H. Lundbeck

Transcript: Financial statements for the first six months of 2021

Date & time: 18 August 2021 at 13.00 CEST

Operator: [00:00:02] Welcome to the Lundbeck financial statements for the first six months of 2021. For the first half of this call, all participants will be on listen only mode and afterwards there'll be a question and answer session. Today, I'm pleased to present Deborah Dunsire, President and CEO. Anders Götzsche, Executive Chief Vice President and CFO, and Johan Luthman, Executive Vice President of Research and Development. Speakers, please begin.

Deborah Dunsire: [00:00:32] Thank you, operator. Welcome everybody to our first half financial results. Thanks for joining us today. With me, I have:

Anders Götzsche, our CFO.
Johan Luthman, Head of R&D.
Jacob Tolstrup, Head of Commercial Operations.
And joining us by phone from Chicago:
Peter Anastasiou, our Head of North America.

Next slide, please. You can see our forward looking statements and you've seen them before, so we'll move right on to slide three. Thank you.

We're very proud of a robust financial results for the first half of 2021, in spite of significant impact from our LoE of Northera. The strategic brands have good momentum, being up 13% in local currency, reaching 4,4 billion Danish kroner. Vyepti has had strong momentum, reaching 177 million and is fully in line with our growth expectations. International markets in Europe have been strong performers, with growth of 6% and 3%, respectively. Northera has been a challenge more so than we had anticipated, with a stronger decline of 60% in the first half. Nonetheless, we've delivered a very solid EBIT marge... core EBIT margin of 26,1% and made good progress on deleveraging. Anders is going to go through our updated guidance with you in a few slides from now. Next slide, please. So the strategic brands are really the revenue drivers

for the company and have returned to double digit growth in the second quarter of 2021. In total, they grew 13% in local currency and all of them are expected to have continued double digit growth as we go into the second half of 2021.

Deborah Dunsire: [00:02:19] As I've said, we're getting strong performance across regions, but Europe and international markets have been delivering strongly. We know that the pandemic is still out there and growth does... was impacted in the first half and is still somewhat impacted. We're still seeing a bit of a diagnosis gap, not having patients and physicians fully back to pre covid levels of interaction. But we are making progress in the world opening up, and right now our core levels are also increasing. So we're getting back towards normal. We're still not quite there around the world, but definitely in the second quarter made strong progress versus first quarter. Next slide, please. Vyepti has continued to show very strong momentum in vial growth, and as I said reaching 177 million in the first half. And we're on track to achieve our expectations for this brand based on the fact that it really is delivering for patients who receive it. We've also got good market access with over 235 million individuals in the US having access to Vyepti when their physicians feel it's the right product for them. We've been accelerating the launch with really focusing on the strength of Vyepti his powerful profile and setting up an excellent prescribing experience for physicians. We reach out to physicians who are migraine treaters, regardless of whether they have infusion capability, because we've made good progress in establishing a network of sites... of alternative sites of infusion, where patients can go close to home. And we've also started to work with some home infusion.

Deborah Dunsire: [00:04:07] So making it easier and easier for patients to get access to Vyepti. We're looking forward to the global rollout of this brand, ramping up starting in the third quarter of this year, and Johan will cover that in a bit more detail. Next slide, please. We've had also robust performance across the other three strategic brands. Looking at Brintellix/Trintellix, we've had growth of 12% in local currency, 18% in Q2. Japan's been a bright spot with its... nto its second year of launch, achieving 4,1% market share, and that's growing very nicely. Just a reminder, we look forward to sustained growth over the next 6 to 8 years because these strategic brands are well protected in their intellectual property. Trintellix patents are issued lasting until March of 2032. The composition of matter expiring in December 2026. With Rexulti, we've seen good growth, 13% up in local currency in Q2, returning to that double digit growth. It also has a long lifespan to continue growing with patents issued out to 2032, Composition of

matter expiring in 2029. Abilify Maintena, the long acting injectables have strengthened. Their market growth has resumed and Abilify Maintena grew 5% in local currency, having been resilient through the pandemic and up 11% in Q2. The one month formulation has had some patents issued. The Orange Book listing goes up until March 2034 and the formulation patent expires in the rest of the world in 2024.

Deborah Dunsire: [00:05:55] You know that we're going to be bringing a two month formulation of Abilify Maintena forward and that has patent protection to the mid 30s, giving us the opportunity to really extend this franchise out into the future. Next slide, please. All three regions of the world had very strong progress with respect to our strategic brands, and we're glad to be emerging from the pandemic. Of course, there is uncertainty out there with some of the new waves that we're seeing. But in general, all regions are progressing back to much more normal interactions. North America is, of course, impacted significantly by the loss of Northera... was our third largest brand and extremely successful brand, built by a very strong commercial organization. In the... North America, the strategic brands are up 12% in local currency and now make up 69% of sales, and we're seeing Vyepti to really start to contribute to growth. International markets have had strong growth in the strategic brands. Japan has been a strong contributor. China is growing by 7% in the first half, even in spite of Ebixa being included in the volume based procurement. Europe has also grown well, with the strategic brands up 10% in local currency, making up 62% of sales now, and they're showing robust growth across most markets driven by demand, because, of course, price is not an option - price increase is not an option in Europe. Next slide, please. Over to you, Anders, to take us through the financials.

Anders Götzsche: [00:07:35] Thank you very much. A couple of financial highlights: In spite of a really strong performance by the strategic brands growing 19% in Q2, we have a decline in revenue, reported revenue, and that is a couple of things impacting. Of course, the Northera decline is the main reason, but also the depreciation of FX is actually hampering the revenue growth. The gross margin and the core gross margin is pretty much in line with last year, so we are keeping up a good traction there. SG&A down some 200 million, and that is due to lower sales and marketing activities, or level of activities. R&D down due to that we last year had the Foliglurax write off, so that's the main reason for the decline in R&D cost. We are extremely happy with the solid performance in earnings, close to 1,5 billion in the first half and the EBIT margin of 18%. We are, as a management team, really proud of that. Core EBIT and core margin,

also delivering a strong performance in the first half, actually creating a solid foundation for the financial guidance that we are coming to in a minute. When we go to the next slide, you can also see from the the quarterly release that the cash flow is solid, and that also means that we will end the year at a net debt level around 3,5 billion - that is our best guess now. And net debt to EBITDA is expected to stay around... unchanged from 2020, around a ratio of 1. Next page, please.

Anders Götzsche: [00:09:24] We have tried to make it a slide to actually explain the moving parts in the first half and also in the second half to... hopefully that will help adding up the numbers for the full year guidance. And what you can see here is that the first half has, as I said before, mainly the decline in revenue is mainly driven by the loss of exclusivity for Northera, and then the FX partly absorbed by the hedging. And as Deborah alluded to, we have... we are down 60% for for Northera, and that will accelerate in the second half - now, we believe that we'll see a decline of more than 80%, adding up to a total decline for the year of 75%. It's also super important to highlight that we believe that the revenue line... the revenue will actually accelerate. We will see more growth in the second half, if you exclude the impact from Northera, and the FX hedging will be more muted, due to that, we are more on par with the last year's FX numbers, but then the hedging is flipping the other way around. So we hope that this will explain a bit about how we expect the second half to actually perform. Next slide, please. So that turns into the guidance and the based on on mainly two factors, we have reduced the upper end of our revenue guidance with 300 million, and that is purely due to contract manufacturing and Northera, because of strategic reasons and Vyepti is delivering exactly as we have expected, it's.... we have seen a strong performance and we are on track to deliver what we said in the beginning of the year. Due to the fact that we have seen a lower level of activities from a promotional point of view, then we have also been able to compensate by cost savings and therefore we have increased the lower end of our guidance for EBITDA, core EBIT and EBIT with 200 million, also expecting a bit better financial performance for the year. You should expect financial expenses to be some 350 million, of which approximately 200 million has cash flow impact. The rest is unreal... mainly unrealized the FX positions. So with that, I would like to hand over to Johan to start going through the strong momentum for Vyepti

Johan Luthmann: [00:11:49] Thanks, Anders. Please turn to next slide. Let me start with Vyepti. We have progressed very well with its global expansion, and approval Australia was obtained in

early June, leading to four approvals so far. The roll out of regulatory submissions continue at a rapid pace and Vyepti is currently on the regulatory view for market authorization with 14 health authorities within Europe, South America, Asia and the Middle East. The EMEA review is progressing according to plan. We have also substantial clinical program ongoing for Vyepti, both within the existing indication on migrant prevention and further expansion of data on its effectiveness in medication-overuse headache, as well as indication expansion into cluster headache. All clinical trials for Vyepti are advancing well currently.

Johan Luthmann: [00:12:45] The DELIVER trial phase IIIb study that evaluates the effects of Vyepti for the prevention in migraine of patients with prior unsuccessful preventive treatments has completed recruitment and we are looking forward to the results in the second half of the year. Additionally, we have initiated a pivotal global program supporting major findings in Asia with the so-called SUNLIGHT study, that is a China centric study, and the SUNRISE study that is a Japan centric study. Those trials are up and running and are actually currently enrolling well. Finally on Vyepti, I want to state that we broadly presented on the program at the annual scientific meeting for the American Headache Society in June with 10 posters. And recently we also had published a relief study in the prestigious Journal of the American Medical Association JAMA. As you may recall, the relief study demonstrated a very fast and powerful onset of action of Vyepti. Next slide, please. Recently, we received the headline data from the proof of concept study on Brexpiprazole in Borderline Personality Disorder. I like to remind you that this 12 week randomized double blind, placebo controlled study assessed flexible doses, 2 to 3 milligram of Brexpiprazole as monotherapy in other subjects with borderline personality disorder. On the primary efficacy endpoint pre defined as the ten week time point read out on the Zanarini Rating Scale for borderline personality disorder. The Brexpiprazole arm did not show statistically significant separation from placebo on change from baseline. However, we saw improvements greater than placebo on the Zanarini Rating Scale at other time points in the study.

Johan Luthmann: [00:14:34] The observed safety and tolerability of Brexpiprazole in borderline personality disorder patients were consistent with the safety and tolerability we have observed for Brexpiprazole treated patients in other indications. Regarding the two other LCM programs we are running on Brexpiprazole (inaudible) Alzheimer's Disease study is on track to report headline results mid 2022. However, our own ongoing post-traumatic stress disorder trials are in a major way impacted by the pandemic, making recruitment very challenging, and it's not

possible for me to provide a timeline for the program at this time point. We progressed very well, we're broadening the early states proof of concept pipeline. The phase one portfolio has been expanded with new entrants. Novel mechanisms and molecules are being evaluated in humans with gatekeeping experimental medicines studies faster. For example, we have now three differentiated MAGLipase inhibitor molecules introduced into humans, with the lead molecule going into a broader set of exploratory patient cohort studies. We also are progressing selected assets into proof of concept phase II studies. Next slide, please. The one I like to highlight here is Lu AF82422. During next half of the year, we will commence a phase II study using our anti,,, alpha-synuclein antibody, in patients with Multiple System Atrophy, MSA for short. MSA is a rare neurodegenerative disorder affecting autonomic processes, including blood pressure, breathing, bladder function, as well as control of motor functions. This makes MSA showing many features with Parkinson's disease, such as slow movement, rigid muscles and poor balance.

Johan Luthmann: [00:16:29] The condition progresses rapidly and eventually leads to death. Apart from symptomatic medications for motor function improvements or lifestyle changes, etc., there is really no treatment that can delay the progression of this devastating disease. We see a substantial potential for 422 in MSA. It's designed to break the core of the pathophysiology by binding to the alpha-synuclein seeds that spread the disease throughout the brain. Overall, the clinical program for 422 will be highly innovative, with early readouts of the treatment effect on neurodegenerative processes using combined biomarkers and clinical outcome measures for decisive decision-daking, followed by an adaptive Bayesian statistics driven, larger, pivotal part. Next slide, please. I also like to mention some impactful collaborations we have recently established to further feed innovation in research. In a new strategic collaboration with the Rice Institute for Biologically Inspired Engineering at Harvard University, Lundbeck will explore effective approaches to deliver drugs across the blood brain barrier. The main goals of the initiative will be to identify transported target proteins that facilitate the delivery of future therapeutics, such as antibodies into the brain. We have also very recently entered into a new strategic collaboration with the US based company Argenta Therapeutics to discover small molecules targeting RNA regulation and splicing of disease causing genes. The strategic R&D collaboration with Argenta critically expands our research platforms by enabling us to pursue RNA processing targets linked to rare neurology indications that were previously considered undriveable. With that, I like to leave over to Deborah.

Deborah Dunsire: [00:18:22] Thanks, Johan. As we look forward into the future, our long term ambition is to be number one in brain health, and that's going to require us to continue to build our pipeline internally, as Johan has described, but also externally, and that's something that Lundbeck has been doing in the past and been very good at executing upon. When we think about how we will develop that pipeline, our future focus is in the targeted indications, niche neurology, niche psychiatry and rare disease neurology with the purpose of making sure that we have a focus on specialist indications of high unmet need, where we can have a focused commercial footprint and where we have tractable biomarker driven development programs, as Johan has outlined with our (inaudible). So we'll continue to build our internal pipeline focused in four clusters of promising biologies where we can bring forward new transformative medicinesm and we'll continue to look for the right assets externally to bring in... to supplement our pipeline and portfolio. Looking at later stage opportunities, we'll be looking at assets that can leverage our infrastructure. We've been extremely successful with multiple projects that Lundbeck has brought in from the outside. Northera is one of those. And so we'll look to leverage the commercial infrastructure and invigorate growth through potentially near-term accretive transactions and then build the earlier stage pipeline assets with novel technologies to accelerate innovation like building alliances and partnerships as we have with Argenta. Next slide, please. We've got very good growth visibility from these strong growing strategic brands over the next 6 to 8 years with no major loss of exclusivities on the horizon. And our goal is today, as it has always been, to deliver long term, sustainable, profitable growth. In the short to mid-term, our goal is to deliver continue to deliver mid-term... mid single digit revenue growth over the next 6 to 8 years and restore the EBIT margin to the 25% cent by 2024 that we spoke about when we did the acquisition of Alder Biopharmaceuticals.

Deborah Dunsire: [00:20:48] That would imply a core EBIT margin exceeding 30%, and we are committed to keeping our dividend policy of 30 to 60% payout of the net result. Lundbeck has been successful over many years, delivering a compound annual growth in those mid single digit range, building on internal assets such as Cipralex, Lexapro, Trintellix. And building very strong assets using external development like Rexulti and Abilify Maintena in partnerships. Or building strength from the acquisition of Chelsea Therapeutics with Northera or (inaudible) from Ovation. As we go into the longer term, we retain that goal of continuous profitable growth and work to build a pipeline that delivers a steady flow of transformative medicines both from our internal

and external innovation. Next slide, please. So the must wins in the second half of 2021 is: Continuing to build those strategic brands, drive that double digit growth that we've seen in the second quarter forward as the world continues to open up pandemic. Continue to build the successful launch of Vyepti accelerating in the in the US and getting those next markets up and running. Strengthening our mid and late stage pipeline as we bring forward assets into phase II from our internal pipeline and seek to supplement through business development. Continue to accelerate our digital transformation and building towards that sustainable, profitable growth as we deliver over time the premier neuroscience pipeline to take us towards our goal of being number one in brain health. With that, I'd like to thank you for attending today. And we open the floor to questions.

Operator: [00:22:41] Thank you. If you'd like to ask the question, please dial zero one on your telephone keypad now to enter the queue. Once your name is announced, you can ask a question. If you find it's answered before it's your turn to speak, you can dial zero two cancel.

And our first question comes from the line of Amal Kapadia of Bernstein. Please go ahead. Your line is open.

Wimal Kapadia, Bernstein: [00:23:04] Oh, great, thanks very much for taking my questions. Can I first just ask about the sequential growth of 21 versus 2022 for the major growth drivers. In particular Trintellix and Rexulti. Rexulti seem to be impacted by Covid. So just curious if the right assumption is for an acceleration in growth in 2022 versus the growth we are seeing this year. I know you talk about double digit growth. What I'm really asking is always an acceleration in that growth next year for these two key brands. And then my second question is just on on the pipeline. So could you provide a little bit more color on the phase I data for 09222, the PACAP inhibitor, and maybe give us some context on the phase II trial design, which you plan to start later this year? I'm just curious if a combination of Vyepti will be part of the trial.

Deborah Dunsire: [00:23:58] I thought you were saying something Wimal. So, Anders will take the first part of the question on Rexulti/Trintellix growth to 22, although I remind you we're not giving you any guidance for 2022 right now. And, Johan, perhaps you can start with the pipeline question on PACAP.

Johan Luthmann: [00:24:16] Yeah. So I start with the pipeline question. Yeah. So we have a... we are really steadily building up our phase I assets and we have a couple of assets now that are ready to go into phase two. The one I mention now, the MSA, the other one is PACAP. We are just finishing up some studies and we are looking forward to talk about that very soon. But we have the package ready more or less to progress also with proof of concept with that asset. The primary interest is, of course, migraine, that's where the biology is strongest. In terms of the design, was that a question about...

Deborah Dunsire: [00:24:54] Combination with Vyepti, considered...

Johan Luthmann: [00:24:57] Combination with Vyepti, yeah, I mean, it's way too early to say how this will pan out. PACAP is a new mechanism for action. Broader mechanism action than CGRP in some degree and more interesting. It goes into more symptomatic functions para-symptomatic... sympathetic nervous system effects and also inflammatory processes. So it could have a broader potential. But obviously we are considering how it may work in combination with CGRP antagonists.

Deborah Dunsire: [00:25:29] Yeah. Our first phase to proof of concept would not be a combination study.

Anders Götzsche: [00:25:35] So. So I think that the first thing that we need to be successful with is of course to continue the double digit growth for for the second half of 2021. And then, of course, we have the ambition to continue to deliver double digit growth, but as the brands are going continuing to grow, of course, there will be, you know, it will be at some point will be challenging to keep up with that pace, but definitely when we look into 2022, we have the ambition for the totality of the three brands, Brintellix, Rexulti... for the two brands you asked, Rexulti and Brintrellix to deliver double digit growth - that is definitely the ambition.

Wimal Kapadia, Bernstein: [00:26:17] Okay. Thank you.

Operator: [00:26:19] Thank you. Next question comes from the line of James Gordon at JP Morgan. Please go ahead. Your line is open.

James Gordon, JP Morgan: [00:26:28] Hello. James Gordon, JP Morgan Sachs. Thanks for taking the questions. First question is just about SG&A and where, because I know the release talked about lower sales and marketing as a result of covid-19. The presentation also says 21 less impacted by covid-19 savings. So not asking for guidance for 22, but just how much benefit do you think you actually are going to account on SG&A for 2021 that we need to bear in mind when we are trying to forecast 2022. That's the first question, please. And second question is on Vyepti. So the trajectory looks like it's continuing, but it's the same line and there hasn't really been an (Inaudible) yet. Do you still think the product could do something like or could do more than half a billion Danish this year or does that now look like a bit of a stretch? And a third and final question. So on slide 17, the 6 to 8 year aim of the company. So the the mid single digit top line growth in the margin expansion. But, just to clarify, is that something you think you can do, even if Rexulti Alzheimer's agitation is unsuccessful and X any acquisitions, or is that already baked in something... Alzheimer's agitation being successful and or getting an M&A boost?

Deborah Dunsire: [00:27:33] Ok, so starting with the SG&A. Anders will take that one.

Anders Götzsche: [00:27:37] So the guidance we have we have made with the SG&A and what we have said is that SG&A this year will be approximately between 41% and 44% of revenue. That is what we anticipate, and that leads into an SG&A level comparable with last year. Then when you go into 2022, what will be added in 2022 is definitely that then Vyepti is being launched in more territories and therefore the spending for supporting by Vyepti will increase to... with how much it will increase? We don't expect it to increase significantly, but there will be an increase and that that is what you should expect. And then when it comes to asking about growth from 6 to 8 years, of course, it goes without saying that 6 to 7 years down the road it gets more uncertain, but we strongly believe in double digit growth for our strategic brands, but when it comes to year 8, then we are getting more challenged. But we also, as you can see, we have patents that are actually protecting the business longer, and we believe there is a opportunity to actually be a bit more ambitious also on the longer... In the in the 8 years timeframe. So we believe based on our internal pipeline and based on our existing brands, there is a opportunity to actually create that. We also know after Trintellix, we will, of course, be a bit more challenged, but we still look into growing the business after that.

Deborah Dunsire: [00:29:10] Yeah, I think to your question on Vyepti, we are very pleased with how it's performing. It has continued to grow. It's on track to achieve our expectations. We look forward to the opening up... continued opening up. Q2 opened up a bit more than it had in Q1 with respect to the pandemic. But we have seen patients able to come in and chronic migraine is so impactful and the need for prevention is great. So patients and physicians did work out during 2020 how to do that safely. So as as things open up, we anticipate the continued growth of Vyepti and it is on track with our expectations.

James Gordon, JP Morgan: [00:29:54] Thank you, and maybe if I could just, just to clarify, what was my third question, it was less about the growth outlook beyond that year, it was more the growth outlook sort of going up to the 6 to 8 year period. Whether this is guidance that you could do irrespective of what happens in the upcoming Rexulti alzheimer' agitation readout.

Deborah Dunsire: [00:30:12] We anticipate that we'd be able to deliver that mid single digit growth irrespective of the Rexulti alzheimer's agitation readout. And as Anders mentioned, it is considering our strategic brands, the portfolio that we have in our hands. Of course, we will look to accelerate and build in business development, but we can't forecast... we can't forecast that in right now.

James Gordon, JP Morgan: [00:30:40] So it makes sense. Thank you.

Operator: [00:30:44] Thank you. Our next question comes from the line of at Credit Suisse. Go ahead. Your line is open.

Jo Walton, Credit Suisse: [00:30:51] Thank you. Three questions, please. I wonder if you can tell us a little bit more about the dynamics of Vyepti in the US. Are you seeing... or what proportion of patients are coming back for repeat prescriptions? Versus you know, new patients... so just giving us some sense of the degree of satisfaction that a patient has when they get on the product. If you can tell us a little bit more... you talk about infusion centers. If you think about what the gating item is to stop getting more prescriptions from doctors, is it... is infusion... is lack of a nearby infusion center the key push back, or is it the fact that there isn't any free product to give away, that there might be if it was, you know, one of the non infused products... so just a little bit more on that push back. Trintellix, you talk about the patent situation there and you

highlight the 2032 patent. There is a court case ongoing, isn't there? And you've settled with a number of players. So is it reasonable for us to assume that the patent really would go out that far? Or given that you settled, we should think about, you know, a realistic time being shorter than that? And my final question would just be on the margins. So going from a midpoint to your core margin, this year is going to be about 21%, but you're telling us that it will be exceeding 30% by 2024. Can you just tell us which is the area where you could see the biggest change? Is there any chance that the gross margin will be substantially different? I suspect the R&D won't be that different because you've got lots of great ideas of things to do. So that's suggesting to us a very meaningful reduction in SG&A. So just checking that you think you can deliver all of this sales and have a meaningful reduction in SG&A for the whole of 2024.

Deborah Dunsire: [00:32:51] Great. So we'll start with the dynamics of Vyepti in the US and infusion centers, and I'm going to ask Peter Anastasiou to take that. Peter?

Peter Anastasiou: [00:33:03] Yes, thanks, Joe, for the questions. A few questions in there that I'll try to address. With regard to new and repeat, we certainly are seeing a combination of both. In fact, all of our metrics keep going up. The number of new patients, the repeat customers, the repeat use in terms of patients coming back for second third infusions is consistent with our expectations. So we are seeing that be on track with what we thought it would be. But we're also seeing the expansion of more prescribers and the depth of that prescribing by those clinicians. And the reason the infusion centers have been important is because at first that... the early days of launch, our focus was on clinicians that have high volumes of migraine patients, certainly, but also have the infusion capabilities. Now, because we have such a robust network of infusion centers, and, as Deborah mentioned, we're beginning to get some traction with in-home infusion, that we can really focus in on the customers that have the highest degree of volume of migraine patients, irrespective of their ability to do infusion, because they can refer to a local infusion center and then, of course, do all the care and follow up for those patients. So that's been a big enabler for the growth, and we expect that to continue. And we're constantly optimizing the support we provide for our customers within, you know, compliant means and, of course, support for patients and continuing to work on, as we mentioned before, broadening the in-home infusion to make it as convenient for the patients as possible. In terms of pushback, you would ask, you know, the main thing that holds back Vyepti is what holds back any new product, and that is familiarity. It certainly takes quite a few visits for some clinicians who are may be

slower adopters to really understand the clinical profile, the value that Vyepti brings. And that's not unique to Vyepti, that's true of any new product launch. And certainly that process has been delayed a bit because of the pandemic impact, particularly last year. But we're really getting some good traction on driving that efficacy message. It's being well received and clinicians are for sure seeing that with our patients in our practice. That's the feedback we get. So hopefully that addresses your questions.

Deborah Dunsire: [00:35:29] And then to comment on the Trintellix patent, we've got these patents listed for the for the compounds and we believe that they're valid and enforceable and will, together with our partner Takeda, support those... the validity of those patents as we go through. We have settled certain cases. And you know... what we built in we don't give guidance on because we believe that the patents are valid and enforceable. So you'd have to make your your choice on that. We've kind of given you the bookends of the compound patent and the and the out years. We do expect a decision coming up in this quarter at least, and knowing that there have been covid delays before with the court. So, but we would expect something potentially this quarter.

Anders Götzsche: [00:36:26] What is actually creating the expansion in the core (inaudible)... it goes without saying delivering growth in the revenue line is a big contribution, you should expect that the gross profit margin will stay around this between 78% and 80%m that is how we anticipated with the existing product mix. You will see a slight increase in in in our SG&A line, due to that we are making the global rollout of Vyepti. And then we have a couple of years now where we have elevated levels of R&D investment due to the Vyepti trials. And then, of course, you would see a reduction again in the in the cost line there. So you will see a more... a bigger impact on the... from the gross profit than you would see the growing cost base. So that is a reason for the margin expansion.

Jo Walton, Credit Suisse: [00:37:32] Thank you.

Operator: [00:37:34] Thank you. Our next question comes from the line of Michael Novod at Nordea Markets. Please go ahead. Your line is open.

Michael Novod, Nordea Markets: [00:37:42] Thanks a lot. A few questions. So also to the side regarding the patents on Abilify Maintena. It also seems that you have sort of increased your conviction in growth for that... or sustained growth for that product. So how do you envision the trends for Abilify Maintena in the coming, let's say, five years? Is that just sort of a steady grower and then adding on or replacing with the two months formulation. And then secondly to IO, we've seen a lot of companies do better in international operations and Lundbeck, too. So maybe you could sort of go into your sort of investment structure in IO. Are you sort of also investing into this strong growth that you may envision also in IO? And also adding to that, it's not only the US that is in focus, but also international operations and the Jacob's area there. And then lastly, maybe Johan could elaborate a bit on the next steps regarding borderline personality disorder and potentially FDA dialogue. Is this something that that you will go to the FDA with and discuss, or should we just consider this to be sort of over and out for (Inaudible)? Thanks.

Deborah Dunsire: [00:39:03] Thanks, Michael, for the question, starting with Abilify Maintena, we do see this being a continued grower, sort of slow and steady, and I think that the new patents that were listed recently in the Orange Book go out to 2034 in the US. Right. They don't they don't influence the rest of the world. And so, again, we believe the patents are valid and enforceable. So we anticipate bringing the two month, which is also... has patent coverage to the middle of of the 30s and being able to work to transition from the one month to the two month given that's more convenient for patients. So the two monthly, I think, gives us some good opportunities for the brand to continue that steady growth into the years ahead. With respect to international operations are handed over to Jacob.

Jacob Tolstrup: [00:39:55] Yeah, thanks. I can give you a few comments on that. So if we look at our global infrastructure today, I think it's fair to say that we are a global company that is covering all important markets within our field. And that also means that we do not plan to sort of increase our investments into the existing infrastructure except for Vyepti, of course, that we are launching. So you'll see investments going into Vyepti, but for the other brands, we do not foresee an increased spending level going forward on that.

Deborah Dunsire: [00:40:27] And then: Borderline,

Johan Luthman: [00:40:30] Yeah, so first to remind you that although we have a lot of very good data on Brexpiprazole, and (inaudible)... this indication, we did not have any prior data, but the biology and the involvement of dopamine and serotonin made us do this proof of concept study. The data, we picked this signal for the main readout at a certain time point 10 weeks in the trial, we did see signals across, but it's a little mixed data, which you often get from a proof of concept study. So we need to sit down and look at this data in its totality. We also need to get some follow up data. Patients are coming back for follow up visits, so it's too early to say exactly how are we going to handle this data. It's not a clear cut proof of concept, but it's not a clear cut in either way, negative or positive. We have to work also with our alliance partner Otsuka to determine the next steps. It may be an interaction with FDA. It may be publishing the data. It may be some other considerations for the program.

Michael Novod, Nordea Markets: [00:41:37] Ok, thanks a lot.

Operator: [00:41:40] Thank you. Our next question comes from the line of Karsten Lundborg of SEB. Please go ahead. Your line is open.

Carsten Lundborg, SEB: [00:41:47] Thank you very much. First question is regarding Vyepti marketing. As you say, Peter, this is a matter of being known in the market, and I was wondering how much will you, or Lundbeck, be willing to commit in terms of marketing spend for Vyepti? We have seen some quite explosive launches of the two tablets in the market by Biohaven and (inaudible), and the market is now more than half a billion US dollars on a quarterly basis. You have around 3% of it. So it's a cramped market, and it seems that you need to make a rather significant step up in terms of marketing costs. And... So any sort of color on that would be would be great. And then secondly, on VBP in China, the impact we're seeing on Ebixa here these quarters, is this... what does... in the plans for now? Or do you know about more coming up? Maybe not this year, but the next year? What's your view on that? Thank you.

Deborah Dunsire: [00:42:54] Peter, over to you.

Peter Anastasiou: [00:42:58] Yeah, thanks for the question, Karsten. With regard to the resources, I think you've probably already seen from us already, we haven't had the same size of sales forces that some of our other folks, our other competitors have, and certainly haven't

committed some of the resources that you see with the orals. And a big reason for that is because they're very different markets. So the acute market is an example which the orals primarily play in, and I know at least one of them has recently been approved in main... in prevention and another one will likely be approved. But the acute market is more than two acts the size of the prevention market that we play in. And so I think that's why you see the kind of resources and dollars and primary care investment and big sales forces and DTC that you see from those others. You know, the prevention market that we play in is certainly still very, very sizable, but it is a different dynamic. And we believe that the kind of investments that we're making certainly are going to deliver the growth that we expect from the brand. And we're seeing that now with the product performing on track with our expectations, but certainly with profitability in mind as well. You heard from Deborah and Anders, our profit ambitions. So we believe we're making the right level of investments in both sales force and and we do expect to do DTC at the proper time when all the conditions are set up to allow us to to help take full advantage of that opportunity. But I don't think you should ever expect us to see the kind of sales force sizes and the kind of resources, particularly that the orals are putting in the market because they are playing in a very different segment of the market than we are.

Karsten Lundborg, SEB: [00:44:47] All right, thanks

Jacob Tolstrup: [00:44:50] So on China. I can tell you that on Ebixa, we have lost approximately half of the revenue level that we had last year about the same time, And I wouldn't say that we have leveled out in terms of generic erosion on Ebixa, but revenue wise, we may have as underlying market growth also helps us in China, which is a significant high and double digit in the Alzheimer's space, also in depression. So I think we're reaching a level where we can stabilize and potentially start to grow Ebixa a little bit again. And then I would say we have a very strong year in China. We are looking outside of Ebixa, we are growing some 26 percent. And then we are also particularly successful, you know, online detailing where that accounts for about 6% of our total revenue in China now.

Carsten Lundborg, SEB: [00:45:42] And you don't have any... you haven't heard about any plans to include other drugs on... coming BVPs or anything like that?

Jacob Tolstrup: [00:45:49] No, so the recently announced round five did not include any Lundbeck products. And then we would have to wait for for the next one, which is supposedly coming out here after the summer at some point.

Karsten Lundborg, SEB: [00:46:05] OK, thanks.

Operator: [00:46:10] Thank you. Our next question comes from the line of Michael Leuchten of UBS. Please go ahead. Your line is open.

Michael Leuchten, UBS: [00:46:17] Thanks so much. Three questions, please. One, just going back to your slide about the Vyepti vials, when I compare that to the sequential revenue progression, it looks like the percentage of free drugs seems to be going up. Can you give us a little bit of a steer how the dynamics could work from sample to commercially relevant, given that you've got 235 million patients with good access? I would assume that repeats at some point naturally become commercially relevant, but maybe that's the wrong way to look at it. Any comment would be helpful. And then two questions for you, Johan. Just, your comments around PTSD - you said significantly impacted, as in the trial. At what point does it become a problem where it's just not feasible to drag it out anymore? And then a question on 82422: Interesting comment on your on your slide about the phase II design, but also the phase III that the base in responsive adaptive treatment allocation. You know, in the past you've commented that taking risks in phase III in central nervous system diseases is a tricky thing to do. How do you make sure that this novel design is actually OK from a regulatory perspective in the MSA setting? Thank you.

Deborah Dunsire: [00:47:40] Ok, so, Peter, do you want to comment on the Vyepti with respect to...

Peter Anastasiou: [00:47:47] Yeah, a couple of things, first of all, at the beginning of the launch, we said... we tried to set all of your expectations that you're not going to have perfect visibility into Vyepti. And that's because, of course, it's not a retail product. It's not even really that much of a specialty pharmacy product. It's 90% going through specialty distributors directly to both physicians and also infusion centers that do buy and bill. So the data correlation is not going to be perfect, and it's tough for you guys to fully rely on what you see in the system. Having said that, to answer your question about free drug, back to the Karsten's question about resources,

we decided from the beginning of launch we weren't going to do a broad sample program like many of our subcube and other competitors have done. And so we have not put much free drug into the marketplace. We have done some pilots here and there, but not enough that I think would affect any of the numbers you're seeing. So there's very, very little free drug in the marketplace.

Deborah Dunsire: [00:49:02] Great. Johan?

Johan Luthmann: [00:49:04] Yeah, thanks for the question. On the PTSD studies, we are about one third into the study and we just got... two trials, as you may recall, one slightly bigger than the other one. And we were just into this study when the pandemic hit us. And since then, it's been a constant struggle. We are far from the enrollment levels we need to have. So obviously we are considering options how to deal with this study. We have a highly decentralized trial already. We have reached out and talked to the regulators in expanding that effort. We have right now an ongoing dialog with the FDA. This is a US only trial. What we can do about this study, there are many, many options on the table. We are still having major efforts going on. Yes, to improve enrollment, but they are not paying off, to be honest, right now. And with the pandemic bouncing back and this particular patient group, we are not very optimistic about it. So we are looking at alternatives to handle this. But I cannot say more than that. We are an active dialog with the regulators about it. You may also know that there are not so many competing trials out there. There are a few small studies in PTSD going on. So there are very few analogs for us to really say, is this us? Is this the drug or is that the actual indication? But all speaks to that is the pandemic that is the main problem. For 422, yeah, it's a great question, I could talk at length about this, but it's actually a de-risking phase III approach. Yes. Based on the science, adaptive designs are not usually what you do in the later stage of the trials. I do have personal experience done that for pivotal trials before and had good experience with the regulators. We have had very repeated interactions with the main regulators on the design of this program. They are very familiar what we're trying to do. And I like to remind you that this is an orphan indication where you have more sort of leverage in what you can do in terms of innovation. There is no priority to build on here. And I would say that particularly the US regulators have been very supportive in building the entire program with us here. So we are we are actually de-risking the phase three by having this adaptive element rather than betting on fixed doses. That gives us flexibility. And we also have an early part, as I talked about, where we really will look at a stop go element built

around strong biomarkers and clinical readouts. So we're not going to go into that phase III without based design if we don't have the phase II signal that's required. So we are very stringent going into phase III anyway.

Michael Leuchten, UBS: [00:51:48] Thank you.

Operator: [00:51:52] Our next question comes from the line of Rosie Turner at Barclays. Please go ahead. Your line is open.

Rosie Turner, Barclays: [00:51:58] Hi. Good afternoon. Thank you very much for taking my questions. Two from me. And just a follow on from Jo's ealier question around patent trials. I just want you to give us a bit of an update in terms of what we're seeing with Rexulti. And then in the release this morning for Abilify Maintena, you flagged some (inaudible) fluctuations in inventory and just wondered if we could go through, kind of, specifically what that was. Thanks very much.

Deborah Dunsire: [00:52:29] So the question, your question. Rosie, thanks, was on Rexulti patent trials. We don't have anything underway right now. So, no comment on that. And then with respect to the second question...

Jacob Tolstrup: [00:52:48] Yeah, that's basically not a lot to, you know, what we also see is that between the quarters, there might be fluctuation in inventory level and it's nothing material, but they are, of course, fluctuation. It's nothing that is impacting dramatically. The trend that we have seen with Abilify Maintena is extremely strong growth in both international markets and Europe, and in the US we have had a steady growing business and but there is fluctuation between the quarters, but the level on hand at the distribution level seems to be leveling out. So it's nothing you should be concerned about.

Rosie Turner, Barclays: [00:53:29] Ok, thank you. I thought regarding the patents. I just thought there was something with Sandoz, I think there was something reported by Reuters back in April, but maybe that's all been sorted at this point... can you comment?

Deborah Dunsire: [00:53:43] We'll go back and get you an answer if there's anything that we've missed.

Rosie Turner, Barclays: [00:53:51] Cool. Thank you.

Operator: [00:53:52] Thank you. And we have one further person in the queue and that's Marc Goodman of the SVB Leerink. Please go ahead. Your line is open.

Marc Goodman, SVB Leerink: [00:54:03] Yes, a couple of questions, first of all, can you just talk about 2022, US, you know, payer negotiations, will there be any major changes in coverage or anything we need to be concerned about? There was a comment about inventory with with Abilify previously. But in any of the other products, were there any major inventory issues that affected the quarter? Just just want to make sure we cover that. Second question is Alzheimer's, there's been a lot of changes going on in Alzheimer's over the past couple of months. I'm just curious about your thoughts and if your strategy is changed just overall about how to pursue that opportunity. And then third, obviously, there asset prices have come down quite a bit over the past, I guess, in this calendar year. Just curious if things are looking more attractive, if, you know, you seem to be moving forward just with the discussions more now just, you know, given given better pricing. Thanks.

Deborah Dunsire: [00:55:08] Thanks, Marc. So, Peter, would you like to start with the questions on inventory Vyepti negotiations?

Peter Anastasiou: [00:55:18] Yeah, first, no major inventory fluctuations, like Anders said, you know, specifically about Abilify Maintena, but the others, I mean, there's always quarter to quarter, but nothing noteworthy or certainly we would have flagged that. In terms of payer coverage, I wasn't sure which product you were referring to, perhaps you were referring to the whole strategic portfolio, but the answer's the same for all of our strategic brands. Yeah, the answer is the same for all of them is that we have good coverage. Of course, for the established psychiatry products, we've had good coverage for many years and it's been stable. In fact, we've had some small improvements to it, particularly for Trintellix this year, where vibrant was this disadvantaged in a couple of formularies. But moving into 2022, I expect it to be stable. And then, of course, for Vyepti being the newest product in the portfolio, we believe that the teams that we have established good coverage for the product. We have 235 million lives that have access to it, a 110 million of them don't even require any kind of branded step. And that's

certainly plenty of coverage for us to be able to achieve our forecast. And I'll also remind you, I mean, you have great visibility each quarter to our ASP and you can see our ASP is very, very stable each of the first three quarters, which indicates that we're not giving away tons of discretionary gross to net dollars. And so that's our intended continued posture with Vyepti. So I expect the coverage to be comparable to what it is now with some small tweaks here and there.

Deborah Dunsire: [00:56:58] Would you comment on the Alzheimer's field changes?

Johan Luthman: [00:57:01] Yeah, thanks, Mark. Obviously, I think you referred to, particularly Aducanumab and accelerated approval based on the biomarker, which changes a little bit the opportunities in this space. Previously, we've seen a few examples of surrogate biomarkers supporting accelerated approval. And it all depends on the validation of the biomarkers. We've seen that in small (inaudible) where orphan indications like (inaudible) in the past. Now we see this for a much broader, bigger indication, which is a major step forward. So obviously we are welcoming this opening up in the neuro space, which you're seeing much more in oncology in the past. And that depends because we have now much better validation on many of the biomarkers and we will apply this kind of strategy across the board. Will that change overall how we look at Alzheimer's? Yeah, that's a bigger question, because obviously Alzheimer's trials are still very, very big and costly exercises and would require, even if you would aim for an accelerated approval, which of course, gets exceedingly harder, the more programs you have there, would still require a big investment - also, including in the biomarkers. We have a tau antibody that we have in early phase I. We probably wouldn't bring that forward without having a strong partnership, which obviously is possible even for accelerated approval pathways, because they are tools that are very similar to the ones you saw with Aducanumab, with pet tracers for tau as well. But we are not really taking on that big beast ourselves.

Jacob Tolstrup: [00:58:39] I just wanted to clarify, there was a couple of questions about this. We wrote in the release about the fluctuations in inventory levels for Abilify. And if you look at the at the half year, there's basically no inventory fluctuations. But you have seen, you know, this one million dollar up in the first quarter. And that was due - or down - that was due to stocking last year due to the pandemic. And then it has rebounded in the in the second quarter. And that's, of course, due to that there was a destocking in second quarter due to the pandemic. So it's it's

minor. It's correct that there were some fluctuations between the quarters, but it's totally to the mind. It's not very material for the full half year, no impact. ....make it razor clear.

Deborah Dunsire: [00:59:28] And then your last question on on asset prices, obviously, we're continuously evaluating the landscape for the right additions to bring into to Lundbeck to continue to drive our growth and rebuild the pipeline. And so I think it's a question of the right thing at the right time and the right price. But as you as you well know, asset prices have been extremely high - so they've come down a bit, maybe not necessarily where some of them need to be, but we continue to look diligently at many different opportunities.

Marc Goodman, SVB Leerink: [01:00:07] Part of my question was in Alzheimer's, you know, does it make sense to to look for an amyloid type product in order to move that quickly and then be on the market?

Johan Luthman: [01:00:18] Yeah, yeah, obviously, this is the big attraction now because the pathway is laid out and other companies that are in phase II and phase III, very interesting assets are planning for this obviously. We don't have an antibody. We had a vaccine program. We had issues with our program, technical problems. So we don't have any active program on amyloid in development right now. So we are quite far behind the field. And the field is right now pretty narrow when it comes to amyloid. It's really the monoclonal antibody approach. We will not resurrect our vaccine program because of the technical issues. May I just add one element to my answer before, I think what we're seeing now is that big indications, the big beast I talked about are getting more fragmented into sub indications and this will create in the future more opportunities within this space. Alzheimer is not the good old global Alzheimer's type dementia that you saw 20 years ago, and it's going to segment up to smaller and smaller indications eventually with different approaches. So that is the opportunity we see in this space.

Deborah Dunsire: [01:01:27] So I don't think we'd be licensing a lookalike for Aducanumab to bring in, and as Johan right on pointed out, even if you can get approved on an accelerated basis on a biomarker, you still need to have the scale of trials to to demonstrate the clinical benefit. And those trials are very large.

Johan Luthman: [01:01:49] You know, others have announced that they will go with phase II data to the regulators, but those data packages are substantially smaller than Aducanumab's. So we'll see how that evolves.

Deborah Dunsire: [01:02:03] Good. Well, thank you all for your attention today and thanks for your questions. Have a great day.