regarding the guidance, Q4 and margin compression, how I would look at this is I think in the first instance, historically, Q4 has always been a lower quarter for Lundbeck. The second point is, as we said, we have some additional R&D spend that is coming in in Q4. Plus, of course, we have some of the, let's say, continuous spend around promotion and Vyepti also supporting the launch in the eight countries that Deborah has outlined earlier and the 2 to 3 countries to come this year as well. Then the other questions, organic EBIT growth going forward. I would say at this point in time, we don't provide guidance.

Deborah Dunsire, President and CEO: [00:35:10] But I think you did say that the EBIT, the FX uplift was offset fully by hedging.

Joerg Hornstein, Executive VP and CFO: [00:35:16] That fully, yes, correct.

Deborah Dunsire, President and CEO: [00:35:18] Jacob, jump in.

Jacob Tolstrup, Executive VP, Commercial Operations, CCO: [00:35:24] I think also a little bit related to currency on costs. I think when you look at cost from the outside. Remember that more than half, 55%, of what you look at in cost increase is driven by FX. So the underlying growth is lower. When that said, we are increasing our promotional spend this year compared to last year, and that's driven by spending into Vyepti. I do foresee going forward that the level of spending we have now this year in the US will be not increasing next year. That will be at a similar level, but then you have the slow ramp up of the other markets, which of course will not carry the same investment levels as especially the patient activation campaign, the DTC campaign in the US is quite a significant cost that of course we won't see in other markets. I don't know if that's helpful to you.

Deborah Dunsire, President and CEO: [00:36:21] And I think the competitiveness question, as Jacob clearly pointed out, we are into that most impacted patient population. So we don't go toe to toe at all in terms of promotional expenditure, but because it is a busy market, it does require continued investment over time. There's not a year where you launch and then suddenly it comes down afterwards.

Emily Field, Barclays: [00:36:53] Thank you.

Deborah Dunsire, President and CEO: [00:36:56] Next question.

Operator: [00:36:58] Our next question comes from the line of Michael Novod of Nordea. Please go ahead.

Michael Novod, Nordea: [00:37:04] Thank you very much. Just a question to the Rexulti patent litigation. So you say in your report that these matters have been concluded and there's

protection up until at least June 2029, including extensions. But you also in your appendix in your presentation, they still show that you have active patents until November 2032. So can you comment whether we should expect something sort of in the middle between June '29 and November '30 to where you sort of have settled with these companies, or how should we think around that? And then maybe for your legacy business, I know it's probably not your focus area, but so how should we sort of expect that to be performing in the coming years? Because it seems now that it remains rather stable also CipraleX. So maybe just some comments from Jacob on how that business is going to perform and how we should model that.

Deborah Dunsire, President and CEO: [00:38:08] Thanks, Michael. We have concluded the patent litigation and we confirm that the compound patent expires in 2029 with pediatric extension in the middle of the year. And we do have patents that extend out. But of course, the compound patent is the strongest and most decisive of those patents. And I'll stop there.

Michael Novod, Nordea: [00:38:34] And are those the settlements for June '29.

Deborah Dunsire, President and CEO: [00:38:40] We're we're not commenting specifically on the on the settlements. So, Jacob.

Speaker5: [00:38:48] Over to you. Yeah. Great question. Thank you, Michael. And I would say that we actually do spend some time on, I would say, especially CipraleX/Lexapro in the portfolio. So we have had over the past few years had a little bit of focus on that part of the business also, because we do see opportunities to optimize that. And that means that CipraleX/Lexapro has performed well, holding on quite well, and that's driven by growth in certain emerging markets, continued decline in others. And then that has meant that we are pretty much at the same level as we were last year. There are some factors going forward that you need to model in. One is that in Japan, we do expect generics coming at the end of this year. That will continue to impact our numbers also next year. We have Deanxit in China, where we do expect the VBP on Deanxit in China. And then I would say in general, for the rest of the portfolio, you should model and erosion, but that could be anywhere from a small-single-digit to mid-single-digit going forward.

Michael Novod, Nordea: [00:40:09] Okay, great. Thanks a lot.

Deborah Dunsire, President and CEO: [00:40:12] Thanks, Michael.

Operator: [00:40:15] Our next question comes from the line of James Gordon of JPMorgan. Morgan. Please go ahead.

James Gordon, JPMorgan: [00:40:22] Hello, James Gordon, JPMorgan. Thanks for taking the questions. Firstly, on margins, so if we talk quite a bit already, but the updated guidance still looks like at the top end, you need quite a sequential fall in profitability. I think there's a mention of a 2 to 3% EBIT benefit in Q3. Was that just the R&D phasing? Or are there any other factors we need to be cautious on when we're extrapolating the quarter and trying to model into Q4? It seems like we need a much bigger sequential sales and marketing ramp than you saw last year. So just to make sure nothing there. And more generally, it sounds like the roughly mid-20s underlying core EBIT profitability is what you really achieve today. And is this the base that we should then build on if we're looking into Q4 and into next year? And then we think about some operating leverage offsetting maybe your share of more Rexulti AA promo build. So mid-20s is where you really are. Second question was gross to net. It looked like on modalities, Rexulti looks a little bit better in the US here. And was there anything unusual here, any stocking or anything else? Or is that a sustainable gross to net to look at, extrapolating forward? And then a final question, interesting comment on the PCAP, so PCAP was in Phase II 838. Is there any read through to your program there? Does that change your confidence at all in your molecule?

Deborah Dunsire, President and CEO: [00:41:44] Okay. Lots of questions there. So Joerg is going to start on the margin.

Joerg Hornstein, Executive VP and CFO: [00:41:50] I think to answer your first question regarding Q3 EBIT. Yes. The 100 million for R&D played a role, but we've also seen some effects out of sales accrual reversals, some onetime nonrecurring price increases and a few other factors. I think that answers that question. I think in terms of core EBIT. We don't provide any guidance on a forward looking basis.

Deborah Dunsire, President and CEO: [00:42:25] I think talking about the rise in sales and marketing that's really being driven by the Vyepti.

Joerg Hornstein, Executive VP and CFO: [00:42:32] Exactly. That's the same thing I said earlier in additional spend promotion for Vyepti. Also underpinning the launch we had this year and the remaining launches this year to have and the years to come.

Deborah Dunsire, President and CEO: [00:42:47] And I think you'd asked about underlying profitability, James. There's there's many puts and takes as we prepare for the AAD ½ launch and continue to invest in the Phase II programs and finishing up those other Phase IIIs in R&D, but also uncertainties in the inflation, how is that going to impact us? So there are a lot of different puts and takes that we'll work through during the the fourth quarter. And then I'll hand over to Jacob on the Rexulti and Trintellix and gross to net.

Joerg Hornstein, Executive VP and CFO: [00:43:23] Yeah, and perhaps a little bit of a brief answer here. There is no real change on gross to net. There are some change, but it's not really what's driving it. It is demand and price that drives the growth for Rexulti predominantly over last year.

Deborah Dunsire, President and CEO: [00:43:41] Johan.

Johan Luthman, Executive VP of Research and Development: [00:43:42] Yeah. Thanks for the question. On the Lilly, we don't really know. It disappeared out of the portfolio, so we have no information really to speak of. In terms of differences. We know there are certain differences between the molecules, and I always think in this space, you should be very, very careful to draw too big conclusions between different programs. Particularly when it comes to an antibody like this. Our antibody is an IgG1 one antibody, which has an active clearance of the target. And our understanding is that the Lilly molecule is different on that aspect. So it's the most potent way our clearing the agent you like to clear. There are also other things to look at which are really going into the weeds of preclinical science. But there are different types of PACAP and you combine the different affinities to different PACAPs and as good R&D people will do compare these things and there are certainly differences across. Enough differences so I would say that there is a little bit of learning. And of course there's always a concern when a

competitor disappears, but we think they're also substantially different to justify our ongoing trial. And we're looking forward to our readout and our study. That is a very robust proof of concept study. And I also spoke to the broader potential, the biology that we like to look into.

James Gordon, JPMorgan: [00:45:08] Thank you.

Operator: [00:45:10] Our next question comes from the line of Marc Goodman of SVB. Please go ahead.

Marc Goodman, SVB: [00:45:19] Yes. Hi. On Vyepti, can you give us a sense of maybe the number of patients that have been on drugs, specifically in the US, for instance? And just give us a sense of what's happening in the doctor's offices. Are they back open or are you able to really push this thing now? I mean, we're just trying to get a sense of what kind of ramp we should be expecting now that the pandemic is really slowing. And then on 515, you talked about putting that into the clinic. And what type of indications are you talking about there? Are you thinking big markets? Are you thinking more orphan type direction there? And maybe just management can talk a little bit more about BD and what they're seeing out there? We've got many, many companies that seem to have been broken from the stock price, and yet some of these areas have not even demonstrated whether there's a proof of concept or not. It's just the stock has broke. And I'm just curious how you're seeing these and if you have more opportunities now than ever before from a BD perspective, and if you're still just focusing on any specific areas, are there any new areas in CNS that you're looking at? Thanks.

Deborah Dunsire, President and CEO: [00:46:38] Great. Thanks, Marc. I'm going to hand over to Jacob first on the Vyepti question.

Jacob Tolstrup, Executive VP, Commercial Operations, CCO: [00:46:44] Yeah, and of course, Mark, there are always different patient numbers, whether you look at current patient balance or you look treatment over time and so forth. But I would say, we have treated more than 20,000 patients in the US. At this time.

Deborah Dunsire, President and CEO: [00:46:59] Yes, and then Johan.

Johan Luthman, Executive VP of Research and Development: [00:47:01] Yeah, I if I understood your question right, it's generally our pipeline and how we look across different assets and where we like to take the pipeline. And I'd just like to remind you that we are a biotherapeutics company now, which takes us more into neurology indications by preference, by having that kind of mechanism action. Many of those are in more rare diseases, more niche oriented diseases, which definitely takes us into the potential of orphan designation. That is never given. Even if you work on the radar, you may not end up in those kind of guidelines. It depends on the competition and where you are, but obviously much bigger chance. We have a number of programs across our portfolio that have a high likelihood of getting that kind of designation. If we get to those indications we're after. We actually done an analysis of this and I would say at least half our portfolio programs have that potential, but many of them are very early, so we should be careful with that.

Deborah Dunsire, President and CEO: [00:48:03] And then on the on the BD side, you know, I think that we have a lot to do as we prepare for the launch of AAD, rollout Vyepti, prepare for the launch of Simtofy in Europe, Aripiprazole two month in the US. And we've got great growth drivers. It puts us in a great position to be very active in looking externally for the right opportunities to bring into Lundbeck but not be desperate. And we've also said that we had a bolus of R&D expenditure with Vyepti and yes, we're still moving forward with that. And as that settles down, we have more room in the portfolio, but we've expressed a preference for those looking at things that will help us address the mid and late decade loss of exclusivities and through partnering, licensing or bolt-on M&A. And with an eye to how do we both build the future growth potential in the revenue line, but also think about things that can add to our pipeline. If you think about the elder deal for us, it brought us many good things. One product that was near to market Vyepti a great drug, but great capability building in monoclonal antibodies, and we're really glad we have that now, particularly as you think Inflation Reduction Act, it brought us now a Phase II asset with the work that Johan's team have done with our PACAP, brought it through Phase I and into Phase II and another antibody that we hope to be starting the phase I on. So that's an asset that gave us both near to market and near term launch with Vyepti, but also some pipeline and capability build. Those are the ideal. They're hard to find. So we do look at a different constellations of things. We've also said that we'll continue to be active on the early part of the portfolio, bringing in things like we did with the CD40, Phase I-ready compound, or new approaches in small molecules with the Argenta deal

that gave us the small molecules interfering with RNA. But when you take it up to the macro level, our strategy remains. We're investing to maximize our existing brands. We're continuing to rebuild our portfolio and transform our R&D and become an ever more effective organization. So perhaps I'll stop there.

Marc Goodman, SVB: [00:50:56] Just follow up on Vyepti. Can you just give us a sense of are these patients you said they were over 20,000 patients that been treated in the US? Is that are they still being treated? Are they coming back for second and third infusions? And just give us a sense of the doctor's office is much better now. Should we expect a better ramp next year than this year because of that reason?

Jacob Tolstrup, Executive VP, Commercial Operations, CCO: [00:51:20] Well, I can give you a little bit of insight. So we track persistency among our patients. And when we compare our persistency in the number of patients that come back for the following infusions, Vyepti is leading among all treatments of the new classes in migraine, meaning that we have more patients coming back and it's almost half of the patients that come back even 12 months later, which is higher than the others. So we have a very strong persistency for Vyepti.

Operator: [00:52:00] Our next question comes from the line of Rosie Turner of Jefferies. Please go ahead.

Rosie Turner, Jefferies: [00:52:08] Hi. Thanks so much for taking my questions. Just a few short ones left. You talked a bit already about the Vyepti kind of DTC and how that's a significant spend. I just wondered how you measure success here and kind of what that means in terms of kind of read through to continued need to spend on DTC. Then in terms of AAD submission, we actually be told once it's submitted or we'd be told once it's FDA acceptance. And then finally, on the MEMORY trial, does this mean a label expansion? This very good data that you reported? Or does this mean just an additional kind of tool for the salespeople for Brintellix/Trintellix? Thank you.

Deborah Dunsire, President and CEO: [00:53:02] Jacob.

Jacob Tolstrup, Executive VP, Commercial Operations, CCO: [00:53:03] So on the DTC and we like to call it patient activation. So what you really would like to achieve is to activate patients. So in the beginning of a launch when you started DTC, which we did in the spring of this year, you're measuring a number of KPIs that are all related to patient activation. That means tracking engagement of patients on a number of websites searches, but more importantly also following up and seeing how many patients are remembering Vyepti, how many are asking doctors around Vyepti and intend to visit a doctor once they have seen a Vyepti in a DTC campaign. And all of those KPIs are tracking very favorably and also in comparison to the other campaigns that are going on for competitive products. And that's the number of data that we have at this time. You need much more data before you can start to quantify that in terms of how much is converted into revenues. And that will take a longer time before you can start to quantify that. At this stage, we see great improvement in patient activation from the campaign that started in the spring of this year.

Deborah Dunsire, President and CEO: [00:54:26] And of course it is our intention to to keep track of that because we need to see those outcomes of patients who actually get prescribed Vyepti. And we always look at our promotional mix across all our brands to say, where can we invest for the most impact? So we will make decisions based on the data that we that we see. Johan.

Johan Luthman, Executive VP of Research and Development: [00:54:56] In terms of our questions for the sNDA for agitation and Alzheimer's disease, as I mentioned, we are very close to submitting it. I think what's most important is the 60-day period. And you mentioned the validation. Of course we anticipate validation or submission and progression of the review. And at that time point we also learn whether it's going to be six or ten month review period and whether it's going to be an AdCom that will look at it or not. So that's the more interesting data when we're really on the track and we know what we're looking forward to in terms of the timelines. Let me just remind you that we have a pretty substantial data package that's going in. It's three large pivotal trials. We have explored the dose range from 1 to 3 milligram. And we also have an extensive safety data package from the indication, but also beyond the indication. So this is a substantial submission for the agency to chew on and for us to put together. But we also think that's a very robust package that we're sending in. Then I think you had a question on MEMORY, if I should take that one. This is a late occurring study, but let me just emphasize

what kind of population we looked at here. Those for people with major depressive disorder that developed dementia. So this was not a study specifically going towards depression in people that had Alzheimer's. It was people that acquired dementia while they were on depression, which is not the label in itself. This is really the depressed patients that just happened to have dementia. The data are remarkably strong and obviously this late in the program, there's just nothing really to think about doing some bigger label extension activities here. But I think it's remarkable strong data that should really be recognized for what it is, including that cognition data I talked about in demented patients.

Rosie Turner, Jefferies: [00:57:00] Great, Great. Thank you very much.

Operator: [00:57:04] Our next question comes from the line of Eric of Goldman Sachs. Please go ahead.

Keyur Parekh, Goldman Sachs: [00:57:11] Hi. Thank you for taking my questions. Two please, if I may. First one, just going back to Vyepti, both on a US perspective and more importantly, from an ex-US perspective. I think ex-US you're saying 10 million Danish in revenues for the first nine months of '22. When should we expect a real inflection in that ex-US revenue base for Vyepti? Is it likely to be 2023 based on your current plans and the feedback you're getting from the physicians? Or is it more likely to be 2024? In the US, the obviously kind of the graph you're showing us shows a very linear, nice, solid growth. Is that what we should expect going forward as well? Or do you think there's going to be kind of an inflection and we start getting to kind of logarithmic growth, not kind of linear growth for Vyepti in '23 and '24? And then separately, as we think about kind of PTSD. Just wondering if you can share a bit more details on what it is that the FDA feedback has been and how, if in any ways does that change your confidence on the outlook for that program? Have you now agreed a statistical plan that allows you to combine data from these two studies, or is that yet to be done? Thank you.

Deborah Dunsire, President and CEO: [00:58:37] Thanks, Keyur. Jacob is going to take the Vyepti questions.

Jacob Tolstrup, Executive VP, Commercial Operations, CCO: [00:58:40] Yeah. Let's start with the ex-US care. I think it's important to say that it is a rollout that means that it will take time in

US market to come into every market globally. I think if you compare to the sales level that we have this year, yes, I would say you would start to see an inflection next year. But of course the sales level next year will still be at a significantly lower level than what you have in the US. So to get to bigger sizeable numbers that will take more time because you need to launch in more markets. Reasonably be launched in Germany, which is obviously a big market for us. We just launched in Canada this month. So now we start to get some of the bigger markets. But then of course it will take time to build up, but you'll see a significant increase in sales next year. But still comparing to a low level in 23 for the US. I do not wish to give guidance because if I start to either talk about a continued growth as we see until next year, but I would say we are constantly working to optimize Vyepti. We have a number of activities in place and I will not rule out that you could see a higher growth at some point, but I'm not sitting here and speculating when that could happen.

Johan Luthman, Executive VP of Research and Development: [01:00:03] Thank you for the question on the PTSD. Let me just remind you that the study was really struggling during the pandemic. And we went to the agency at the point, where we saw, it was more or less impossible to continue with the current design. So we went with the submission very, very early in the year and had had the Type C meeting in the early of the year. Actually, the submission was even before this year, so that was at the situation when the pandemic was very, very high in the US and we struggled with this study. Remember, this is a US study. And the agency has been extremely busy during these days and it took us a longer time than we expected to get formal final feedback. The Type C meeting was very supportive of our ID, but they needed to look at our statistical and analytical plan, which took quite some time to get back. In that time period, the pandemic situation changed and so did the agency view in terms of the easiness to run trials under lockdown or not lockdown. So obviously, they have shifted their view a little bit. We are now basically finishing the trials as they were originally designed - two separate trials. No difference in the analytical approach. But we have also, through that discussion, got stronger confidence in what we need to provide to the agency because they did comment on our statistical and analytical plan in detail, which means that we can be more aggressive in how we finish up the trial, but it will be the original design. The two trials for always independent but analytical plan will be each trial and then they are very keen on replication of course, and they didn't give us any leeway on that.

Keyur Parekh, Goldman Sachs: [01:01:57] So just to follow up, is it fair to then say that to be able to file you would need both the studies to be positive? Is that kind of what you're trying to tell us.

Johan Luthman, Executive VP of Research and Development: [01:02:09] No, that's up for the agency. It's a review issue, as they would say. And as we would say. It depends on the data entirely, but they like to see two independent analysis and that that we have strong respect for in this field of research. So they like to see two different studies and how they come out and how they look at the data. One is fixed dose, one is flexible dosing. There are a lot of details that you can potentially discuss, but I'm more in the business of awaiting and see the result and then we see what we do.

Keyur Parekh, Goldman Sachs: [01:02:42] Thank you.

Operator: [01:02:44] Our next question comes from the line of Colin White of UBS. Please go ahead.

Colin White, UBS: [01:02:52] Hi. Thanks for taking my question. Just a quick one for me. The hedging loss suggests that you hedged favorable rates. So just how long will that last for?

Joerg Hornstein, Executive VP and CFO: [01:03:04] I couldn't fully understand your question. Could you repeat this?

Colin White, UBS: [01:03:09] And I'm just wondering, you're hedging loss suggests your hedged at favorable rate. I'm just wondering how long you're going to be hedged at the rates you're currently hedged for.

Joerg Hornstein, Executive VP and CFO: [01:03:22] So we basically hedge our exposure on a 12-month rolling basis going forward, potentially sometimes even up to 18 months. So that's what we're currently doing. Why is the hedging impact so much severe? Just just think about the dollar in principle accelerated strongly, especially from Q2 into Q3. I think we saw a rate of around 715 in Q2, whereas we went up somewhere to 760 around in Q3. Of course, if you have an, let's say, rolling hedge underlying such an acceleration, then your hedge rate doesn't, let's

say, go up to the same extent, which puts you in a situation that you're hedging effect at year end becomes more severe and therefore I increase to 600 million.

Colin White, UBS: [01:04:22] Thanks.

Operator: [01:04:23] I'll now hand back to our speakers for closing comments. Please go ahead.

Deborah Dunsire, President and CEO: [01:04:29] Thanks, everyone, for joining us. We're very proud of a strong third quarter and look forward to finishing the year strongly. Wish you all a good day.