Lundbeck

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Transcript

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LaQuinda	I was really depressed. I pretty much just stayed in the room. You can't understand what it's like to be in constant pain, nausea, dizziness, light sensitivity, sound sensitivity.
Mirza	[Non-English].
Narrator	Billions of people are impacted by neurological and psychiatric conditions globally, and this is predicted to grow, affecting patients, their families, and society as a whole.
Helle	I keep thinking, if this is the worst, I can survive, a month later, it is worse.
Ditte	[Non-English].
Martha	It was hard for me at start to accept that my diagnosis is going to be a part of my life always, so I started out fighting it till about some years ago. I finally found some kind of place in my life, and what I'm supposed to do and live with the symptoms that I have.
Narrator	Lundbeck has an unparalleled history. For more than 70 years, we have maintained our commitment to neuroscience. And today, we're one of the only pharmaceutical companies solely focused on addressing brain health.
Morten Grunnet	Many of us have encountered family or friends suffering from neurological or psychiatric disorders. Making a difference to these people's lives is really what makes our work so meaningful.
Narrator	Throughout our history, we have launched more than 30 therapies. And today, our treatments are helping more than 8 million people every day. Building on our strong legacy, we hold ourselves accountable for driving focused innovation and curiously exploring new breakthrough treatments within neuroscience.
Sheng	[Non-English].
Larrisa	I really hope that I can be there more for my family, especially my sister and my niece.
Narrator	We pride ourselves in being quick to adapt. Our focus will allow us to grow and deliver on our commitment to helping patients, people, and society.
Charl van Zyl	Good afternoon, everyone. Very nice to see you here. It's actually fantastic to have quite a full audience here in the auditorium. We, of course, also would like to welcome those online. We have a number of people who have joined us online today, so it's fantastic to have this audience here. And, of course, we are broadcasting today here from our headquarters in Copenhagen. And this is a fully integrated headquarters. We

have research, development, we have manufacturing, we have supply chain, we have commercial. So this is a group of people working together here on the site that are simply driving focused innovation. And today is very much about that. It's very much about the simple words that you see on these slides. It's about focused innovation that will drive sustainable growth. And that is everything that we do in terms of our strategy and how we want to build the future together.

Now, what you will see today, just to orientate you a little bit to the context of today, is very much a dialogue with you to go deeper into our Focused Innovator strategy. And you will see this through the lens and through the voices of the leadership team here, the executive leadership team, who will be on the stage to present also their view of how focused innovation works for us. And the intent of having a capital markets event like this is really to allow us to go deeper into what's the substance of our strategy. And we expect the outcome from today for you is to have a better clarity on how we see the mid-term growth, better understanding of the pipeline, really what are the milestones and the triggers that will evolve over the next 12 to 18 months. And really, what is behind our strategy, the people, the leaders that will help us transform and, of course, perform in terms of building our Focused Innovator strategy.

Before we continue, there is, of course, important Safe Harbour statements. The discussion today, of course, will include forward-looking statements that are, of course, subject to change. And also, importantly, we made, of course, an announcement last week on the agreement that we've reached with Longboard. We know that this discussion today is only for informational purposes, because the tender offer is not commenced yet. And so today's discussion, of course, is not there to solicit any trading of the common stock of Longboard.

So, it was essentially Q4 for last year, about 12 months ago, that we introduced, at our Research and Development Day in London, the Focused Innovator strategy. And there were three important questions that we addressed, and questions that we reflected on ourselves, but also that we heard from many of you. The first was the question on how does Lundbeck grow through the mid-term, when we are facing some loss of exclusivity. The second question was, really, can we see the long-term growth perspective of Lundbeck, so what's in the pipeline essentially to build that long-term growth? And the third one was clarity around our capital allocation strategy. How will you fund that journey going forward? Now, I can say today, this is 12 months down the line, that we haven't got all the answers, but we have many more answers than 12 months ago. And I want to share with you a few of those answers to all the proof points of our strategy as we go forward.

And this is really what you see here. We are growing our strategic brands by 19%. This was through the half-year mark of 2024. We are seeing significant growth on Rexulti, Vyepti and Brintellix as key drivers of that growth, more growth than what we have seen 12 months ago, and that's also why we believe our mid-term guidance is being extended, and that we can see also different peak sales potential of these assets.

We also see fundamentally a very different pipeline, that focus on innovation, and what is coming out of this pipeline is completely different profile than we had 12 months ago. And I will share more about that, of course, in a second. And thirdly, we have also clear swim lanes in terms of profitability and how we think about capital allocation, how we fund that going forward. And, of course, today, also, we will be clear on that, that our guidance around our adjusted EBITDA will remain within a corridor, even though we will absorb some additional costs due to the acquisition development area.

And so when I talk about the different profile of a company, this is one important message for you, if you think about Lundbeck, say, 12 months ago, and where we are now, there have been huge advances in the pipeline and in where we stand today. And if there's one message for you today, then it's one which is in 2026 we will have four phase three programmes that are really the answer, or one of the answers, towards the long-term growth for Lundbeck, the growth that will be delivered in the next decade through many of these assets that we will develop and bring to the market towards the end of this decade.

Now, we often get the question, neuroscience, what is that? Is that a risky area? Is this an attractive area? And the answer is, emphatically, yes, it is a very attractive area. We are in this space for nearly 70 years, 100 years in existence but 70 years in neuroscience. There’s a huge unmet need, the societal burden is significant, but we also see a segment of our industry growing at high-single-digit in the next years. And what we also see, of course, is an increase in regulatory approvals, and we see capital inflow into this neuroscience space. And it's driven by a better understanding of the science, a deeper understanding of what we also call the Decade of the Brain, in a sense what we are in right now. And Lundbeck is really poised to capitalise on that opportunity.

And the way we do this is very much in this illustration here, that you see. We start with a patient in mind at the centre of everything we do, trying to understand, first of all, the pathobiology, but also understanding the unmet need. What we are working on needs to be differentiated versus what is today available to these patients. And we do that in this clockwise fashion, through deeply understanding the biology, the

pathobiology. What is really the disease? How can we ensure that we understand the causes of the disease and, therefore, how can we address them?

Then, as we develop the molecule, we put it through a very rigorous approach to make sure that the preclinical tests are rigorous, to ensure that the molecule speaks, and it's clearly defined that this is a molecule we want to take forward into the clinical stage, which is where the patient speaks, and that's where we really understand the full value of the opportunity. And, of course, in that full circle, we bring these treatments, these transformative treatments, to patients through our commercial organisation, through our operating model that we have on a global level, and ensuring that we have the best way to serve these patients and have access to these medicines that we bring to them. It really starts there, at the centre of understanding the patients. And I can tell you through the video that you've seen, this is what drives the company. This is the secret sauce. This is the purpose of why we're here, to really bring differentiated medicines through this rigorous scientific process, to bring them to patients.

Now, as we go into a perspective a little bit on the longer term, I want to, again share with you something that I've spoken to you before about. This is our roadmap, our leadership roadmap. How do we see ourselves transform the company into the future? We're very much in this phase of focusing, focusing on ensuring allocation of capital to the investment of the organic brands to grow them faster than what we've grown them before, but also to be very clear that we allocate capital in a way that is going to drive and fund the innovation pipeline that we need for the long term growth.

And we are doing that through a very purposeful approach around capital reallocation, looking at all areas across the company to ensure that we can allocate either towards growth of our organic or innovation in terms of pipeline. But we see a journey that we are on and a journey where we are growing into areas where we can scale, where we can have significant scale, in a way that allows us to play to win, which is really in the severe migraine space, neuro speciality, which is one of our pillars of our strategy, but also advancing with the pipeline that you will hear about later, into the neuro-rare space, and also the acquisition that we have announced recently with bexicaserin, building that strong neuro-rare franchise that allows us to scale in areas that we haven't been before, and allows us to really build a position of diversification of growth into the long term for the company.

But we also see ourselves, as we advance the pipeline, we will be open to partnering, partnering on the pipeline, commercial

partnering. We are a company with strong recognition, and we attract that commercial partner opportunity as well to us. So continuing to think about how we will bring our medicines to patients might not always be ourselves, but through partnerships as well. And in this phase of scaling, we are also, of course, as of today, building aggressively into this area of how we transform our fundamental engine into AI and ensuring that we are well prepared to leverage this benefit that we would see, both from research, from development, from commercialisation across the company.

And as we enter into the end of the decade, we see the pipeline, these four, just at least today four, phase IIIs, advancing into launches, into acceleration of our growth into the next decade. And of course, through this, we are building an industry-leading neuroscience company and platform that we will have for the future.

Behind every transformation, and we are performing and transforming Lundbeck, is a great leadership team that you will see today. This is a leadership team that's highly experienced, bringing significant international expertise. And, of course, a lot of this team has assembled over the last 12 months, but I am very confident with the team we have that we are able to now lead and drive a great future for Lundbeck and really set ourselves up for our ability to play to win.

So now I'd like to just conclude a little bit my opening part by just orientating you to what you will now see going forward for the rest of the discussion. We really want to go deeper into how are we focusing to play to win. And you've seen three pillars of our company, in a sense, our history and our current legacy, of course, in neuropsychiatry, but we also have a strong position with Vyepti in severe migraine in neuro speciality, and we're building a strong pillar in neuro-rare. So we're seeing, through that lens, how do we see that evolve over time, through the pipeline, through the commercial efforts to bring that forward into a strong engine that will continue to drive sustainable growth and allow us to play to win.

So this is the emphasis of where we are and what we would like to discuss with you now going forward, deeper into that area. And you will see this through the lens of the leadership team and the management team. And therefore, it's my pleasure to welcome on stage, first, a new member to the team that you might not have met before. Maria Alfaiate, who is our head of commercial and corporate strategy, and Maria will host the next session. So, thank you, Maria. Welcome.

Maria Alfaiate

Thank you very much. Good afternoon. As Charl just alluded to, next week, I will be completing my first three months with

Lundbeck. So I decided, since I'm new to most of you, just to give you a bit of background on myself. I've spent the last 20 years working for big pharma, for Bayer, for AstraZeneca, and also for MSD, or Merck & Co. in the US, over a variety of different roles. So, some roles are more operational at a country level, others more strategic at a global level, across sales, marketing, early commercialisation, portfolio strategy, and also market access. And I'm delighted to have joined Lundbeck, we are at a game-changing period in the life of Lundbeck, and I'm also delighted to have joined the executive management team.

For the next section, where we will be showing you what focus means for us at Lundbeck and how we win, I will be accompanying my colleagues from the executive management team, and I would like to welcome them on stage now. Tom Gibbs, who's our head of the US, Michala Fischer-Hansen, our head of Europe and international operations, and also Johan Luthman, our head of R&D.

So, as Charl mentioned, our focus innovator mindset permeates everything that we do across the value chain. And through this next section, together, we will be providing you an overview of how, indeed, we are focusing and how we're planning on building a pipeline for future success. So we will start by looking at our operating model. We will start by looking at the performance of our in-market brands and how we're really driving them for growth, and also how we are partnering with R&D to deliver life-changing medicines for patients. So I would like to introduce the next section where we will be understanding a bit more about how innovation in patient care and in customer centricity is indeed driving growth for our brands in the US, with Tom.

Tom Gibbs

Thank you, Maria. And hello, everyone. During Charl's presentation, he outlined the key principles of our Focused Innovator strategy. And when I think about how we translate this strategy for the US, it's very clear that the greatest contribution that the US can make in support of our Focused Innovator strategy is to help deliver our mid-term growth, and to do this by accelerating Vyepti and Rexulti performance as efficiently and effectively as possible. Now, delivering on this imperative requires that we build a commercial engine that operates at a higher level, functions at a higher level, as we think about it through how we're engaging our customers, but also how we're functioning internally. So let's first think about this through our customer-facing model.

One of the things that we had to do first was really increase our patient focus. Now, put yourself in the shoes of patients in the US. They have to overcome significant complexities to get the diagnosis and treatment they need and the outcome that they

seek. And this is especially true when you think about diseases that are treated by specialists or in rare disease. So we've created an integrated, patient-centric model that fully supports patients across their journey to help them overcome barriers. And then, if we think about our model through an HCP lens, healthcare practitioners are incredibly busy, and we have to develop, and we are developing, new, innovative and more impactful ways to engage HCPs the way that they want to engage with us, to deliver relevant information in a timely manner, to influence behaviour.

And then when we think about our internal operations, I want to start with our culture. We needed to change the way that we come to work every day. We need to change the way that we approach our business. As Charl said, we need to play to win, and we needed to be guided by the leadership behaviours associated with our Focused Innovator strategy, so curiosity, making sure that we create a psychologically safe environment where people feel compelled to speak up, to share their thoughts and perspectives, and know their voice will be valued and heard, and have the courage to bring forward bold solutions for significant challenges and significant opportunities.

Adaptability. Driving innovation in everything we do, whether it be improving the known or creating the new. And then combining our purpose-driven organisation with a performance-driven organisation. And that performance-driven organisation links to the fourth pillar of our commercial engine, which is comprehensive capital allocation. We need to make sure that we maintain a high level of financial discipline, where we're dynamically and disproportionately allocating resources to our greatest opportunities, informed by advanced analytics, facts and data.

Now, over the past 12 months, we've made a set of strategic choices to support the four pillars of our commercial engine, and we've translated these strategies into an operational plan to drive precision execution in support of our Focused Innovator strategy and accelerate performance. And to date, the results are encouraging. Let's look at Rexulti first. When we compare MAT July 2024 to MAT July 2023, Rexulti has grown 18%, and that's driven by the successful launch of our AADAD indication. Vyepti. When we look at the time frame from July 2023 to July 2024, Vyepti's market share has increased 33%, going from 6.6 to 8.8. And then if we look at the Abilify Asimtufii launch, I would suggest the Abilify Asimtufii launch is ahead of schedule, and it's enabled the Abilify LAI franchise to sustain double-digit growth in a relatively flat market in 2024.

So when I think about it, I'm incredibly proud of what the team has delivered to date. Yet, we're also humble enough to know

that we have significant work in front of us. We now have a differentiated product portfolio, an incredibly innovative pipeline, where we have the opportunity in the US to build multiple-billion-dollar franchises. And that begins with delivering $1.3 billion for Rexulti by LoE. Now, this assumes a positive outcome for our PTSD indication. We have the ability to build a $1-billion-plus severe migraine franchise, driven by the results that you're seeing with Vyepti. And we have an opportunity to establish a rare disease franchise model that supports a multibillion-dollar neuro-rare disease portfolio, anchored by amlenetug and bexicaserin.

So, I talked about how we're looking at optimising our commercial model within a single market. Now, what I'd like to do, and what we would like to do, is be able to talk about how we're optimising the commercial model across markets. Michala?

Michala Fischer-Hansen — Thank you, Tom. Good afternoon, everyone. It is truly a pleasure to be in front of you at such an exciting time in Lundbeck's history. I want to give you a bit of insight into how I plan to drive this transformation within the region of Europe and international operations. If we start by giving you a snapshot of what this region looks like, this is truly a diverse region. We are represented by roughly 2,500 employees across the globe. We have offices in more than 50 affiliates, and partnerships in many more. And we represent DKK 10 billion revenue, about half of Lundbeck's business. We have all the brands. Roughly 60% of our business is coming from the strategic brands, and they are growing at roughly 20% compared to last year. And then we actually have a sizeable business in the mature brands, roughly 40%, which is holding steady and actually remaining stable, despite significant competition. What is critical for us is we're building on a very strong foundation, and we have to, of course, maintain this solid performance through the midterm, while we prepare ourselves for the future and transforming towards a Focused Innovator.

So let's take a look at what that looks like. Essentially, this is really about evolving our commercial model across the geography and ensuring that our go to market approach fits the needs of the business and the patients. When we look at the region, or we look at Lundbeck, we have about 80% of our revenue coming from 12 markets. Those 12 markets, we need to make sure that we capture all the potential that is there. These are markets that have 80% strategic brand share, and there is significant more potential just from the sheer size of these markets. Key is really that we transform to become a Focused Innovator due to the good environments in these markets and allocate the right investment levels so that we can play to win in these 12 markets.

We have a handful of, basically, Northern Europe and Central Europe markets as well, that are smaller markets. Still hold potential, but of course, due to the sheer size of these countries, the potential is not unlimited. Here is really about making sure we capture the synergies across the markets and that we leverage the best practices and learnings from other markets so that we don't overinvest in these smaller markets, but that we still capture the potential that is there for us.

And that leaves roughly 25 markets, affiliates, where we need to evaluate the best commercial model for Lundbeck in the future. This really means that we need to look at our current model. We need to look at what is the right model for the future when we transform into a neuro-rare, neuro-speciality business. And this can involve both changing our current commercial model in the market, but, of course, also evaluating partnership opportunities. So, really, in essence, it is about for us to target our capital spending, to support long-term growth for the key products and the key markets that we have in the region.

So, Tom and I have now given you a sense of what we are planning to do commercially, to transform, to become a Focused Innovator. But, of course, we can't do that without a sustainable and innovative pipeline. So I invite Johan to give you some insight into that.

Johan Luthman

Thanks, Michala. It's truly an exciting time to be in neuroscience. I have, through my many years in academic and industry research, never felt that we have a better time than now. If you look at what's happening across the neuroscience field, if you look at molecular neuroscience, through system neuroscience network analysis, we have great tools today. Every week, there is some new tool coming through that we can apply in our research. We can also bring more and different drug modalities into play, here. Basically, every drug modality that is used in the pharma industry is actually today being applied in neuroscience drug development.

You will later [00:28:14 unclear ?] participate in a breakout session, visit our Biotherapeutics Labs. We have, the last four, five years, really built an excellent capability in biotherapeutics, which is one of those drug modalities that play a very fundamental role in neuroscience. What has also been quite remarkable is the development of various biomarkers. And those are not just biomarkers for early readouts, for looking at drug effects on target. They are actually now also becoming biomarkers for drug registration. And we have a number of biomarkers now that are validated for accelerated approvals, or are co-primary endpoints for full registration.

The regulatory pathway has really been changed a lot. And if you

look at the field of, what I mentioned, accelerated approvals, neuroscience is number two in terms of accelerated approvals after oncology. And if you look overall, neuroscience is the top three of drug approvals with the FDA and with the EMA. The last eight years, neuroscience has been among the top three.

So what is coming through the pipeline? Well, it's really been a remarkable journey in migraine. We have now prevention treatments where there were none. We have now a CGRP class of drugs that came six years ago to the market, and Lundbeck is part of that journey. We have also now, since many, many years of nothing, a breakthrough in Alzheimer's disease. Last year, we saw two full drug approvals in Alzheimer's disease, after 20 years of nothing. One of those drugs was Rexulti, for a completely new indication, behaviour and psychological problems in Alzheimer's, treated particularly towards agitation. This is a completely new breakthrough, together with the disease-modifying drugs we saw last year and this year.

Neuroimmunology, you may say that's been around for quite some time. Yes, MS has been extremely successful, but we still see very successful drugs coming into the MS space. But now neuroimmunology goes beyond MS, myasthenia gravis, neuromyelitis optica syndrome, and other indications are now coming through with strong and very powerful mechanisms, where we have very, very strong underpinning biology.

Rare neurology, it's an amazing space. We are entering into this field more and more. We've been there before. Here you see very innovative drug modalities coming through, antisense gene therapy, etc., for diseases with very, very high unmet medical need, many of them inborn. And finally, we also see some breakthroughs in psychiatry. A very different thing here. You see well-established mechanisms that finally break through and start to deliver to the marketplace. So there are many, many drugs coming through that explains that neuroscience is among the top three in drug approvals.

So how do we operate in this space? We have a long, long legacy. Over 70 years ago, we launched an anti-psychotic drug, and since then, we've been in neuroscience and fully dedicated to neuroscience. We have a strong legacy to build on. Now, we are embarking on a Focused Innovator strategy, building further on our psychiatry core, reinforcing what we do in neuro-speciality, and now bringing forward a number of products for our neuroscience diseases.

How do we play in this space? We are listening. We're listening to the biology. We're listening to the molecules and to the patients. We have systematically built our R&D to start with strong biology. Why? Because that's where we find the best

readouts, and that's where we're finding those biomarkers I talked about. This is fundamental to be successful, but also, quite frankly, to kill your darlings in phase one. We really need systematically to weed out and bring forward the best opportunities. The best opportunities should be underpinned by really strong molecules. That's where we're listening to the molecules in early development. And finally, we like to take the molecules that we tested out into the right patient populations. Stratification of patients, better innovative trials, all these are things you will see from us in the future, and already seen in some programmes.

We have, as I said, a very strong legacy in psychiatry. We have delivered a number of very strong, impactful drugs, most recently Rexulti for agitation in Alzheimer's disease. And we also have brought forward Abilify Maintena two months recently. We're still building on that, but now we start to focus more into the neuro-speciality field. And here we have a strong position with Vyepti in migraine, and we're building further on that with our anti-PACAP molecule, as well as other things we can play with now. We are also building up our neuro-rare presence. Amlenetug, multiple system atrophy antibody, is moving ahead towards phase III now, but we also have other very interesting ingredients in our pot. One is the anti-CTH molecule that I will come back to. So, Maria, how do we meet the patient's needs?

Maria Alfaiate

Thank you very much, Johan. We've been giving you a lot of information, so I will try to summarise the key points here. By optimising our operating model, in reality what we're doing is still meeting the needs of patients in different markets. And you've heard from Tom, on the one hand, how we are creating a true patient-centric model in the US, but also how we are creating a unique customer experience that will be very relevant as we move into newer disease areas in the future. You also heard from Michala how the focus in Europe and international operations is allowing us to really unlock the potential of key markets, leaving no patient behind, ideally. And you also heard from Johan how our choice-full R&D allocation of capital allows us to leverage our resources for brand support, on the one hand, but also how it will help us continue to build our pipeline into the future.

So, moving from focus into how we win. We've previously shared with you that, again, focus will be a part of how we win in the future. We've already shared with you some of our key, or these three key, areas where we believe we will be able to win, but I would like to take you back to our mission video. There, I believe it's very clear that Lundbeck has the history in neuroscience. We have the legacy, we have the skill. But I would like you to also understand we have the will to stay true to our legacy, to our history, but to unlock the potential of the future. That's exactly

what we will be doing. Over the next few presentations, we will take you through how we build on our psychiatry core, and use it as a springboard into the future, but also how we are reinforcing our neuro-speciality position, and also how we establish a neuro-rare franchise. So to tell us about how we've made advancements with Rexulti in the field of AADAD, back to Johan.

Johan Luthman

Yes, thank you, Maria. I talked about it already, I think it's a remarkable thing that we brought this very well-established product for other indications into agitation associated with Alzheimer's disease dementia, AADAD. That's the indication we have in the US, and we're expanding this drug into several other markets, but the US is the main market. We have generated more data on this molecule, and I think this is extremely important what you hear, because many of you know what I'm talking about, you're caregivers, you're taking care of Alzheimer's dementia patients. And we went out and talked to caregivers and asked them, what is the most bothersome thing with your loved one?

If you think about cognition, you think often about dementia. And that is a problem, truly, in Alzheimer's, but agitation is the true problem that drives people to the nursing homes. Agitation symptoms that caregivers bother most about are the aggression realm, cursing, verbal aggression [00:37:47 unclear ?], spitting, it's actually very high on the list. We have also physical non-aggression, like trying to be in another place, wandering about, leaving home, being found out on the streets. Big problem. And verbally agitated, repetitive sentences or requests for help. That is what bothered patients and caregivers the most.

Rexulti has the strongest effect on those behaviours. We also took a look from our pivotal trial, the last one we did, in a set of three pivotal trials, the 213 trial, and continue that into an OLE, trial 1A2. And what you see in this graph I think is important data as well, because it shows that when you continue treatment with people that have responded well to the treatment, here defined as a clinically-meaningful effect, which are 20 points on the Cohen-Mansfield Agitation Inventory scale, you see that already at the end of 12 weeks, which was the registration end point, we had over 50% of the patients showing a clinically-meaningful effect. But when we continue out, that goes up even to 75%.

What we're also seeing in this OLE study is that when we switch patients from placebo over to active treatment, they're also quickly reaching that 50%, and they also go up towards 75%. So that means that we're showing sustainability of the effect for the treatment. It's an intermittent treatment in the label, but now we show beyond the 12 weeks in the trial.

As you may remember, we took this drug also into another indication, PTSD. We had a readout last year, and it was somewhat mixed. First of all, I'd like to emphasise this trial was run at the height of the epidemic, COVID epidemic, and that's not a good indication to study during an epidemic. PTSD people don't want to leave home. So that's a hard trial to execute, but you manage to finish it up eventually. Two trials in that programme. One trial was positive, clearly positive. The other one didn't beat placebo.

However, overall in this programme, we also had a phase II programme, and when we pool this data set together, you see what you see on the left side, here. So, overall, we see a clear benefit of the treatment. This we generated in discussions with the FDA. We had a pre-NDA meeting with them and discussed what they wanted to have, and we've been working on a dataset they wanted to see. And now we submitted for an sNDA approval last year, and we're looking forward to PDUFA date, February 8th. So, how are we doing in the marketplace? Well, Tom?

Tom Gibbs

Thank you, Johan. So, to me, commercial performance begins with meaningful clinical differentiation. And the data that Johan just presented further enhances the overall clinical value proposition of Rexulti to drive further growth. And this is particularly true when we look at AADAD. The strong growth that we're seeing in AADAD is now propelling the overall demand growth for Rexulti. So if we look back to May of 2023, when Rexulti received the approval for the AADAD indication, monthly TRX volume has grown 361%, based upon the latest data that we have, which is July 2024. And during that same time period, the non-AADAD business has grown 15%. AADAD now contributes 17.5% of the overall TRX demand for Rexulti, and 22% of NBRxs. We expect by the end of the year that the AADAD indication will contribute over 20% of the total TRX demand for a Rexulti, and play a more meaningful role in terms of driving growth of the overall brand.

So when I think about how we're performing in AADAD, I would say we're pleased, but not satisfied. From a performance standpoint, the results are in line with our expectations. But when we look at AADAD, we see so much significant opportunity in front of us, as the diagnosis and treatment rates are still very low and the unmet need is significant. If we look at Alzheimer's disease, it is a public health issue in the United States. 6.7 million Americans, age 65 and above, are diagnosed with Alzheimer's. 50%, one out of every two patients, will develop agitation at some point during their disease course. And only 34%, one-third of these patients, are being treated.

So, as we look at it, through an alliance lens, Lundbeck and Otsuka are committed to investing the necessary resources to

maximise the opportunity for AADAD, both from a business standpoint as well as from a patient standpoint as well. And we think these investments will continue to help drive growth for Rexulti, both from a brand market penetration standpoint, but also from a market growth standpoint as the diagnosis and treatment rates go up.

So now what I'd like to do is for us to look at how we view the overall potential for Rexulti. It's important to remember that Rexulti was launched with two indications, schizophrenia and MDD. And at the asset level, we have been able to build a blockbuster in a very competitive MDD market. And we continue to believe that we will drive incremental growth in this base business, but where we see the accelerated growth, it's in AADAD, as we just talked about. So if we take our current indications, our base business with MDD and schizophrenia, and combine it with AADAD, we believe that Rexulti will achieve blockbuster status from a Lundbeck point of view.

Now, when we think about how we fully maximise the opportunity with Rexulti, it does include that PTSD indication, which we believe is an exciting and significant opportunity. But as Johan said, we're also cautious, because we know that there's risk involved with the sNDA filing, which we'll find out in February. So if we do get that indication, we do see further upside, and it will be further upside based upon the mid-term guidance we have given, because the PTSD indication is not included in our mid-term guidance.

So we've talked about Rexulti becoming a blockbuster product, exceeding that billion-dollar threshold for Lundbeck in the US, and now, what we're going to talk about are Brintellix and Abilify LAI franchise, which collectively have the opportunity to deliver over $1 billion or DKK 7 billion. Michala?

Michala Fischer-Hansen

Thank you, Tom. So, let's start with Brintellix, the little engine that could. Here you see a brand that has several years in the market, and you see here six years of continuous growth, delivering almost 15% compound annual growth rate over the period. This growth is largely driven through Europe and international operations, and we really see that it is the big European markets, Japan and China, that have driven the growth. The focus here is to continue to maximise the potential, and we expect to see mid-single-digit growth in Europe. We, of course, have patent expiries coming. And in the US, as you know, we have given the rights to commercialise, so we will cease the commercial activities for Brintellix as of January 25, giving it back to Takeda, so that we can continue investing in other opportunities here in Rexulti.

The Abilify franchise holds a similar story, also a product that has

been on the market for an extensive period of time, but continues to deliver strong growth. Again, you see almost 15% compound annual growth rate over a long period of time, and you see here that the growth is coming from many places. We actually hold over 30% market share in several of our key markets, and we continue to outgrow the market. The focus here in the mid-term is really to roll out and launch the two-month option, Abilify two-month option, and ensuring that we drive the conversion from the one-month to the two-month. We believe the two-month provides patients with a very relevant alternative, both in terms of sustained efficacy but also in terms of convenience of a two-monthly injection versus a one-monthly injection.

As you know, we got the approval in Europe this year and have begun to roll out in Europe. We launched in the US last year, and very encouraging results so far. I think Tom touched upon it earlier, but we're seeing now 15% NBRx, and we're seeing almost 11% of the total Abilify LAI franchise share in TTX. So a very strong start for US in converting, and the encouraging news is that we see that the conversions are not just coming from the one-month, but also from the oral version, the aripiprazole version in the market. Analogues suggest that we can expect conversion of around 20% to 25%. We are cautiously optimistic that we can probably exceed that ambition.

This brings our psychiatry core part of the presentation towards the end. But, again, you're getting a lot of information, so to ensure that we are hammering the point home for you, I invite Maria to close.

Maria Alfaiate

Thank you very much. So Michala already started summarising for us the key thing that you need to retain is that by building our neuropsychiatry core, we're still able to accelerate growth with a focus on our key markets. You've heard from Tom that the performance of Rexulti is indeed accelerating. You heard it has even surpassed some of our initial estimations. The growth on Trintellix and Brintellix in Europe and international operations is significant, and again reinforces our position in psychiatry, but also how we are fully leveraging the performance of our strategic brands with this focus on the key markets.

So moving on to the next area of focus for us, you've heard us also mention that we want to reinforce our position in neuro-speciality. And as you know, Vyepti was this first step into this space. It was, so to say, our beachhead into creating a migraine franchise. And given the performance of Vyepti that you're familiar with, I would say that not only Vyepti gave us the right to play in the migraine space, but it is becoming a clear signal that we should have the right to lead in migraine. So, to tell us everything about how Vyepti continues to exceed our expectations in the market, Tom.

Tom Gibbs

Thank you again, Maria. So, Vyepti is the foundation of our neuro-speciality franchise, and will continue to be the foundation moving forward. And we're going to continue to invest in Vyepti to make sure that we can drive and maximise growth of this asset. So, although we do look at all of your estimates for Vyepti, and the way that I measure performance is really focus on how we're doing within our competitive market space, and then our performance versus other industry analogues. And when we use these benchmarks, Vyepti is setting new industry growth records when we compare Vyepti to other medical benefit products at the same time point in its life cycle.

So back at the end of 2022, we were analysing Vyepti performance versus other medical benefit analogues, and we are performing basically in the middle of the pack. In 2023, year four on the market, we set an ambitious target to drive 50% growth in demand, which would match the highest growth rate of medical benefit products within year four. And, as you can see, in 2023, our demand grew 63%. We exceeded that forecast and set a new benchmark in terms of performance for medical benefit products.

And if we look at 2024, year five in the marketplace, we expect, based upon current performance, to at least double the rate of growth of our nearest analogue competitor. And we do expect this dynamic to continue. And the reason for that is based upon favourable market dynamics, as well as strong brand fundamentals. So, if we look at it from a brand market dynamic standpoint, what we're seeing is that the number of subcus that are being used are getting fewer and fewer until ASPs are transitioning to Vyepti. And then from a brand fundamental standpoint, we are seeing 66% of our growth coming from existing prescribers, so increased depth, and 33% of our growth coming from new prescribers, increased breadth.

And what's helping deliver that growth for Vyepti is really this patient-centric model that I referred to in my previous presentation. Through our patient model, we're making it easier for physicians to prescribe Vyepti, and making it easier for patients to get infused with Vyepti. I think it's really important to understand that we manage our Vyepti business at the patient level, not at the population level, like other migraine companies. So we have built a fully-integrated patient ecosystem that supports the patient across the patient journey from activation, activation, origination, diagnosis, treatment, reimbursement, fulfilment, and persistency.

And what that allows us to do is to activate levers within that patient journey to help patients overcome barriers, but also to influence brand choice. And over the last 12 months, within this differentiated patient experience within our Vyepti fusion

network, we've been able to increase the written-to-infusion [?] ratio from 50% to 65%. The 12-month persistency for Vyepti has increased from 45% to 55%. And just for reference, the 12-month persistency for Botox is 37%. The 12-month persistency for subcus are 31%, and it's 27% for Qulipta.

So as we look ahead, we see the opportunity to even further elevate and enhance the efficacy of our patient model, taking conversion rates from 65% up to 75%, which will be best in class, elevating our persistency rates to that 60%, which will further define what best-in-class persistency looks like. And importantly, this model also gives us the ability to scale, to develop a rare disease model that will be able to support our emerging rare disease franchise for Amlenetug and bexicaserin when launched.

So as we think about Vyepti, we do see a $1 billion opportunity for Vyepti in the US, but we also see significant opportunity for Vyepti in Europe and international markets. So, Michala?

Michala Fischer-Hansen — Thank you, Tom. To me, Vyepti is really an amazing story. We launched it four years ago in the US, and we began the rollout outside the US in 2022. Today, 30 countries have access to Vyepti, and patients are benefiting by Vyepti on a daily basis. It is truly becoming a global brand, and Lundbeck is well-positioned to take a significant position in this marketplace. There's still a high unmet need in migraine treatment, and that's why I think we have so many opportunities here.

We've seen phenomenal growth in the US, and we've seen Tom's plans to continue this. In Europe and international operations we're gaining significant momentum, growing triple-digit, and we're benefiting from the great learnings and practices that the US have shared with us, so that we can expand our position with Vyepti in these markets as well. And key for us is really to ensure that we allocate the right investment to the right growth markets.

As Maria said, growth of Vyepti is really exceeding our expectations, and we're confident that we will reach blockbuster status earlier than originally indicated. And on top of that, Asia represents a significant opportunity, of course depending on the SUNRISE readout that Johan will come back to in a minute. To me, the launch of Vyepti really demonstrates that Lundbeck has the ability to successfully build a market and launch a global brand and drive a very strong launch performance across the globe. And we can do that on our own when we need to. To give you a little more on what lies ahead from a clinical point of view, I invite Johan back to the stage.

Johan Luthman — Yes, thank you. The first time I met this CDRP biology was over 40 years ago, when I did studies on the human distribution of

CDRP. 2009, I got really involved in this CDRP class for drug development. At that time point, I had no idea that the best drug that would emerge out of this would be an antibody and an antibody for IV administration. Vyepti has really converted into a remarkable drug, I have to say. This is a very impactful class, but Vyepti is really the most powerful agent in that class, and we continue to build on this with more data.

Here, you see a few examples of that. One, to the left here, is when we look at the sustainability effect. Here, you have a combined index of headaches and the severity of the headaches, which, of course, are clinically very relevant. And we see data out to two years. This is extremely important that we see this sustained effect over such a long time, because one of the problems in migraine is that people cycle through different treatments, but here we see a very sustained effect with reduction throughout two years.

Migraine, for those that don't have it, you think it's headache. It's much, much more. One of the most troublesome symptoms is actually not the headache and pain attacks, it's something called brain fog. Brain fog is really what as sounds, it's being foggy in the brain. Cognitive deficits. You basically are not performing where you'd like to perform. That can occur during attacks, but also in the interictal periods. Here you see some data on Vyepti that I think are quite remarkable. If you see the effect on brain fog through a different rating scale here, 86% of patients see some benefit in the brain fog. What we also see is that almost a third have very much improved in the brain fog. So this drug really goes beyond the migraine attacks themselves.

I said we're letting the patient speak. We're also letting the patient speak when it comes to the treatment effect of Vyepti. We did a pioneering adaptive trial in the Asian markets for Vyepti. We started with the SUNLIGHT trial, which was really trying to understand how the Chinese population, and also the Japanese population, responded to the drug, which was very important because there were, at that time point, very few studies done in the Asian markets.

Through the SUNLIGHT pioneering study, we got important information so we could build the SUNRISE study, the follow-up study, the pivotal study, in a much more solid way. We're looking forward to have a readout of that trial shortly. That will, if positive, build a foundation for us to enter into the Japanese and Chinese markets.

So, I have been talking about how great CDRPs are, but unfortunately, that is far from enough. 40% to 70% of patients are still not responding, in spite of the set of drugs we have now, including the powerful CDRP class, well to treatment. There are

lots of remaining medical needs in migraine, and that's why we like to stay in this field, to try to serve the patients with all those symptoms. Treatment response, of course, very important, but also symptoms beyond the migraine attacks. I talked about brain fog, but there are many other cognitive and other behavioural problems you have with migraine. Quality of life is very, very important to restore in people, particularly when you have chronic migraines. Also, more convenient treatments are important.

So we see a great potential as a company to stay in this field, not only because we like to serve the patients with the still remaining unmet need, but also because of the market potential. Maria?

Maria Alfaiate — Thank you very much, Johan. So, as Johan mentioned, there's still huge unmet medical need in migraine. So despite the good results that we see with Vyepti, the task is not done, and we step up to the task. So, you know that in terms of our pipeline, we've shared already some of the highlights, we have assets that have the potential to be first in class, meaning that they can help us address the needs of migraine patients all over the world. We know that we have, with this the potential to build a true migraine franchise, of which Vyepti was the first step, as we've mentioned before, but we're talking about addressing the needs of something like 2.5 million to up to 3 million patients worldwide. And the market currently is worth $11 billion.

Johan Luthman — Thank you, Maria. In R&D, there are many fun things you can do, but the most fun thing you can do is to have a positive, clinical proof of concept. We had that last year. We had our anti-PACAP molecule. In April, we had a readout from a proof of concept study with IV administration of this antibody that we took from pre-clinical level up to this stage. So now we're embarking on a more ambitious programme, aiming to bring this molecule into a full, pivotal programme. But before we do that, we'd like to sort out a few things. One is maybe a very mundane thing, but it's fundamental for R&D, finding the right dose. So now we have a dose-ranging study for those arms, but we also try out an alternative administration route, through the subcu administration.

So we have the PROCEED trial ongoing right now. It started this summer. It's sort of one-fourth into it, so it's still early days, but we hope to have a readout from this trial so we can guide the pivotal program where to start in 2026. We have a potential market entrant, if that trials go well, in 2029.

Maria Alfaiate — Thank you very much, Johan. So, of course, there is indeed the potential to build a true migraine franchise. It's what patients want. It's also what the market wants. Migraine has been a way

for us to reinforce our neuro-speciality position, and we have spoken to you about how we continue to drive growth using Vyepti as a base, but also using Vyepti to prepare us for the future with other assets in this area.

We're fuelling the growth in the US with a true patient-centric model, with a true, unique customer experience as well, but also, by focusing in our key markets, we are able to drive an amazing performance in Europe and international markets. By addressing unmet needs with Vyepti, we're also not forgetting that the job is not done, and we're in this for the long run. So we will be bringing to the market drugs like anti-PACAP and developing a franchise with amazing growth opportunities still.

So we're approaching the final of our dedicated areas where we said we would be playing, and that is exactly how to establish a neuro-rare franchise. And through this section, Johan and I will do a tag team to take you through the key considerations. We spoke to you before about our appetite or our openness to consider external innovation. It's not a big mystery. Most of the successful pipelines in the industry are made up exactly of this combination of internal and external assets, and we see it at Lundbeck as one of the ways to augment our internal innovation to ensure that there is enough strategic fit between the inside and the outside. And we see it as an opportunity to increase our success.

You are probably curious about what this meant for us. We have received questions from you in the past, so I imagine last week, finally, you were able to see how we were becoming more concrete with our deal with Longboard and how we are now adding bexicaserin, the latest pearl, to our collection, to join an already amazing set of assets that holds really good promise for the future.

Johan Luthman

Thank you, Maria. I'd like to take you through a few slides that explains why we're so excited about the potential to acquire this company and this asset. So we'll focus on bexicaserin, which is the lead asset of Longboard, but before we go there, I like to explain a little bit what we're dealing with here. Epilepsy is a major clinical problem. Another major problem is that we have very few treatments that are fully effective. Many patients are not responding well to treatment, so there is a big need for additional treatments. You probably also know there is a lot of add-on treatment, you're combining, it's polypharmacology in this field. But 25% to 40% of epilepsy patients basically are drug resistant.

Epilepsy is today classified from various angles, but one angle is the type of seizures you have. You can have generalised seizures, and that is actually a seizure that starts throughout the brain. The whole brain starts to backfire or over-fire. There is

also focal seizures, that were called before partial onset seizures, quite often from the temporal lobe that can spread out to become generalised seizures. You can present with different types of behavioural problems, epilepsy. So, seizures can be very discrete events, clinically, to major, grand mal attacks.

The underlying reason why you get epilepsy varies. It can be acquired, brain trauma, infection, tumours. First sign often of an astroglioma in the brain is seizure. Syndromal, there are many syndromes, metabolic, etc. What we start to figure out now is that many of them actually have polygenetic, common variant reasons. So they have a little bit of underlying genetics, also, those syndromal ones.

And then we have a big, big group of genetic causes. That's actually the majority. Over 50% of all seizures are due to genetic causes. Those could be ion channels, transporters of signalling molecules, etc. Sodium channel mutations are the most common. There are more than 900 different monogenetic reasons for getting epilepsy.

Developmental and epileptic encephalopathies, that's a subgroup of the big field of epilepsy, but it's a very, very important subgroup, because that's where the really severe diseases are. These are patients with developmental disorders. So they have other problems, they have cognitive problems, behavioural problems, motor problems. They could be autistic. And then they have epilepsy. The epilepsy is part of the pathology. It actually drives some of the other symptomatology, including cognitive deficits. And often they regress in the development. They hit that at very early ages, in many cases. And, of course, in the monogenetic cases, you're born with a problem.

So if you look at this group, very big group, of developmental and epileptic encephalopathies, there are only a few of them that have approved treatments, but there are a lot of different types. So to drill down a little bit more on this, these are US numbers, but if you look in this DEE group, as we call them here, there are about 120,000 patients in the US with approved treatments. That's for Lennox-Gastaut, for Dravet and the other indications that have approved drugs. But when it comes to many of the other DEEs, there are no treatments around that is approved. There is some off-label use, of course. So within this big group of these, we have Lennox-Gastaut, we have Dravet, and then we have other these combined into this.

Why did we get so interested in bexicaserin? Well, it had an interesting mechanism of action and good data. So let's start with the interesting mechanism of action. This is, if you may, a best-in-class molecule, but it actually also has elements of being first-

in-class. This molecule is selective for its agonistic effects on 5-HT2C receptors, which is a validated target for antiseizure effects. But it doesn't carry any binding agonistic effect on other 5-HT2 receptors. And that's fundamental, because the 5-HT2B receptor carries a big liability, valvular pathology, heart disease. 5-HT2A receptors carry problems with pro-psychotic effects. So here you have a validated mechanism and the unique mechanism being selected for the [01:12:36 unclear ?].

The selectivity, by the way, is carried by this secondary mid [?] in the eight position of the molecule for those that are chemists here. That's really very important to say, because the company that is behind this, Arena and now Longboard, they really know what they were doing. They had a structure activity relationship going after that selectivity.

So, this is a very, very nice underpinning for the rest of the story. Of course, they did the classical thing of pre-clinical evidence and decision models. They went into healthy volunteers and looked at the effect of the drug. What is important here is, of course, drug-drug interactions, that it is well-behaved in terms of other drugs, that's part of the equation here to be effective. But, of course, what was driving our big interest was, of course, the so-called PACIFIC study, a phase 2a study that looked at various DEE populations.

These data were communicated earlier this year, and they also initiated and have communicated an open label extension part. This molecule carries differentiation potential because of that unique profile that I talked about. If you compare to other common treatments in some of the DEEs, cannabidiol and fenfluramine, we have a potential here for Dravet syndrome patients by themselves to be more efficacious and definitely have a better, more compelling safety and tolerability profile.

We also have the possibility for Lennox-Gastaut to have a very strong effect, but also across the DEE spectrum, into paediatric populations, of course, eventually you'd like to include children down to two years into this, because that's really where the big medical need is. There are a lot of other benefits with this asset, and one is that the FDA also liked the data, and they provide a breakthrough destination for the molecule for this new indication of DEE.

The selectivity also carries the potential to avoid burdensome safety monitoring REMS programmes. So this is a truly exciting molecule that was underpinned by the data that you see here. Here, you see the three different populations I talked about. Dravet, Lennox-Gastaut, and other DEEs. This is the PACIFIC study, the 2a study, that made us very interested in this asset. This is on top of standard of care. The patients are on various

treatments, including Epidiolex.

So what you see here, combined in the study on the left side, is almost 60% effect in reducing motor seizures, that are seizures that translate into motor symptoms. That's quite remarkable data on top of other treatments. If you look through the different subgroups, which, notably, some are small, but in the Dravet symptoms, the patients that were involved there, they had a very, very strong response rate, but also in Lennox-Gastaut and other DEEs.

The other thing that really made us excited was the open label extension study, because we're talking about an agonist therapy, tachyphylaxis, tolerability can play a role, but here we see, out to nine months, a sustained effect, with about 50% reduction in the mode of seizures. So this is truly a very strong indication of being a strong drug and a differentiated drug.

I'd like to shift gears now from this very interesting asset to another, I think, very interesting asset that we have in our portfolio, and that is our multiple system atrophy antibody anti-alpha-synuclein. For those of you that will be part of the breakout session later, you will hear more about this programme. We will present specifically on this programme the phase II data, etc. Unfortunately, Dr Wolfgang Singer came down with some disease, infectious disease, and couldn't travel, do we'll have another presenter for the clinical background of MSA.

Just a few words, I talked about the joy of a proof of concept when it's positive. We've been blessed, because early this year we had a readout in our AMULET trial. This was a highly innovative trial, adaptive design elements, but also, most importantly, Bayesian statistics with the progression model, which truly showed encouraging data that this drug works in a disease that has no treatment. Patients with this disease die within six, seven years. So, Maria, how about the market potential here?

Maria Alfaiate — Thank you very much, Johan. So, as Johan said, and as you know, because we've told you about the asset before, in multiple systems atrophy, we're aiming to have a first-in-class disease-modifying drug. So we're talking about an antibody that has a superior technical profile. Johan already mentioned we have achieved clinical proof of mechanism, but also there is a very clear, well-defined regulatory pathway. So we are talking about potentially addressing something like 26,000 patients worldwide, but with a range of potential from a sales point of view between something like 1.5 billion to 3 billion. And also with the launch around 2029, so 12 to 18 months after the launch of bexi, we could be looking into launching amlenetug.

Johan Luthman — Charl talked about potential to have more assets in phase II by

some years, and this is one of them. It's a really, really interesting asset in rare diseases, neurohormonal disease, and it's our anti-ACTH antibody. It's first-in-class. No one has approached this biology with this kind of mechanism before. We are doing two trials now to explore the full potential of this drug. We have already proof of mechanism, I would say a little bit more than proof of mechanism in the congenital adrenal hyperplasia study. That's the blue illustrations, here. What is that? That's a disease when your adrenals are under-functioning. You have less cortisol, and with the homeostasis in the body, that means that the pituitary gland says we need more ACTH. So it starts to fire up, and that leads to stimulation of the adrenal or other things that you don't like to have.

If you're a woman with this disease, you get masculinisation which is leading to things like no menstruation, etc., hair growth in places you don't want to have it, etc. There's really no treatment today that nips it up at the top, at the beginning of this hormonal cascade, the ACTH generation. Looking at an indication like that is quite interesting, because we have very strong biomarkers. That's why we're so confident, even though this is a very early stage asset. So we have readouts already now that are highly relevant biochemically, but also we see clinical signs of really good effects.

The left side here, the red side, is Cushing's disease, where we just started up a study. A few subjects included. Cushing's disease is a very different thing. You have benign tumours in the pituitary gland overproducing ACTH. The only treatment that is partially effective is surgery or blocking downstream, at the receptors. So, again, we go to the core of the problem, hitting the tumour cells that are overproducing ACTH and stopping that from coming out.

So we have already now data also from that study. Very early, but signals that the molecule is doing its job. And that's why Charl is so bullish and pushing me and R&D that this will be a phase II programme. But we really believe in this one.

Maria Alfaiate

And I think Charl is also thinking about the roughly 15,000 patients who are currently being poorly treated. The existing options are not good to address these drugs. That's why we believe in the science, but that's also why we see a market potential. We could be looking at the first-in-human, first-in-class antibody with a favourable safety profile that acts, as Johan just mentioned, directly into ACTH. We believe that we will be able to bring clinical differentiation and also interesting characteristics, not only in Cushing's disease but also in CAH. And there are, of course, clinical diagnostic criteria which are helping us, are guiding us, in the development programme. So the potential for these two indications combined could be

superior to 2 billion USD as well. And here again, we would be bringing the assets to the market roughly around 2031. So you're starting to see a pattern here.

Johan Luthman

Yes. I talked about that we're letting the molecule speak, and I will soon talk about one example here. But I said, we like to kill our darlings in early development. We just announced that we actually killed a darling. That's our monoacylglycerol acetate inhibitor molecule, MAGLi for short. Inhibitor 74. It was a peripherally restricted molecule that we explored in a nice set of very decisive pain studies. And the molecule told us, we don't like this. So we stopped that programme. That we announced today. That was part of the Abide acquisition. But we have still MAGLi inhibitors in clinical development. That programme has not ended overall.

But let me talk about something a little bit more exciting. Our CD40 blocker. Many of you may know about this biology, because other companies work on it. It's a pretty exciting area, and exciting areas tend to aggregate R&D people. So this is a mechanism that has been studied for several generations. We are kind of on a third-generation drug here that is substantially de-risked from side effects that the previous molecules had. We have a binder. It's not a true antibody. It's blocking CD40 ligand, but not through an antibody-type of molecule. It's another type of binder which binds to albumin.

We decided to put this molecule into thyroid eye disease. Why? Because we think the mechanism is well suited for it, and it's also a good indication to test this mechanism of action. We will let the molecule speak. Here, we're looking at autoantibodies. Thyroid eye disease is a consequence of Graves' disease, where you have extrusion of the eye. So we are also looking at the growth extrusion of the eye, which is very fundamental, because we think in the mechanism of action, we may actually affect tissue growth as well.

But these are really great mechanisms, broadly active, and could potentially work in many other indications. Other companies have shown already this mechanism to work in multiple sclerosis, and also some non-neuro autoimmune indications. But this is a big field. Maria.

Maria Alfaiate

It is a big field. And although we cannot tell you more about other subsequent indications, with such an interesting target within the neuroimmunology space, which is where we would position ourselves to work, there are multiple opportunities. Johan just mentioned multiple sclerosis, but also neuromyelitis optica, myasthenia gravis, and others. So there is tremendous growth potential, even by addressing these smaller disease areas. Thank you very much, Johan.

So I'll try to summarise again how we believe that by establishing a neuro-rare franchise, we are indeed creating an R&D innovation engine with a compelling pipeline that will help us build a sustainable pipeline and sustainable revenue into the future. We are combining internal and strategically selected external opportunities, which include, as you know, bexicaserin as well as amlenetug. There is huge unmet medical need, and we are trying to play exactly in that space by providing scientific breakthroughs. We like to work on what is exciting.

And finally, we have the competencies, we have the organisation, we're well positioned to exploit the opportunities that come from these science areas, and we believe that we will be able to deliver game-changing products and a game-changing pipeline.

So we've taken you through a very big journey, a very long journey, and I will try to summarise how we are, with a Focused Innovator mindset, driving sustainable growth by creating a pipeline of truly amazing assets with either best-in-class or first-in-class potential.

On the one hand, building upon our psychiatry core, with continued growth of Rexulti in the US, as we've heard from Tom, but also Brintellix in Europe and Japan observing some of the midterm or upcoming LoEs, enabling also the extension of our midterm guidance. So we're reconfirming that.

When we're reinforcing our neuro-speciality position, you've heard from as Vyepti achieves things that we believe are wonderful, we're also going to continue to build on this migraine, on this disease area, to establish our neuro-speciality position, and also how we are establishing a neuro-rare franchise with amlenetug and bexicaserin as two of the key assets that will drive our future and have the potential to anchor a multi-billion US dollar franchise. So with that, I would like to welcome Charl back on stage, who will help us through the Q&A.

Charl van Zyl

Thank you, Maria. Thank you so much. So, I know we've covered quite a number of elements, of course, today. There is still one part that will follow, which is our capital allocation and financial dimension. But we have addressed essentially two of the important questions. One was, how do we see the mid-term perspective of our organic growth, and, of course, how do we look at the long-term pipeline. So we really want to take the moment now to hear your questions, questions you might have, and I would ask you to guide your questions maybe more to the parts that you've heard. And then, of course, the financial part we will have, as a follow-on with additional question and answer time as well. And there are also, of course, those online able to post your questions as needed. Microphones are available for

us just to make sure we hear the question very carefully. I see one hand up in the back, please.

Thomas Bowers

Thank you. Thomas Bowers, from Danske Bank. So I'll maybe just kick off a few questions on bexicaserin. Looking at the competitive landscape right now, of course, Fintepla with a similar mechanism of action, broadly, so I'm just wondering, when you are excluding Fintepla patients in the phase III, as I understand it, how should we think of you positioning yourself in the market? And also, if there are any plans for any head-to-head comparisons that you need to do in the clinical setting?

And then, second question, just on the DEEs. So, I understand that you are looking at plus 15 or at least 15 different diseases within DEE, so is there anything that we should be concerned about in regards to the balance in the phase III? So just maybe to give us any understanding on whether there should be concerns of potential noise in the phase III.

And then just lastly on the formulation, we're looking at three times daily, so is there anything that you are working on that could make it into a twice or once-daily, also in terms of looking at the competitive space? Thank you.

Charl van Zyl

Great. Thank you for that question. So, maybe we start with the question around how we see this positioning from a clinical perspective against fenfluramine. Johan, you may want to comment there.

Johan Luthman

Yes. First of all, the PACIFIC trial did not include fenfluramine- or Fintepla-treated patients, so they were not included. And since the drugs have fairly similar mechanism of action, it probably wouldn't make sense. It's more that you can drive the doses up for this one. So, you have to think about the ethics for the patients to write the REMS programme. The side effects, of course, is where we have the strongest profile, but we expect, also, through that more unlimited dosing paradigm, to be able to drive efficacy more.

But we are not including that. And I say we, but it's them still. It's Longboard. So, we, we have not concluded this deal yet. And there could be things we like to change a little bit in the programme if we take over this, but that's how it's planned to go ahead. Maybe I can go on with the other two also.

Charl van Zyl

Yes, please.

Johan Luthman

The DEEs, not 15 others. There are hundreds of others. The DEE is a broad, broad family. That, I tried to explain. We're talking about hundreds, maybe thousands, of different reasons to have a DEE. So, this is the remarkable, and also very exciting, breakthrough that, now, the regulators are open to find a treatment that is approved for this big, big basket of different

indications.

Would that lead to some worries about variability in the study? Yes, it does, because when you have more heterogeneous populations, it could be a more variable response. There are various ways to build this together, this puzzle. Longboard has embarked on a separate Dravet study called DEEp SEA, and then they have DEEp OCEAN that is just, also now, starting up.

That will be Lennox-Gastaut and the other DEEs. So, there are many possibilities to play, here, with the different indications, sub-indications, but the main thrust should, and will, be overall for DEEs, not slice it up. And as you see, the most sizeable populations are still Dravet and Lennox. So, that will drive most of the presumed powering of the study that they're having.

BID/TID, yes, that's a good question. It's TID right now. It's a good half-life, but not perfect, like six/seven hours. And you need to have relatively stable exposure. The programme has an inbuilt bridge to look at BID as well.

Charl van Zyl — Thank you, Johan. So, I think, just to wrap that question, what we see with bexicaserin is really the best-in-class profile that we see with the selectivity and the design. So, as Johan said, I think what we see clearly is the opportunity with the ability to differentiate. So, we have a question here. We just need a microphone, if possible.

Martin — Martin [01:33:25 unclear ?] here. It'll be two questions on the migraine franchise. And we saw your peak sales charts on VYEPTI, which has also continued to go up after the potential launch of PACAP. So, how do you think these two products complement each other on a commercial scale? And then, just about your new soft guidance on the R&D ratio of towards 20 to 25% by the end of the new strategic period, how much is that driven by Longboard?

Charl van Zyl — Thank you, Martin, for that question. So, maybe we first go to how we see the co-positioning VYEPTI, anti-PACAP. We spoke about the non-responders, certainly in CGRPs, but maybe, Maria, you want to comment on that?

Maria Alfaiate — Yes, I can start. So, as Johan said, we're talking about very different modes of action. So, in reality, with anti-PACAP, we could target everyone, including the patients that are currently on an anti-CGRP. So, it could be used with an anti-CGRP. It could be used with non-responders to anti-CGRP. We have not yet defined the root, but in essence, one does not exclude the other, from a commercial potential point of view.

Johan Luthman — Maybe I can add a little bit. In the PROCEED trial that we have ongoing now, we allow people that have been on CGRP and have not responded well. So, we're going to have a sniff of that

differentiation. We're not pushing that hard in that trial, but we're going to get a sniff of that. But, as Maria says, it's a broad biology here. This could go into, not only the pain signal itself, but also this autonomic system and all the symptoms that are related to autonomic system stimulation and migraine.

Charl van Zyl

Thank you. And, Martin, we will certainly come back, also when Joerg speaks about the guidance. But what I would say is, of course, as we see the pipeline evolve more to Phase 3, there's natural growth of investment as we enter into those Phase 3 areas. But strategically, we see, for a focused innovator, being in this 20/25% ratio is what we want to go for. Now, the way we do that is, we have also, and we will discuss a bit more, undertaken significant capital, reallocation, 10% of our current capital, to free that up, to reinvest in innovation.

So, and of course, we're looking, as Michala had said, at our commercial operating model. So, those effects allow us to have that flexibility to operate within that 20 to 25% range, while also maintaining this adjusted EBITDA of 30 to 32%. Today, we're, of course, guiding more to 30 because of the acquisition that comes in there. But happy to discuss that more when Joerg is there. So, we have questions, please. Yes, Thank you.

Charles Pitman-King

Charles Pitman-King from Barclays, thank you. So, just, maybe, first on REXULTI, thank you for the new peak sales guidance today. You've given two targets, one excluding PTSD and one including. I'm just trying to think a little bit here about the upside potential, and we think about the progress to the 8th February PDUFA. Just thinking about your confidence on an approval and whether or not we could, potentially, see an AdCom related to this indication, just given the kind of variability in the results seen?

And then, just second, on VYEPTI, again, looking at the peak sales, I'm just wondering if you could provide any geographic breakdown of that? What proportion of those sales could be reliant on positive Asia data? Thank you.

Charl van Zyl

So, let's talk about, maybe REXULTI, PTSD. Johan, maybe more the view?

Johan Luthman

Yes, maybe I can start, and then maybe you can talk about it. So, for our confidence, yes, it's a tie because the rule of thumb in psychiatry is, you need two positive trials. Now, we have a third also, the Phase 3 trial in the pot. I'm cautiously optimistic about this, but we are not putting this into our guidance, because it's at that level. And why am I cautiously optimistic? Because FDA really like to work with us on this.

We did actually delay, a little bit, the submission of the sNDA, to do more analytical work they requested. I'd also like to add that

Lykos had a little story this summer, hammered by an AdCom. We don't think we get an AdCom for this. We might, but we don't think so, because this is an extremely well-established drug with a completely different profile. I don't think there's any readthrough, what happened to Lykos for this.

Charl van Zyl — And Tom, maybe Joerg, the question more, also as we see a success scenario of PTSD, how do we see that also play into our current resource, leveraging our field force?

Tom Gibbs — Well, what I think is really interesting about the PTSD indication is that it really fits into our current footprint. If we look at PTSD, only 23% of patients are diagnosed, but 80% of those patients are treated within the psychiatry speciality. So, we can cover that opportunity within our current Sierra sales force, which also covers MDD.

And because of the familiarity of psychiatrists with REXULTI already, we believe that there's an opportunity, both from a PTSD standpoint, to expand the utilisation of REXULTI, but also, it will have a spill-over effect to strengthen our competitive position in MDD.

Charl van Zyl — Thank you.

Johan Luthman — Did you have issue on VYEPTI?

Charl van Zyl — Yes, the second question was Charles' question around the contribution of, our outlook for, VYEPTI from the rest of the world. So, maybe, Michala, you want to comment, especially Asia as well?

Michala Fischer-Hansen — Yes. So, my confidence depends on Johan's confidence. But of course, Asia represents a sizeable opportunity, because there is a huge unmet need, and there is, of course, a significant patient population. And then, of course, there's pricing, that's different. So, I think I'll say it's a sizeable opportunity. When you look at the graph, you can see EU and international operations delivering more than it has. And of course, Asia represents a big part of that.

Charl van Zyl — Yes, I think, Charles, you saw on the slide, certainly equal populations probably, in terms of US, ex-US, but we see, at this stage a billion coming from the US and 300 million from the rest of the world. So, that's based on price differences as well. Hope that gives you some direction. Thank you. Michael?

Michael Novod — Thank you. Michael Novod from Nordea. Just cycling back to the patients switching in migraine, most of the patients are switching. So, how do you see the potential for, actually, patients starting on an oral, moving straight on to VYEPTI at some point in time, as well as the potential for combining PACAB or anti-PACAB with VYEPTI, also to drive increased persistency and thereby,

also having patients much, much longer on a large base of sales for Lundbeck?

And then, secondly, to amlenetug, how does this specifically differentiate from potential competition in the area of MSA or other related diseases?

Charl van Zyl — Thank you, Michael. So, let's talk about patient switching.

Tom Gibbs — So, as I stated in my presentation, what we're seeing is a positive market dynamic, as it relates to the evolution of the treatment paradigm. We are seeing VYEPTI moving up the treatment paradigm, where previously, it was reserved for fourth or fifth line, and now we're seeing it used much earlier.

One can imagine a market dynamic where you go from orals to VYEPTI, and we do see that in some physicians that are broad loyalists. But I would say, it's more common for a patient to go from an oral to a sub-Q to VYEPTI. But we see that evolving and changing.

Charl van Zyl — And then I think, there was a question, really, from Michael around our views on fixed combinations, or combination of VYEPTI/PACAP. Johan, You want to comment on…?

Johan Luthman — Yes, I said, one of the fun things is to get the proof of concept positive. What is also fun, that you unlock new opportunities with validating biology further. And we are not foreign to the idea to do various combinations here and build on this biology further. We have not talked so much about it, but there are many opportunities here. You could do various things or combination therapies. Of course, VYEPTI, PACAP.

That depends on whether you show that you really have a different biological spectra you reach into, which we, of course, hopefully, will see with it.

Charl van Zyl — Yes. And, Johan, you may want to comment on the amlenetug, but mainly also the mechanism where we see other competition coming in.

Johan Luthman — Yes, it's a good question. We're watching our competition. I'd like to say we are smart, and I think we were smart because we took multiple system atrophy with our antibody for many reasons. Other people went to Parkinson's disease, and that's where they are, right now, active. Takeda has an MSA study going on, together with MedImmune, AstraZeneca. It's substantially delayed.

They are struggling a little bit with enrolment, for some reasons, so we don't know where they will land, and we don't know which doses, etc. They had not been, so much, leading on this. That could be, if they have a positive readout, that some of that's coming behind us. But we are starting Phase 3 now, and we are

done with our regulatory interactions, etc. There is no other drug mechanism at play for MSA. So, that's really, effectively, switched an antibody into our field.

Charl van Zyl — Thank you. Question, we start over there.

James Gordon — Thank you. James Gordon from J.P. Morgan. It was just a question on what looked like quite substantial SG&A savings and whether there's any offset when we're thinking of a top-line forecast. So, I heard that for VYEPTI and REXULTI, you've got a bullish view on the big 12 markets, but is most of the SG&A saving from moving away from these small and other markets? And might we need to be a bit more cautious about our projections there?

Or is the big saving really about, you're really focusing on VYEPTI and REXULTI, and so the other products won't be so big, and maybe we need to be a bit more cautious on some of the other products?

Charl van Zyl — So, if I understand your question correctly, James, I think your reference to the SG&A part, there are two factors to it. There's definitely an impact from an operating model, how we will be in different countries, based on our segmentation. That's one factor, but also what we're doing, significant investment in analytics, AI, the omnichannel. So, we also see the model shifting from a traditional field force frequency reach to a more specialised model over time.

So, that means, also fewer people over time, of course, in some of these more specialised treatments that we see.

James Gordon — So, should we think of the savings being more geographic or more product-focused? And which way should we, potentially, model some of it?

Charl van Zyl — Yes, it's, it's a good question. It's, a little bit, a mix of these, but I think, certainly, the reallocation is to where we see VYEPTI and REXULTI as the mid-term growth driver. So, that's where we will make sure that we invest there, to play to win there, yes. Thank you. I think, I'm looking at a time check here. We have, maybe, one more question. Is that okay? Over here, please, one more. Microphone, if we could get. There will be time for a second Q&A. So, please hold those questions, if there are others as well.

Lucy Goddington — Hi, Lucy Goddington from Jefferies. Just a couple. So, on bexicaserin, it looked like Longboard felt like they could get launch in 2027. So, just wondering about the 4Q 28 launch that you've guided to. And then related to that, is the plan to keep the existing Longboard staff on, particularly what they brought in, commercial-wise?

And then, for REXULTI, the midterm guide, what does that factor

in, in terms of performance within the schizophrenia and depression indications? And does it assume any success for Axsome in agitation Alzheimer's? Thank you.

Charl van Zyl — Okay, so let's start with launch date for bexicaserin. Do you want to mention that?

Johan Luthman — Yes. You never know how a trial goes until you start, and you've been running it for a while, so timelines are always a little uncertain. Of course, Longboard has, now, some experience from the PACIFIC study, etc. Some of us in Lundbeck also have some experience in the past with those indications, but that's years back. So, it's really hard to know with the enrolment rate. I think we think it's realistic, maybe, to have a little longer timeline than their estimates.

They may be under different pressures or have been under pressures with timelines. So, that's the simple answer I can give you.

Charl van Zyl — Yes, on the question of integration here, Lucy, I would just say that we, of course, are not discussing integration in detail today, but I think our mindset, going into this, is, we will learn a tremendous amount from Longboard as well. There is an innovative company here that has advanced the product very quickly. So, we will look at this, of course, once we see post-closing. But it's a mindset of, we will certainly complement each other in this space.

And then I think the question, last one, Tom, for you, around how we see the other indications on REXULTI.

Tom Gibbs — So, as I stated, we do have a large base business in MDD, and we continue to expect incremental growth consistent with what we've seen previously. Where we see the biggest opportunity is with AADAD, in terms of really accelerating that growth and becoming a more and more important part of the overall franchise.

The question on Axsome, see, I think you can think about competitors in two ways. They're either friend or foe. And when you think about the low diagnosis and treatment rates that I talked about in AADAD, we actually see there being an advantage to having another competitor in the marketplace to raise awareness and appreciation and the urgency to diagnose and treat more patients. And they are contemplated in our projections.

Charl van Zyl — So, there will be a second Q&A, so keep some of those questions, if you don't mind, and we will certainly have a chance to address them with you in the second Q&A. So, I want to thank the Management team for the presentation. And we now move to the final part, which, of course, I would like to just, again,

emphasise, it's the most important component of our three questions.

We've discussed how we see the midterm. We see, of course, pipeline, but then, of course, also how do we see our capital allocation strategy and how do we fund that journey going forward? And it's my pleasure, therefore, to invite to the stage, with no introductions needed here, Joerg Hornstein So, thank you, Joerg.

Joerg Hornstein

Thank you so, Charl. So, we're now coming to the third question. How are we going to fund it? But I think, before we talk about funding it, let's think about, that there is no value without growth. And that requires for us also to reflect a little bit on our performance over the last two and a half years. We have come incredibly strong out of the gates, post the pandemic. We grew sales 8%, 10% into H1 of this year, on the back of an underlying strategic brand growth of 16%, 19% leading into H1.

Now, if you think about the dynamics, first of all, we came slow out of the gates with VYEPTI. This was the first biologic acquisition for Lundbeck. This was the first compound to be launched into a specialised patient model. But, as you've seen from Tom, we're incredibly happy on the current trajectory, on the potential, leading into 27, of around 5 billion, 9 billion into 33. Now, growing and improving your profitability at one and the same time is usually a tricky one.

Now, not only were we putting significant investments behind the AADAD indication launched last year, into the global rollout of VYEPTI, but we also significantly increased our R&D costs. We spent around 3.5 billion in 23. We brought this up to 3.94 billion around this year. And we are actually guiding towards, and I will come back to your question, James, later on, on the R&D corridor, to 20 to 25% going forward.

Now, at the same time, we improved our margin significantly. We issued new, ambitious, but more realistic mid-term financial targets in the beginning of 23, of 30 to 32% of adjusted EBITDA margin in the mid-term, latest by 26. And at the same time, we significantly increased our free cash flow generation, up now to 18% consistently, as of revenue.

That clearly allowed us to, first, deleverage relatively quickly from the older acquisition and also provide us with a significant organic debt capacity to fund the announced acquisition of Longboard.

Now, let's shift, shortly, the focus to on a mid-term guidance. We communicated, today, a continuous update of our guidance, mid-single-digit CAGR rolling into, or through to, 27 on the back of a high-single-digit CAGR for strategic brands. Now, what are

some of the underlying dynamics? REXULTI first of all. You've seen the base on our existing MDD and AADAD indication. We're seeing, actually, a mid-teen-digit CAGR into 27.

That does not account for PTSD. PTSD would be a significant upside. That's fair to say. And we could probably think about much significant impact on our mid-single-digit guidance, probably increasing it by roughly 50%. But keep in mind, it would also change, a little bit, the spending profile, because we would fund, significantly, the launch during the course of 25 before it then becomes significant from 26 onwards.

VYEPTI, you heard Tom say about expecting tripling sales, beating analogues year over year. And at the same time, think about the Abilify LAI franchise, where we see meaningful contribution from the two-month treatment, helping us with the generic erosion that we see predominantly coming in via the vials.

On Brintellix/Trintellix, we talked about strong growth, a growth story in Europe that has launched in 22, that we have pulled into the mid-term, that is driving, together with Japan, growth in our Brintellix/Trintellix franchise, while at the same time, we see some LOE pressure coming out of Canada and, of course, the US, which was one of the reasons why we divested that brand back to Takeda.

At the same time, again, disproportionately, I think, is what Tom called it, allocating our resources towards REXULTI and VYEPTI, that clearly gives us the confidence to raise our guidance, bring it into 27 to offset the aforementioned LOEs. But how does that look in the long term? So, let's shift, a little bit, our, let's say, mid-term focus into the long-term ambition of Lundbeck.

Where I'm standing now, and I'm comparing that to where we were standing, pretty much a year or one and a half years ago, we have seen significant progress. I think it was one and a half years ago where we saw the positive results from PACAP and sent the asset into a Phase 2b. We have just proceeded with the, let's say, initiation of the Phase 3 of amlenetug and think about the profile of Lundbeck in 2026, what Charl said.

Four Phase 3 assets. So, if we think a little bit about the long-term ambition, it looks, now, differently, as we would have projected it one and a half years ago, and the events just a week ago give us even more confidence to project an overall revenue ambition of more than 30 billion beyond 2030 by allowing us to have the right in-market assets in place, while also seeing, at the same time, our pipeline contributing, allowing us to offset significant LOEs around REXULTI, Brintellix, Abilify, and some erosion on our mature brands.

Now, we talked a lot about capital allocation. And if you think about successful companies, they usually take around 5 to 20% of their capital and keep it flexible, that I can reallocate it in different opportunities. And very often, we talk about capital allocation, but we talk about what do you do with your excess resources, what is your dividend policy, etc. That is super-important, but that's not where capital allocation starts. And I think, how do we look at it?

In principle, it sounds like a complicated concept. It's not complicated. You need to have clarity on your organic uses of capital. If you reflect a little bit on the story we heard from Tom, Michala, Maria, and Johan, you know we are going to spend our money. Continuous growth of VYEPTI, building on that acceleration. Exploiting the full potential of REXULTI. At the same time, funding the progress we have seen in R&D, getting to these four late-stage Phase 3 projects in 2026, while, at the same time bringing the pipeline of Lundbeck more into sustainable shape.

So, that's the clarity about where we're spending our money. But where's the money going to come from? I will give, in a minute, a bit more details on the capital allocation programme that we have, in principle, launched in the beginning of this year. But a big piece is that, first of all, we see additional potential in REXULTI and VYEPTI. That is reflected in our mid-term guidance, reflected in our long-term ambition and also gives us a certain amount of capital to be reinvested.

At the same time, you heard Michala talking about key strategic markets, overall markets, Michala's and Tom's organisation together comprising 81% of global sales. That means, we have to clearly assess our go-to-market model. You can't cut your way into growth, and purely focusing on profitability very often leads to the case that you reduce yourself to subcritical stage. So, we will be much more focused on funding strategies and not funding projects.

Operational effectiveness is capital allocation going beyond the go-to-market model. We have set up a transformation innovation office in the beginning of this year, and we have roughly 41/42 very concrete initiatives tracked against the 2023 actual baseline, translated into target structures and travelling through a stage-gate process, as they develop maturity and, basically, have commitment from project owners and everyone from day one.

Targeted divestments is another emphasis of where you use your capital. And I think the announcement we had a couple of months ago on the divestment of Trintellix in the US and giving that share back to Takeda is a case in point for capital allocation.

Now, if you're clear on the organic uses, if you're clear on the sources, there is, of course, certainly available options you look at in the form of excess resources.

A big part is the BD activity or the acquisition, assuming successful closure by the end of the year, that we just now announced, related to Longboard Pharmaceuticals. The balance sheet, we will always maintain investment grade. Dividend, we've been very steady in our 30% dividend payment over the last couple of years. And share buybacks is one of the instruments that we might be looking more into, going forward.

But let's talk a little bit about capital allocation. I think what we're putting forward here is the largest capital allocation in Lundbeck's history. So, what are we aiming for? We're aiming for, if we look at 2023, of a cost ratio of 72%, we're looking forward to improving that by 27 by 2 to 4%. If you now say, where's that coming from, what are the sources of capital, then I talked earlier about the acceleration of the strategic brands.

I talked about the impact of your commercial model adjustment, as well as the optimisation of your production model. The clear definition of brand profitability spend, targets in the relevant countries and cost efficiencies across the full operating model of Lundbeck. If you sum this up, we're talking about a programme, roughly, of around 1 to 1.3 billion of contribution in the year 27.

At the same time, we take about 500 million, if you look into 27, out of this amount, needed for the additional acceleration of the strategic brands, but at the same time, into specific investments we are doing into R&D that I referred to earlier, sustainable pipeline shape, late-stage development. Now, if we look at this programme in total, and we're saying, not only does it lead to free up capital, but it also leads to one-time costs.

From a one-time cost perspective, what we're saying, over the duration, between 24 to 27, we will incur, in principle, roughly, you can say, a billion of one-time costs. You heard Johan speaking earlier about the write-down that we have just taken on part of the MAGLi or Abide platform that we acquired in 2019. So, roughly 547 million, or, to be exact, 547 million, out of that 1 billion are attributed to that write-down, are being recognised in Q3 and have been communicated today.

So, overall, that would put us in a position to say, from a 23 baseline, from 28.4% of adjusted EBITDA margin, we feel comfortable rolling the existing corridor forward of targeting a 30 to 32% adjusted EBITDA margin. But there's also the impact of the foreseen Longboard acquisition. And if we think about the implications, then they are threefold. One is, of course, the additional spend for the Phase 3 programme, which, together with the pre-launch costs that you would incur prior to the

anticipated launch in Q4 28, would amount to roughly 700 million in the year 27.

And at the same time, you have approximately 600 million of integration costs, whereof the majority of that is going to impact this year. It's being adjusted for. It's not impacting our full-year guidance. Which would put us into the position of saying earlier mid-single-digit CAGR revenue growth and an above-30% adjusted EBITDA margin. Looking for that improvement in total cost ratio of around 2%, rather than the 2 to 4% we said earlier, because of the impact of Longboard.

Now, when you do capital allocation, of course, you need to have a pecking order for your excess resources. And we will always look at creating the most value-creating constellation in our organic business. That's where true capital allocation starts. That's where we talk about transparency, comparability and prioritisation. In a second instance, a resilient balance sheet. We still have firepower, following the acquisition of Longboard, but we will always maintain an investment-grade rating.

From a dividend perspective, the current dividend policy stays in place, targeting a dividend distribution of around 30 to 60% of net profit per year. And then, what do you do with the excess resources? The same fair competition principle on the back of transparency, comparability and prioritisation is then something, a muscle we train in the application of capital allocation in our operating business, to also look at how we give priority treatment to certain initiatives for additional access resources, which may be business development. Which may be strengthening the balance sheet, delivering quicker. Maybe an extraordinary dividend, or maybe share buybacks.

Now, let's bring all the factors together from a revenue guidance, from a capital allocation programme, rolling up into 27. We talked about the mid-term guidance, in terms of a mid-single-digit CAGR through 27 for total revenue. And we also specified high-single-digit CAGR for strategic brands through 27. What are some of the key drivers we talked about? VYEPTI accelerating or continuing to strongly grow, and basically tripling its revenue by 2027. And we also specified REXULTI with a mid-teen-digit CAGR until 27 before accounting for PTSD.

At the same time, we bridge between the 30 to 32%, becoming the more-than-30. There are some underlying drivers, the 20 to 25% of R&D spend, as we see a corridor, including Longboard, in the future, going forward. And at the same time we see the implications, we talked about the total cost ratio, but let's look specifically at the sales and distribution costs. And if you look at the sales and distribution costs, then they're roughly 37.6% in 23. And we aim for, here, more around 30 to 35% in 2027.

Now, let me summarise. The midterm guidance is a reflection of clarity on the strategic choices and contributors. The capital allocation programme that we're kicking off is the most significant and biggest Lundbeck has ever done. And if I can leave you here with one sentence, we're not cutting for margin, but we are placing our assets for yield, and that's a fundamental difference. bexicaserin, with the envisioned blockbuster sales potential that we announced, is a significant growth potential.

But in principle, if you look at our neuro-rare franchise, it's the fourth pearl in a string of existing pearls. So, overall, if we think back of where we're standing now, the confidence we have, then think back of the long-term ambition, where the in-market assets, the pipeline development, the recent acquisition of Longboard and the launch of bexicaserin are providing growth into a value-creating future.

With that, I would like to hand over to Charl for some closing remarks.

Charl van Zyl

Thank you, Joerg. Thank you so much. So, when we started out earlier today, I said, one of the important outcomes of today was to provide you more clarity around these three questions we have. These questions around our midterm growth, how we see the long-term pipeline, and how we fund that journey. I also said that we are humble, in a sense, that we have not got all the answers, but we have many more than we had 12 months ago.

And so, I'm really proud of what we have achieved over the last 12 months. And to leave you with two bits of information, again, this is a picture of the next few months and the next year and a half or so of milestones inside Lundbeck that you could expect to see. This is a picture of a company that's investing in its long-term future, investing in the growth in the mid-term. It is a company that's dynamic and really a strategy that is there to bring sustainable growth and long-term success for Lundbeck.

And when we look at our journey of these three important questions our strategy is addressing, then it's very clear, today, that we have provided clear guidance around how we see the mid-term, where we will invest, how we will invest in our key strategic brands, but also importantly, that we are really seeing a complete change in the profile of Lundbeck, a company, now with significant opportunities in the late-stage, first-in-class, best-in-class opportunities to build that long-term sustainable future for the company.

And a very clear focus of how we put our capital to work to bring the strategy to fruition. So, we are really, this moment where we stand today, in a very strong position. And Lundbeck is here, in a sense, playing to win for the long-term success of the company. So, thank you for your attention. I know we would like

to, now, go to some final parts of the Q&A, and this is why I would like to invite the entire Management team to the stage.

And we have, I would say, a good 20 minutes or so for questions and answers. And I think, also here, as the Management team come on stage, we would, of course, have microphones available for you to ask all the questions you might not have been able to answer earlier as well.

And before we go to questions, I do want to just, again, make sure we introduce, also, two of the members who were not speaking today, but certainly you have four questions, Lars Bang, who is our Head of Manufacturing and Supply Chain, and then Diane, who's our Head of HR, or our People and Culture Leader. So, thank you. So, I think we start with you, Martin, yes, since you have your hand up.

Martin

Thank you very much, and just three questions. Firstly, one to Johan, one of your favourite topics, attrition rates. Just if you look at the… And I will not ask about the difference between CNS and other therapeutic areas, but more on the potential four Phase 3 assets you hope to have in 26. If you should rank them of ability [?] from a risk profile, then how would you do that?

And then a second question, just because now you were so kind to share some roads between all the patent expiry of REXULTI in 29, that's also at the same time that you, hopefully, shall invest a lot of money in product launches in 28 and 29. Can you talk a little bit about how you will balance that, also from an EBIT margin point of view, to Joerg?

And then finally, just Joerg, one of the things that we see a lot is a lot of one-offs in Lundbeck. I can remember, there haven't been anyone one-offs for the last couple of years. So, how should we see one-off programs beyond the Longboard impact over this 2027 period? Are there any kind of restructuring programmes you are planning, so we should see a different EBITDA margin than the adjusted?

Charl van Zyl

So, let's start here with a very difficult question for Johan. How do you think about your different children in this situation and where you place prioritisation, if there is any?

Johan Luthman

Yes, thanks for that question. Obviously, we do have our internal assessments on probability of success, and you would love to get them from me, so you can plug them into your models, but I'm not sharing. But we wouldn't go to Phase 3 with anything unless we really thought it would work out. So, that's the strategy we're having. Can I guarantee that? No, that's not the game we're playing here.

Everything comes with risk adjustment. But you can look at the assets yourself. Here we have, hopefully, bexicaserin and a

portfolio. A validated target, substantially improved mechanism, but still a validated target. Yes, we can always not do it right, but it should, kind of, work, if I put it that way. Amlenetug is breakthrough, complete new innovation. It does come with more risk, of course. PACAP is somewhere in between.

AZH, we talked about now, it's a Phase 1 asset. Of course, we're impatient, but it's super-early. But I gave you a flavour that I really think we have something here that's cooking. So, that's the best I can give. No percentages for you.

Charl van Zyl

Thank you, Johan. To the question on investment in this period of LOE, I think, was your second question, with REXULTI, of course I can start, but anyone else would, please, add. Obviously, when we think about a product nearing its LOE, there is a period before that, that we are decreasing our investment because we start reallocating to the new launches.

So, there's a high component of reallocation, especially in that last year or so before the LOE, because the investment you make is not going to drive significant additional growth at that period of time. So, it will require reallocation and shifting from a strong push model to more of a specialised model that we see today with VYEPTI, for example. But, Tom, I don't know if you want to add?

Tom Gibbs

No, I think you talked about it. Traditional discipline, lifecycle flexing, means that, once you get to a point where you're not going to see the return on investment, you start pulling away resources to optimise profitability. I think the other point that I would make to your point, is, if you look at the trajectory revenue curve for rare disease products versus retail products, it's much steeper, and you get a faster payback.

Charl van Zyl

Thank you. Then the question, really, that I'm sure many people have, which is our capital reallocation, is it a one fix, or is it really a sustainable approach of how we think about the future? And I think this is the question that Martin has.

Joerg Hornstein

Well, before I come to that, I would, first, like to answer on the adjustment question. If you take a step back, and you say, why are we working with an adjusted EBITA, then it's very simple. If you don't adjust for one-time costs, or, for example, restructuring costs, companies shy away from embarking on them in the first place, because it is usually then, first, a question of, how am I going to handle these restructuring costs in the existing financial targets/incentive schemes of a company?

We operate differently, and measuring performance like that actually incentivises a company to put these projects forward. I think, when it comes to, we're not going to guide beyond 27, but what I can say is that we have a very good understanding on

how we measure value. And if you think about it from an economic profit perspective, then we can see, right now, that clearly, if we think of the profit we generate from a 1% improvement in margins versus 1% higher growth, then we're more in the growth camp.

That's where we can generate more value. So, we will never embark on an initiative where we, effectively, destroy value. And that is true, also beyond the programme going forward, even in cases that we would have to right-size organisations due to LOEs, which we have a lot of experience and discipline in from our history, while also being very selective, in terms of which launches to prioritise and where.

Charl van Zyl — Thank you, Joerg. We have a question in the back. Get the microphone there, please.

Unidentified Questioner — Thank you. [02:18:26 unclear ?] from UBS. Two questions, please, both on bexicaserin. The first one is for Johan, please. So, just wondering, for the second Phase 3 trial with LGS and other DEEs, have you, or Longboard, discussed with the FDA, with agreement how many patients are you going to enrol for how many subtypes? So, have you actually agreed with the trial design, say, if that trial is successful, it's going to be straightforward, you're going to have a broad label? So, that's the first question.

And the second one is probably for the broader team. So, just wondering, how should we think about the 1.5 billion peak sales you've guided for bexicaserin? So, just wondering, for example, if you only get a label for Dravet and LGS, what would that peak sale look like? Thank you very much.

Charl van Zyl — So, Johan, do you want to talk about Phase 3?

Johan Luthman — Yes. Just to remind you, we are not the same company yet. So, we have to be careful, and we have not been participating in any FDA conversation from our side, and that's obvious. So, we are very impressed by the Longboard team. They have done a great job, and I think, obviously, they have good conversations with the regulators. In terms of the studies they are embarking on now, we have not been part of designing them, but obviously, they have had pre-discussions with the regulators, FDA.

And they have submitted their protocols they are starting. So, I assume there is something that linked to what they hope to achieve with the breakthrough designation, which is the bigger pot here. To get a breakthrough, that requires also that you get a commonality of DEEs in one pot. I think, for practical reasons, you slice it up a little bit in the studies, and you want to power certain populations more strongly.

But that's all I can say. It's us looking down at, or into, the data,

basically, that we've been reading.

Charl van Zyl — Thank you, Johan. I will start with your second question. So, of course, when we build a forecast, we look at extensive market research. we look at the profile, we present this to customers, we look at switch rates, we look at prevalence, all of those aspects. So, we build a forecast based on, really, a market understanding of the dynamics in the market and what is a competitive environment. So, this 1.5 to 2 is based on, clearly, a broad label that we said LGS, Dravet, and DEE.

And so, today, we're not going to be in a position to guide, based on subsets of that. But certainly, the broad guidance that we have given and the ambition we set is based on a broad label, and we feel the asset can achieve that, based on the Phase 2 data we've seen. Thank you. Thanks for that question. Well, Michael first?

Michael Novod — Thanks. Michael Novod from Nordea. Just a question to Joerg around the gross margin. So, two things on the gross margin. How far progressed are you on switching manufacturing process on VYEPTI? How much is that potentially adding, and can you detail how the gross margin, just for modelling purposes, is going to evolve over the coming years?

Charl van Zyl — That could be a question for [02:21:44 overtalking ?].

Joerg Hornstein — The start should be with Johan. Why don't you start with the progression?

Johan Luthman — Yes, we have had the role of… There are two things here, the data we have, and the regulatory view on the data. And we have great data, and lots are coming from [02:22:05 unclear ?], quite frankly. We really need to show comparability, etc. And then, we also have clinical data that compares the assets, meaning the show sell at the peak manufacturer assets. And then we had regulatory interactions.

We've been through most of those interactions already at the global level. And we have not said where we are, but we feel quite confident to progress with the regulatory process now.

Joerg Hornstein — And I think, specifically on the gross margin, the first one I would say is, don't think of cost savings on VYEPTI purely coming out of CHO, because I think, if we look at, since the acquisition and to the launch, I think Lars and his team have pretty much halved, you can say, the cost per vial, even on the back of PACAP. Now, we don't specifically guide beyond, I would say, the current level of the adjusted gross margin, which we adjust as well.

Very simple, because there's a large amount of amortisation of product rights in there. So, if you take that out, you get a better understanding of the true operating performance of our margin.

I think the current level is the best level we can give for the time being. CHO gives you a significant step up, in terms of lower cost, but at the same time, as you have biologics from your own pipeline coming in, the first two/three years are usually a bit of a run-up period before it contributes exactly on the way, where you want to have it contribute.

So, there are also some offsetting factors in it, but I would say, for the time being, significant cost improvement, depending on the exact launch date in the relevant regions, but we don't further guide beyond current level.

Charl van Zyl — Thank you. Charles?

Charles Pitman-King — Charles Pitman-King from Barclays. Just for Joerg, on margins, thanks for the updated target for 27, but just thinking about the corridor that was previously there between now and 27, how should we think, maybe directionally, about margin between now and then? What year could theoretically represent the trough, as you fund these Phase 3 programmes?

And then, just secondly, a question for Lars. Given this exciting stage of Lundbeck, obviously, reliable logistics and supply are key, but with an ever-increasing range of assets to manufacture, how do you feel about Lundbeck's current capabilities and what might be needed, going forward? And would you consider further outsourcing?

Charl van Zyl — Thank you, Charles. So, maybe, let's go to the first question, if you feel you can provide.

Joerg Hornstein — I don't think we break it down. You will get a very compelling full-year guidance for 2025, this I can promise. But on the other hand, of course, capital reallocation also requires, especially on some of the structural initiatives, that they're probably more towards, I would say, meaningful contributing, not necessarily from 1st January in 25, but that is a bit more, as soon as it becomes, structurally, a full run rate would be at 26, but that's as far as I would go currently.

Charl van Zyl — And Lars, I think the question here is, on a portfolio that's changing, how do we think about manufacturing strategy?

Lars Bang — We think a lot. With regard to the small molecules, expansion will not happen, because the new products are low volume. On the biologic side, we have actually started a little bit. So, we can, for development purposes, or tox purposes, produce antibodies in-house. We can make cell development upstream, downstream, and produce, so Johan can run his tox studies.

And in the other end, we produce final packaging for VYEPTI. We do that in-house. Then you could say, okay, then there are two chunks in the middle, or at least two chunks, but two big

chunks, drug substance and drug product. And we pay sub-suppliers, CDMOs, a lot of money at high margins. But at this point in time, we don't have the volume to be competitive.

So, we are not going to build a drug substance factory over the next foreseeable future. What will come first, when it comes, will be biofill, and that is much cheaper than drug substance.

Charl van Zyl — Thank you, Lars. Manos? Can we have a microphone, if possible, here? Thank you.

Manos Mastorakis — Thank you. Manos Mastorakis from Deutsche Bank. So, I guess, to Johan first. So, bexicaserin, if you had it in your own pipeline from the preclinical stages, what would you have done differently? And I ask this question because you have extensively talked before, and PACAP is an example of that, of how careful you want to be, when it comes to figuring out the dosing, incorporating biomarkers and all that.

So, what would you have done differently, and how comfortable do you feel? What makes you comfortable, and maybe uncomfortable, when it comes to this asset? And then maybe I can squeeze in a second question, which is a little bit more commercial. So, Lundbeck used to talk about REXULTI ADAD being a slow burn. How would you describe that uptake right now?

And if you could give us a little bit of qualitative feedback on REXULTI from physicians, from patients, any data that speaks to, potentially, reduced rates of admission to clinics or care homes, as a result of improving the agitation component that Johan talked about earlier? Thank you.

Charl van Zyl — Johan?

Johan Luthman — Yes, a great question. We actually have worked on this molecule in our labs, and that's how we build confidence in it. This is a small molecule. We can make it. So, we actually have had our own studies on it. And so, it's living up to our standards, how we like to see a selective drug for [02:28:43 unclear ?].

Would we have started on a programme like this today? No, we wouldn't, because there's a time element here. They are much more advanced, and Arena, the predecessor, worked on this for quite some time. I know them since before. So, they have had a very long time. We wouldn't start a programme in our labs on this target today, of course, because it's too many years of cooking to get there.

But when we look at our different criteria, how to progress the molecule, and we do a solid due diligence, it would be a molecule that we would have progressed to, particularly now, since it's a validated target all the way to the market, but a refined molecule.

So, I wouldn't say it's much different, because if there would have been a completely new mechanism of action, we would have probably done bigger, a little different proof-of-concept studies. But here you have, already, that partially de-risked. So, I don't think we would have done it much differently.

Charl van Zyl — Thank you, Johan. Tom, slow burn of AADAD? I don't think that's how you see it.

Tom Gibbs — Well, as I said in the presentation, we're pleased with the progress we're making, because our results are in line with expectations, and we expect them to continue on that trajectory. As it relates to anecdotal feedback within the marketplace, if we're looking at the community-based setting, we have seen and heard examples of where patients were at their last potential opportunity before moving into a long-term care facility. And REXULTI has been able to keep those patients at home for a longer time.

If you look at it in the long-term care setting, and I'll give you my own personal example, instead of my mom being knocked out for 23 days from a benzodiazepine or a sleeping agent, on REXULTI, she was able to be alert. And we had more meaningful interactions and more moments, if you will, than we had, based upon other treatments.

Charl van Zyl — Thank you, Tom. I am looking at the time, and I know that we've been sitting for a long time. So, there's a time now to, first of all, say thank you to you for being here, and also to thank those who have been online. And we will say goodbye to the online participants. And we will now take a natural break outside in the lobby. And I think ten past three, is that good for us, to be able to reconvene before we go to the R&D tour?

So, again, on behalf of the Management team, I want to thank you for your participation today. Thanks so much.