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Full Year 2023 Financial Statement

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Transcript

Speakers:

Charl van Zyl

Tom Gibbs

Jacob Tolstrup

Johan Luthman

Joerg Hornstein

Operator

Ladies and Gentleman, thank you for standing by. Welcome and thank you for joining the financial statements for the full year 2023 of Lundbeck. Throughout today's recorded presentation, all participants will be in listen only mode. The presentation will be followed by a question and answer session.

If you would like to ask a question, you may press star, followed by one, on your touchtone telephone. Please press the star key, followed by zero, for operator assistance. I would now like to turn the conference over to Charl van Zyl, President and CEO. Please go ahead.

Charl van Zyl

Thank you. And it's my pleasure, of course, to welcome you to the annual results call for 2023, as well as our full year guidance. It is, for me, a pleasure to be able to present to you the great results and momentum that we see in the company, so I want to thank you for joining today. If we can go to the next slide, please. As part of our forward looking statements, what we discuss today is subject to change. Let's go to the next slide, please.

I, of course, have the pleasure of also being joined by the team today here. Our two heads of geographies, Tom Gibbs and Jacob Tolstrup. We will also hear from Johan Luthman on our progress on the pipeline, and Joerg will talk to us more specifically about the results, but also, the outlook for 2024. If we go to the next slide, please.

I just want to pause for a moment, in a sense, and let you know that the work that we're doing at Lundbeck is very much to solve and improve the life of patients, like Ronetta Stokes. And it's very much also our focus, as a company, to be in this position where we can solve complex challenges for patients.

And so, today's goal, in a sense, on this call is very much to talk to you about our results, but also, the strategic direction that we are setting for the company, to ensure that we are able to serve more patients, and of course, solve those complex challenges in the space of neuroscience. So, if we now go to the next slide, please, to really position for you a little bit where we are, as a company, and where we are going.

Of course, this is consistent with some of the discussions we've had a few in the past, but it's really clear that we are pivoting our strategy towards a very focused innovator going forward. Meaning that, in a sense, we are very clear on addressing areas of very high unmet need in neuroscience, being very clear on where we play, as a company, and also, being very clear on how we think about investing for the best return of our investments to, also, the shareholders.

From a long term perspective, clearly, as we look at this, we are, essentially, as a company, addressing a strategic challenge,

which is really looking at long term sustainable growth for the company. And this is also how we are positioning our direction, and the efforts we are putting in place to bring that long term sustainable focus for the company going forward. So, if we now go to the next slide.

And this is really where I'd like to address with you the great performance and strong results that we've seen in 2023 across all the areas of our company. And the important highlight I want to just bring out here is record revenue of 20 billion. We see a very strong growth of our strategic assets. Today, they make up 69% to 70%, and we see them grow at 16% on a constant basis.

We are also really pleased to see the performance of Vypeti. That is growing very well on a constant basis, and we are seeing all the strong signals in the US that this is going to be an important growth driver for us going forward. In 2023, we also launched the additional indication for Rexulti in AADAD, and we see very promising and strong results also there on the launch that will give us confidence to continue to invest further in this asset.

You will also see that our adjusted EBITDA is at 7% on a constant basis. This is a reflection also that we are investing for growth, and also investing in R&D as a long term success is very much dependent on us doing that very well, and ensuring that we can drive the innovation for the long term of the company. You'll also see strong results and contribution from Brintellix and Abilify.

These are strong assets that contribute very well to our cash flow position, and continue to grow really well in the state of where we see them today. So, with these results, in a sense, we get a foundation of strong momentum, strong growth, and you will also see that confidence translating into 2024, where we want to continue to invest, very selectively, in the growth of key assets, key geographies, and of course, invest further in R&D, as well. So, if we could it go to the next slide, please.

Again, I want to just bring it back to some of our conversations we've had with you in the past around where we are going and how we see ourselves going forward. So, in the fourth quarter of last year, we did a strategic review, which was an important exercise for us to, essentially, look at a few questions. The first was, can we grow more with what we have?

And we feel very confident, at this moment, that the investment we are making behind Rexulti and Vyepti are important investments for the long term growth of these two assets. Furthermore, we have looked through a number of initiatives across the company, to ensure that we can create the financial flexibility and capital reallocation potential to invest more in a

very strong and emerging pipeline that we see coming forward, as well.

And so, as a principal and a mindset inside the company, we're very much focused on return on investment, preserving our midterm guidance that we have said to you in the past, which is 32% by 2026 of adjusted EBITDA. And we feel confident, at this point, with the direction that we are setting that we can achieve this. And furthermore, as a focus innovator, of course, we have a strong pipeline, as things are emerging, and Johan will talk more about that.

But we are also fuelling that thinking of further innovation with inorganic, and very focused areas around business development, to further strengthen that pipeline going forward. So, with that, I would like to, therefore, hand over to Tom and Jacob to take us through the geographic performance. Thank you, Tom.

Tom Gibbs

Great. Thank you, Charl. Next slide, please. We are very pleased with the performance of Vypeti in 2023, and this has been fuelled by accelerating growth in the US, and supported by the continued global rollout of launches ex-US. Vyepti global net revenue for fiscal year 2023 was DKK 1.697 billion, and this represents 74% growth over prior year. Net revenue for Vyepti in the US was DKK 1.578 billion, and this represents 66% growth over 2022.

Importantly, in 2023, we began to see meaningful contribution to global sales by markets ex-US, with Vyepti now available in 23 additional countries. Over the course of 2023, we saw Vyepti demand accelerate 92%, when comparing weekly vial demand in January versus December. And this was driven primarily by new patient starts. Additionally, Vyepti market share reached 8% of the US anti-CGRP preventative market for the first time in December. This performance was driven by two key factors.

First, an effective customer facing model and marketing mix, which we will continue to invest in to further accelerate growth in the US. And second, the rollout of new data from the PROMISE 2 study, which demonstrates 40% of patients taking 300 mg were migraine free over a month. And this is very compelling data in the marketplace. Next slide, please.

Rexulti also delivered a strong performance in 2023, growing 20% over prior year, and delivering DKK 4.525 billion in global net revenue. Absolute revenue growth was primarily driven by the US, which delivered 90% growth over the prior year, and net revenue of DKK 4.206 billion. Notably, revenue ex-US grew an impressive 35% versus 2022.

The launch of AADAD continues to progress as planned. We are

now using claims data to track the progress of the launch, as we believe these data are the most accurate reflection of indication level data. As of November 2023, Rexulti AADAD prescriptions have increased 161.3% from the pre-launch trend. Importantly, we are seeing very good uptake within the long term care channel, with claims data showing a 333% increase since the launch in May.

The AADAD launch is driving growth for the overall Rexulti brand, with monthly demand growth of 18.8% from pre-launch AADAD levels, and this data is through December 2023. This compares to approximately 5% to 6% volume growth over the previous eight months prior to the AADAD launch. I will now turn the presentation over to Jacob, to discuss performance for our other strategic products.

Jacob Tolstrup

Thank you very much, Tom. Let's go to the next slide, please. So, on Trintellix, we're very pleased to see overall growth of the brand. As expected, the US has been declining. It's a decision that we made, together with our partner, some time back about optimising the profit from Trintellix in the US. That said, we are seeing growth in the fourth quarter of 2023 of 2% in new patient starts.

Going forward, however, you should expect that the growth that we expect to see overall for Twintellix and Brintellix around the world will be driven by markets outside of the US. Looking at Europe international markets, we see very strong growth of 14%. We are very pleased to see that performance, especially in the light of a product being on the market for ten years or more in certain markets and geographies.

That is driven by several factors, one being a good product. Of course, we found a great positioning over time, and we have a product that delivers on its promises. It's also important to say that the speciality high growth that we see in Europe is driven by market where we see opportunities to expand ourselves for reaching high prescribing GPs, which has paid off quite significantly for the brand over the past two to three years.

Also, Lundbeck is a recognised market leader in psychiatry, especially in MDD. We have a long heritage, and we're building upon our heritage there in our connections with the thought leaders in the field. Going forward, we expect continued market share gains for Brintellix, despite a market that is crowded with many different treatment options.

And I would have to say also that the launch of Japan is exceeding our expectations. We now have 10% volume growth. We expect the growth to continue in a market where we still have about seven years before we reach ROE. Next slide please.

The Abilify LAI franchisee is doing exceptionally well for us, and continues to do so. US growth of 16% and ex-US growth of 7%, despite some price cuts that we've seen in recent years. Going back in time, looking over the past few years, the franchise for Maintena has outgrown the other franchises in the LAI field. And we expect that to continue, also with the launches of the two month version.

In the US we launched Asimptufii in June, and we're very pleased to see a 30% volume growth of NPRDs in the US for the combined franchise of the one month in the two months in the US since then. In Europe, we are very pleased with the recommendation for approval for the two month version. We expect an approval, and hopefully, we can start the rollout in Europe in the spring of the two month version, which will be called Abilify Maintena, 960 mg or 720 mg.

Then finally, we also have Abilify Maintena available in 34 markets today. I'm very pleased to see that we have 20 markets with above 25% market shares, ten markets with above 30%, and finally, UK and Italy with 40% market share. With that, I will turn it over to Johan. Thank you.

Johan Luthman

Thank you very much, Jacob. Let's turn the page for further information on R&D. 2023 was a very productive year, with many events in our pipeline, cross brand, lifecycle management, and with critical progression in our innovative pipeline. During the first half of the year, we had two FDA approvals, both together with our partner, Otsuka.

First, in May, we had the important indication expansion for Brexpiprazole with the FDA approval for the treatment of agitation associated with dementia, due to Alzheimer's disease. This was the first full approval in 20 years by the FDA for any Alzheimer disease therapy, and the first approval ever for a treatment for behavioural and psychological symptoms in dementia, of which agitation and aggression constitute a major medical problem.

What we keep hearing, in our interactions with various leading clinicians in the US, is that this approval is really welcomed, reinforcing how critical it is to have an approved therapy for agitation symptoms of this disease. We have dedicated medical affairs efforts to increase the awareness of this breakthrough therapeutic option at key Alzheimer's conferences, such as AAC.

While we are happy to see a full publication of the most recent pivotal trial of the programme that came out in JAMA Neurology last year. During the last year, we also progressed with submissions for approval of Brexpiprazole for the indication in Canada, Singapore, Australia, and Switzerland. We were therefore pleased to see the approval by Health Canada two

weeks ago, an approval that was well received, and even recognised by public media.

We also had an additional FDA approval during the spring last year for Aripiprazole two months ready to use long acting injectable, suspension for intramuscular administration, that Jacob talked. This product, Asimptufii, is an important addition to the Abilify Maintena brand in our long acting therapeutic offerings to patients.

The EMA review of the Aripiprazole two months has also been concluded, as we announced two weeks ago, with a positive CHMP opinion. So, we are looking forward to the EC, the European Commission, decision on the product in the coming months. We also obtained headline readouts in at least eight major clinical trials last year.

In September, Lundbeck and Otsuka announced the results from the phase III clinical trials of Brexpiprazole, studying the potential of the drug in the treatment of posttraumatic stress disorder, PTSD. Data from these trials, together with the previous phase II trial, constitutes one of the largest clinical development programmes ever conducted in PTSD.

Importantly, PTSD is a very serious mental disorder, with a wide range of symptoms with no therapeutic options seen in more than 20 years. It's therefore important that we have continued interactions with the FDA to decide our next steps. Last year, we also opened up the books on a trial in the Eptinezumab cluster headache programme, and in particular, obtained data from the randomised double blind eliminate ALLEVIATE trial in episodic cluster headache.

There were not entirely what we aimed for in the design of the trial, but still clearly supported. We have subsequently been reviewing the data with leading clinical experts, who have been receiving the data very positively. In April, we announced an encouraging positive readout from our first in class anti-PACAP monoclonal antibody 222 in the so called HOPE trial.

This trial outcome constitutes a breakthrough for a new mechanism of action in the prevention of migraine. It's not often, in R&D, that you get the chance to be part of a clinical proof of concept, so for Lundbeck, this was, then, to cherish. But this is, indeed, also the first clinical new mechanism that works since the testing CDRP in 2004.

The HOPE trial data were presented at the International Headache Conference in Seoul in September, and the results were extremely well received by leading KOLs. We have subsequently embarked on the full development programme for PACAP, which has, as the next step this year, the initiation of a

phase IIb trial for full dose evaluation, after subcutaneous administration of the antibody.

We also had overall solid progression in our innovation pipeline with an additional first in human programme start, and as many as five new highly innovative research programmes initiated. I would, however, like to draw your attention to an event we announced last week, our AMULET trial. A phase II trial with our anti-alfa-synuclein antibody 422, where we obtained encouraging data. So, with this, I would like to go to the next slide.

So, 422 was evaluated [?] in an exploratory proof of concept trial in a very devastating, rapidly progressing chronic disorder, Multiple System Atrophy, MSA for short. MSA is a fatal neurodegenerative disease with no treatment options. It is characterised by pathological aggregation of alpha synuclein, a neuronal protein that is normally believed to regulate synaptic vesicle trafficking, and thereby neurotransmitter release.

However, alpha synuclein can also be pathogenic, causing so called alpha synucleinopathies, a neurodegenerative disease characterised by an abnormal accumulation of alfa-synuclein protein in nerve and glia cells. There are three main synucleinopathies, Parkinson's disease, dementia with Lewy bodies, and MSA, and MSA is the purest form of them, and the most aggressive of these diseases.

MSA is a rare disorder, characterised by autonomic dysfunctions, with symptoms, such as tremors, slow movement, muscular rigidity, and postural instability. There are generally two types of MSA at diagnosis, cerebellar form, which predominantly shows a balance and coordination loss, and that's the most common form, and there is also Parkinsonism, or MSAP type, which shows primarily with muscular stiffness, slowness, and tremor.

We have brought our D1 [?] antibody 422 through a very early set of phase I studies. The antibody came originally from a research collaboration with Genmab. These studies included Parkinson patients for target engagement verification, and some other dose-finding [?] of studies.

And thereafter, we embarked on the so called AMULET trial to test the antibody’s effect in MSA. AMULET is a small trial that was tailored for maximum signal detection in 61 patients recruited from the US and Japan. The trial had two arms, placebo and active treatment, given every month, an IV, for between 42 to 72 weeks.

And when all subjects reached at least 48 weeks, we took a look at the data. The trial is still ongoing as an open label study. The

primary analysis of the clinical outcome measure UMSARS was based on a baseline progression model. That's an approach, aiming to study critical longitudinal changes during the disease course. Various parts of the UMSARS scale were used, but the prime analysis was done on the total score. Next slide, please.

The AMULET trial was initiated at the end of 21. We enrolled well throughout the trial, due to high interest from investigators and patients, and we could obtain the results a little more than two years later. The AMULET trial has shown signals of efficacy across UMSARS clinical measures, and also, on some secondary clinical outcome measures, as well as on some biomarker endpoints.

The primary endpoint, UMSARS total score, showed slowing of the rate of disease progression, although not reaching statistical significance. We should, however, note that there is very little prior information to sample size the trial in MSA in contrast indications, such as Alzheimer's disease. And that we have pioneered the baseline progression statistical model to identify effects on longitudinal change.

The secondary endpoints included assessment of function, global impression, autonomic symptoms, and global disability. Biomarker endpoints included volumetric MRI assessments, some biofluid markers, such as alpha synuclein for target engagement, and NFL in blood and CSF. What is very important to note is that 42 was generally very well tolerated.

I'm not going to dwell more on the outcome of this trial, since we have secured a late breaking presentation at the upcoming ADPD 2024 conference on March 8th, where we will reveal more details. What we will also now do is to seek opportunities to speak to key regulatory agencies, and in parallel, plan the next programme steps that will include the initiation of a phase III programme, once we have fully analysed data for proper trial design and obtained sufficient input from agencies. Next slide please.

So, we have had several important events during last year, and also started 2024 with several interesting events, marked here with green tick marks, such as the AADAD approval in Canada, progressional Aripiprazole two months in Europe, and now also the PoC readout for disease modification. However, this coming period will continue to be quite news rich.

Naturally, we look forward to the European Commission’s decision Aripiprazole two months shortly. We also have expectations to be able to finish the Vyepti SUNRISE trial, a trial that is aimed to pave the way for further expansion in Asia, namely, Japan and China. It's also important to progress into clinical full development studies with 22, our PACAP asset, so

the proper dose is identified for pivotal programme.

This will, hopefully, provide a very new, interesting expansion of treatment opportunities in migraine prevention. Finally, I'd like to highlight that we have recently initiated some additional exploratory proof of concept trials for other programmes, such as our anti-CD40 ligand programme, 515, and our anti-ACTH programme 909.

And we're expecting to get additional PoC trials started during 2024, such as for 909 in an additional indication, Cushing's disease, and also, start phase II for our innovative dopamine agonist programme for motor symptom treatment in Parkinson's disease. With this, I would like to hand over to Joerg Hornstein, our CFO.

Joerg Hornstein

Thank you, Johan. Now let's look at our financial performance for the year, and the outlook for 2024, which, as Johan indicated, is an important year for our pipeline. Next slide please. Our full year revenue grew plus 8% at constant exchange rate, driven by our strategic brands, which were up plus 16% for the year.

The adjusted gross margin, which is removing amortisation, depreciation, and other adjustments linked to sales, travelled roughly in line with the revenue for the year, which means the margin for the year is almost unchanged. One should always be careful when focusing too much on quarterly fluctuations in cost ratios. But a note about the fourth quarter is necessary here.

The quarters impacted by higher contract work, quarterly fluctuations in scrap [?] costs, mainly related to mature product and environmental provision. Moreover, the fourth quarter of 22 was negatively impacted by the Vyepti provision for obsolescence of 228 million that we adjusted back then, but that did not reoccur in Q4 2023.

For the full year, the adjustments on gross margin included 312 million provision for Vyepti inventory obsolescence, and 15 million restructuring costs for the closure of the sterile manufacturing line in France, in comparison to the 228 million for Vyepti inventory obsolescence recognised in the fourth quarter of 2022.

Sales and distribution costs grew 18% at constant exchange rates. This is driven by sales and promotion activities for Rexulti in the US, due to the launch of Rexulti AADAD in June 2023, as well as activities for Vyepti in the US and its continuing global rollout. Sales and distribution costs are impacted in Q4 by restructuring provision regarding our commercial footprint that we have also adjusted for.

The increase in administrative expenses in 2023 is attributed to digital investments, the CEO transition, and higher legal costs

and provisions for ongoing litigation. R&D costs decreased by 7% at constant exchange rates, in line with our previous communication. Adjusted EBITDA grew by plus 7% at constant exchange rates, reflecting the increased revenue and additional investment for sales and promotion activities, benefited by the lower R&D costs in 2023.

The reported growth of 17% can be decomposed as follows. A positive organic growth of 7%, negative FX impact of 4%, the positive hedging impact of 15%. The adjusted EBITDA margin improved by two percentage point to 28.4% in 2023. Next slide, please.

Our EBIT grew by plus 12% at reported rates, despite increased SG&A costs and the higher adjustments of approximately 200 million, in comparison to 22, improving our margin by 0.4 percentage points. Net financial expenses decreased for the year by 47% to 202 million. The decrease is mainly driven by the non-reoccurring CBR paid in Q1 2022, and the favourable development in interest income to lower debt levels and higher interest income on cash in the year.

The effective tax rate of 23.5% is in line with the full year expectations, reflecting the reduced deduction of the Danish R&D incentive. Net profit increased by plus 20% to 2.3 billion, and adjusted net profit and EPS increased by plus 13% to DKK 4.2 billion and DKK 4.22 billion respectively. Next slide please.

The cash flows from operating activities in 2023 represented an inflow of 4.1 billion, compared to an inflow of 3.5 billion last year, clearly showcasing the strong cash generated ability of our company. The operating cash flow is obviously a reflection of the strong EBIT performance, further benefited by adjustments for non-cash items of 2.4 billion, mainly driven by higher amortisation, the higher provision for Vyepti inventory obsolescence, and other provisions.

This was negatively impacted by changes in working capital, driven by lower milestones payables in 2023. The cash flows from investing activities with an outflow of 498 million, driven by Capex investment and the payment of a sales milestone in 2023, in comparison to an outflow of 1.8 billion in 22, which included the 1.1 billion payment of the CDR.

The cash flow from financing activities with an outflow of two billion in 23, compared to an outflow of 0.4 billion last year, primarily driven by higher repayment of loans, and the now fully repaid revolving credit facility, under which 1.2 billion was drawn last year, as well as the higher dividend payment in 2023, connected to the improved net results in 22. The year closed with a net cash position of 0.7, compared to a net debt position of 2.2 in 2022, effectively deleveraging the company, and bringing us

into a very strong financial position for the future. Next slide, please.

To focus on the underlying operational performance, we are, from now on, introducing a constant exchange rate guidance, excluding effects from exchange rates development and hedging. In 2024, revenue is expected to grow at a range of 7% to 10% at constant exchange rates, reflecting continued and sustainable growth, driven mainly by the demand of our strategic brands.

Key growth drivers are the continued strong growth of Vyepti, especially in the US, the growth of Rexulti, following the launch of the AADAD indication in the US, the increased sales of Brintellix in Europe and international markets, and the contribution of the Abilify LAI franchise in the US. The mature brands, and especially Cipralex, Lexapro, Deanxit in China, and Sabril are expected to face increased generic erosion.

For your reference, considering the current exchange rates, the revenue growth rate in reported is expected to be around four percentage points lower than at CER. Please allow me to address the reported rates in a bit more detail. The difference between constant exchange rates and reported are the impacts of hedging and the foreign exchange development.

We had a positive 137 million hedging effect in 23, and we are forecasting a negative minus 50 million to minus 75 million. At the same time, our guidance predominantly sits on the closing rates for 2023, having seen quite some volatility, especially in our main currencies, in the past few weeks. That is, of course, a development that we will frequently update, as part of our quarterly reporting.

Adjusted EBITDA is expected to grow 10% to 16% at constant exchange rates in 24, reflecting the necessary investments that are driving the significant revenue growth, and that will support our capabilities in innovation going forward. These investments are reflected in higher R&D costs for 24 at a range of 3.9 million to 4.1 billion, driven by the progression of early stage to mid-stage for several of our projects, as well as higher sales and distribution costs, due to increased Vyepti and Rexulti promotional activities.

Also, here, considering the current exchange rates, the adjusted EBITDA growth reported rate is expected to be around nine percentage points lower than at constant exchange rate. We are also showing other relevant financial information for you to consider, when assessing the company's expected financial performance in 2024, and as alluded to earlier, this will be frequently updated.

The midterm financial target is aiming for mid-single digit revenue growth and adjusted EBITDA margin of 30% to 32% by 2026 remained in place, excluding, of course, any potential material future business development activities. With that, I will hand over to Charl.

Charl van Zyl

Thank you, Joerg, and it's my pleasure to make a few concluding remarks. First of all to say, based on what you've heard here, we have clearly delivered on our 23 priorities, and with these great results, we really feel very confident around how are we entering into 2024. And I want to congratulate the leadership team on these great results.

What I would like to do is just go to the next slide, and give you, again, a sense of what we have discussed with you in the past, the direction of how we see the company evolve, and of course, 2024 is an important first year of that journey for us. It is a journey where we will very much focus on where we play, focus very clearly on where we invest, with clear growth expectations on our strategic brands, predominantly, Rexulti and Vyepti, and focus a lot of that investment in the US.

We will, during this phase, also be very disciplined around our capital allocation and reallocation potential, towards more investment, where we can, and innovation, where it makes sense for us, while preserving our midterm guidance that we have given to you in the past. Of course, as you would have seen from the results that Jeorg presented, we are in a strong cash position, as well, cash flow wise, but also, from a firepower perspective.

And we'll use this in a very targeted way to look at other opportunities externally, to foster, and also potentiate, our internal pipeline going forward. As we enter into the mid-stage where we see, potential, clearly, from a migraine franchisor that is emerging, with anti-PACAP, as well as strong momentum that we see in Vyepti, we see potential to scale more in migraine, in severe chronic migraine.

Also pipeline readouts that could emerge on the neuro rare space, that will give us additional opportunities for vectors of growth for the company. We also see, in the mid-stage, certainly, areas for further partnership, as we are familiar with partnerships, of course, in the company, we also see them as a position of strength to further reach more patients in different geographies.

And as we go towards the end of this ten year cycle, we are also clearly seeing more of the organic pipeline that you see today coming to the markets with some breakthrough potential. And of course, also a very strong and well-funded neuroscience research platform that will drive long term success and

innovation for the company.

So, that's really what we wanted to conclude with you today, and I would really like to now go to Q&A. I will hand it back to the operator. Thank you.

Operator

Ladies and gentleman, at this time, we will begin the question and answer session. Anyone who wishes to ask a question may press star, followed by one, on their touchstone telephone. If you wish to remove yourself from the question queue, you may press star, followed by two.

If you're using speaker equipment today, please lift the handset, before making your selections. Anyone who has a question may press star, followed by one, at this time. The first question comes from the line of Marc Goodman with Bloomberg. Please go ahead.

Madhu

Hi, good morning. This is Madhu on the line for Marc. Two questions for you. Could you first talk about how you're thinking about the growth trajectory for Rexulti in 202, given the feedback you've heard from the field so far, and the activities in upcoming medical conferences to increase awareness?

And then could you also talk a little bit more about the design of the study for the PACAP molecule in migraine, in terms of how many dose arms there will be, and if the doses being tested are the same as the prior HOPE study? Thank you.

Charl van Zyl

Tom will answer the first question on Rexulti.

Tom Gibbs

Thank you for the question. As I've previously stated, our experience to date continues to confirm our belief that the AADAD represents a large market opportunity with significant unmet need. And as we talked about previously, it is a nascent market that needs to be developed.

And the partnership of Lundbeck and Otsuka are committed to making sure that we make the appropriate investments to continue to raise awareness about the disease burden, the prevalence, and the diagnosis and treatments of AADAD, not just for our business, but also, for the patients that we serve. As we look forward, we are expecting to continue to see the growth trajectory that we've seen over the back half of the year.

As I've stated earlier, we're seeing a very good uptake, when we look at our claims data, of 161.3% growth, when we look at our overall claims data. And we continue to see very rapid uptake in the long term care setting, which is really important, 333% growth, as this, we see, as the leading indicator of how the broader business is going to go.

And I think, importantly, we are looking at the AADAD launch to continue to drive the overall brand, as we've talked about. And

we're seeing that to date. If we look at the overall brand metrics, we see record highs in December for NRXs, TRXs, and TRX share, and that's the expectation we have moving forward into 2024.

Johan Luthman — This is Johan, I will take the question about the design of the PACAP trial. Just to remind you a little bit about the HOPE trial. It was a trial, where we studied two doses, a high and a low dose, and then, of course, placebo. And it was an IV study. So, it's very important for us now to establish that we can basically get the drug working well after subcu.

There is no reason to believe it wouldn't, but you have to establish this, because obviously, there could be differences in growth administration [?] and placebo responses, etc. You may recall the data we talked about, particularly at the International Headache Conference in Seoul. We had very similar effects with the two doses, the high and the very low dose that we used, which was a pleasant surprise, to be honest.

Meaning that we hammered the target with a high dose, really, to show solid proof of concept. But we also had a sniff on a dose that is maybe more doable, from a cost of goods, etc., point of view. And it worked. As it looked, it was smaller, half the size, but it looked like it worked equally well, to be honest. So, now we're going down in doses. We are exploring further down, and seeing how far down we can go.

We have not posted a trial yet. We will reveal that, when the trial is getting up and started. But we'll have a little wider dose range, and we will definitely go down and explore where we start to lose the effect. So, that's the most critical element of this. I often preach this, it's very important to find the right dose and the right dose range for drugs, when you move forward.

So, that's why we're not rushing into a big phase III trial. We could do that, but we need to have the subcu, and we need to find the solid understanding about dose sensitivities. Just very quickly, the readouts will be very similar. This is going to be a monthly migraine dose [?], etc. So, in terms of what we're looking for, as primary and secondary, it will be no surprises, quite traditional.

But also, if I may add, very critical in moving forward in this programme is also to look for differentiation, and that will build into the further programmes, not so much in this next study.

Madhu — Thank you.

Operator — The next question comes from the line of Michael Novod with Nordea. Please go ahead.

Michael Novod — Thank you very much. Just a question around cost allocation

going forward. We've seen you close down at least one subsidiary, so cost allocations between IO and the US, also in terms of driving further growth for Rexulti, as well as Vyepti. And then secondly, maybe I missed it, but have you seen anything regarding filings for Abilify Maintena, i.e., any generic filings that we are not aware of?

And then lastly, could you please just confirm if you use an FX rate, you said until the end of 2023. Is it fair to assume that the FX rate going into your report guidance is around 6.75 instead of the current spot rates? Thank you very much.

Johan Luthman

Maybe I'll take question number one and number three. Starting with question number one, I think we don't provide any guidance, in terms of, let's say, regional cost splits of our business. I think what it's fair to say is that, of course, with specifically the trajectory of Vyepti in the US, and the further build out of Rexulti in the US, following the AADAD approval in June last year, the growth rate in the US is getting more and more important for us, in comparison to the other regions, which strongly deliver in 24, as well.

Your answer on question number three, which was on the guidance. I think it's fair to say that, as I said earlier, we provide, in the investor deck on slide 58, let's say, the spot rate at the end of the year, and also, the, let's say, current trending levels. Don't only concentrate on the dollar, because if we look overall, and you can see that in our results, as well, by looking at CER and reported, many currencies, other than the dollar, also impact our results quite significantly.

And if we look at FX rates that we used for, let's say, the guidance in 23, versus the guidance in 24, then you can say that pretty much six out of our eight main currencies are down by approximately more than 8%. So, I don't speculate on currency, that's why we change to a constant exchange rate guidance. We will update reported guidance frequently. And we leave this up to you to decide to what extent this is an upside or downside.

Jacob Tolstrup

And Michael, I will try to answer a little bit on your question on a bill of payments in the generics. So, first and foremost, I think it's important to say, because we communicated that in the past, that we do not expect generics in the US anytime soon. If we look at a region, like Europe, you do have generic versions on some of the other LAIs.

Not in all markets, in some selected markets, where they do have an impact. So, that's, of course, something that we also think about in our planning going into future years. So, when I say that we do not have signs of generics on Abilify or Maintena, you cannot say that that's the absolute truth, because at this time point, we cannot know. But we do not see am indication at this

time point, but that doesn't mean that they're not on the way.

Michael Novod — Thank you very much.

Operator — The next question comes from the line of Charles Pitman with Barclays. Please go ahead.

Charles Pitman — H. I'm Charles from Barclays. Thank you very much for taking my questions. Just firstly, on M&A, obviously, there's been a lot of pickup [?] in the news lately, and you are targeting further buildup in cash. I think you've previously mentioned your business development plan of a string of pearls target.

I was wondering if, given, Charl, you've been in the role a little bit longer still now, and we're looking forward now to your short, mid, and long term targets, as well as this total BD firepower number you've given us, I wonder if you could give us any insight on the cadence at which you intend to apportion this.

And maybe if you could give us a bit more detail on where you think that you need to focus, in terms of therapeutic areas. And then if you could just reconfirm how we should think about this firepower, as far as a cash debt, potentially as equity split goes. And then maybe just secondly, if you could give us a bit more detail around the gross margin.

So, if you could give us an idea of what the one-off gross margin impacts have been in 4Q 23, and why you anticipate, and have such strong confidence, in the improvement of FY 24, despite the continued generic erosion of your mature brands? That would be very helpful. Thanks.

Charl van Zyl — Charles, I'll start with your question on M&A strategy, and would be happy to build further on what we also discussed at the JP Morgan event, which is really where we see today, our current growth and the investment we are making behind our existing assets, we feel we have a growth position that can carry us through the midterm LOEs, and really focus our M&A effort more to solve the long term, which is the post 2029 window.

So, when we look at M&A, we look at it in three buckets, building. In a sense, on existing strength, or on where we see the pipeline emerging in the future. And so, those three areas are really continuing to look at opportunities in the neuro psychiatry space, so it builds off our current commercial footprint and potential.

Secondly, we are looking in spaces, where we look more at neuro speciality, where we are today with Vyepti, of course, and building around that with the business model and field force that we have there, could we add additional opportunities into that organisation? And then the third one is in the neuro rare space, as you will see sometimes in our pipeline.

Of course, there is a number of assets that might emerge from

there, and we know that also, in the neuro rare space, there is a high unmet need. So, we will continue to look there, as well. We, on average, monitor about 30 different opportunities, depending on datapoints and where they are, and what might be feasible for a transaction.

So, I would say 2024 is not a must for us. We are not driven by entirely needing to do M&A, but we will look at it, as you stated, in a series of deals over the next three or four years will be important. That would be in the in the window of potential to launch by 2028, and contribute, then, revenue at the timeframe when we face the LOE of Rexulti.

So, that's how we see it. Of course, the cashflow position of the company is strong, but also, firepower, we feel, is reasonable to execute on these types of deals we're looking for. And so, from that perspective, we will drive that strategy forward, but not necessarily that it's fully committed to, and must be done, in 2024. I could maybe handle the next question to Joerg.

Joerg Hornstein

Let me take care of two questions. The first one was, I think, the guidance we give, regarding our year end cash position is basically, at the end of the day, the net cash of for to 4.5 billion. We are net cash in a very comfortable position, but ultimately, we're not debt free. We still have an outstanding €500 million bond.

And I think, at the same time, I would reiterate here, that we have just proposed a dividend of 697 million, which is basically, a 21% increase versus last year's dividend. To come back to your question on the gross margin, I think, as I said earlier, I would look less at Q4 fluctuation, but more the full year adjusted gross margin, which came in at 88.3% in the guidance we provide going forward, which is around 88% to 89%.

That's a good indication, and we feel comfortable achieving that.

Charles Pitman

Thank you.

Operator

The next question comes from the line of Xian Deng with UBS. Please go ahead.

Xian Deng

Hi. Thank you for taking my questions. Two, please. The first one is on Rexulti. I can see, from your slides, the AAD launch seems to be going really well. But if I look at my IQVIA TRx script for total Rexulti, it seems that, at least from my end, that you haven't really seen an inflection point.

So, I was just wondering if you could actually give us a sense about actually the trends in depression, how that has been going for the pipeline [?], and how do you think about it going forward? Especially considering the competition this year and possibly next year. And then the second one is on 422, alfa synuclein.

Given that you are initiating on phase III, can I just first clarify that's going to be MSA? And have you already spoken to regulators on your phase III initiation? And also, does that mean that this could actually be launched before, earlier than you previously guided during the R&D day? Thank you so much.

Tom Gibbs

Thank you for the question. I'll handle the Rexulti question. I think, as you said, we're very pleased with the progress that we're making with the AADAD launch. We're seeing claims data, both in the community and the long term care setting growing, I think, very impressively with 161% growth overall, and 333% growth in long term care.

As it relates to the overall brand, as I said, if we look at overall demand units, starting in April of 2023 through December, we have seen 18.8% growth. And that compares to a growth rate of about 5% to 6% in the previous eight months. So, we have seen an acceleration of growth, due to the AADAD launch.

If we look at claims data, specifically, as I said, AADAD claims prescriptions through November are up 161%, but we have also seen growth within non-AADAD claims, as well, with growth of 8.9%.

Joerg Hornstein

And maybe I can try to answer your 422 question. Obviously, we have been doing an exploratory proof of concept study in MSA, so that's where we're going, primarily. That's what we hope to de-risk for the study. And we have now much, much more to look at. As I alluded to before in my presentation, we don't have so much prior information to build on.

Now we have a much more different situation. We can build on prior data, and design that programme moving forward in MSA. Interesting different readouts in the condition that has very broad symptoms, so we will look very carefully, in the phase III, what we're going to have readouts on. You are really pushing me a little bit here.

We had a readout last week, and it takes some weeks to, first of all, write an application to go to the regulators, and then get acceptance. So, obviously, we've not been to regulators to discuss the post AMULET trial data. But we've been to regulators a lot before, so we have quite a lot of ideas of what they would think for a programme moving forward. But it changes quite a bit, when you have data to go there, so we need another round with regulators.

And launch earlier. Yes, first of all, we need to get started with what we do next and think through that. And that will, as you have already asked about, include discussions with regulators. I would like to remind you, we have an orphan [?] destination in Europe, and we have sakigake in Japan, and to get some

designated pathway in the US would be something we're looking forward to discussing with the US regulators.

Now we have clinical data, which they usually like to see, to get that priority pathway that you'd like to see. And that can also lead to, of course, faster programmes. You get priority with the regulators. They also help you much more in the pathway forward, and often, the reviews are faster. But now we're looking forward very much in the future.

But we are looking forward to having that opportunity to discuss what we can do to move faster. And why is that so important? Well, of course, it is interesting for the company. But this is a horrible disease. An absolutely horrible disease. And we have that open label ongoing, and we'll see how it will be, in terms of patient interest and investigator interest to participate.

We had good help running this trial, and I would assume we will have very good help with patients wanting to get into a new trial, which is one of the key ingredients to move fast. So, there are many things here, and many opportunities, but I cannot really say what they will be, in terms of launch predictions, at this stage.

Operator

The next question comes from the line Charlie Mabbutt with Morgan Stanley. Please go ahead.

Charlie Mabbutt

Thanks very much for taking my questions. Charlie Mabbutt from Morgan Stanley. Firstly, on Vyepti, I was interested to know how you believe the preventative market share in the US could continue to trend, and where you see a potential peak. And equally, the rest of the world launch, you said, is progressing very well. So, how do you view the rest of the world opportunity for Vyepti?

Particularly if you can compare it to the US? Then secondly, on the Abilify long acting franchise. Would you be able to help us think about the ex-US revenue profile with the two months version, obviously, coming to market, or potentially coming to market very soon, and the patent potentially expiring at the end of the year for the one month? Thanks very much.

Tom Gibbs

Thanks, Charlie, for the question. I'll start with Vyepti in the US. As I had said, we're very pleased with the progress that we're making with by Vyepti, in terms of its adoption within the anti-CGRP preventative marketplace. I think it’s important to note not only what our share is, when we look at the overall market, which is 8%, but we also look at where, based upon our market position, what the overall share is for patients who have failed one or more CGRPs.

And if we look at that market share, which is probably a leading indicator for the trajectory, it's at 9.6% as of September, and based upon the volume growth that we've seen over the course

of the last quarter, we expect that market share to continue to grow.

Jacob Tolstrup — And, Charlie, maybe I can just add for the ex-US market and the rollout that we see there. We expect a vial sold on a similar level compared to the US, but of course, taking into account that we have markets that are launching sequentially at a different pace. If we look at our objective so far, it looks very promising in many markets.

Even though we are coming in quite a bit later than the other CGRPs, we have, in some places, the second best CGRP launch, despite coming in later than, for instance, Emgality and Ajovy. So, we're very encouraged about seeing that. Our positioning, as we mentioned in the past, is more towards severely impacted patients, which naturally, leads us into the chronic space after failures.

What we also see that is especially encouraging from the US is that physicians are starting to use it much more frequently and sooner in the treatment paradigm. So, I think we are just seeing the start of Vyepti here. We expect solid continued growth for many, many years to come.

Then you had a question around the two months. Very true, we expect to begin the rollout in Europe quite soon. Hopefully, we'll get the final approval in Europe soon. You should see the positioning there, similar to the US. It's about offering additional treatment options for patients that will enjoy, or are enjoying the one month, and then they can go to a longer version.

And we will do our best to optimise the franchise between the two. At the time where we expect generics, that will, of course, have an impact on the one month. So, we also, in our projections, do not expect Asimptufii to become as big as a one month, but a very solid treatment option in our LAI franchise.

Charlie Mabbutt — Great. Thanks very much.

Operator — The next question comes from the line of James Gordon with JP Morgan. Please go ahead.

James Gordon — Hello. James Gordon, JP Morgan. I have a couple of mainly financial questions. One is on base business performance. The base business looked like it declined about 20% in Q4, whereas it had been flattish. So, just in terms of why there was such a sharp decline in Q4, and what does guidance assume for the base business for 24?

How much better do you think it would be? The second question on SG&A. SG&A was quite a bit above consensus in Q4, and I think it was partly some one-off factors. So, the EBITDA level, how much of that was one off? And is it correct that roughly, the

guidance assumed SG&A growth mid-single digit in 24? Is that the right assumption for what you need to support the Vyepti launch and LAI launch?

And two other quick ones. Cost reallocation. Is it just closing some less important geographies, and it's quite minor reallocation? Or might we get an update later this year, where you say, we've made this big saving, there's a cost savings plan, and that's going to have a more transformational impact on the company?

And a final quick one. Any estimate for how much of Rexulti you think now it does come from, or did come from, AA in Q4?

Jacob Tolstrup

Thanks, James. A quick answer to your question around, I believe it was the mature product performance in the fourth quarter. I think there are always declines, especially among some of the mature products. And also, there are quality variations here that we have to look out for. So, don't use the Q4 as a trend, looking into 24.

I would say, though, that the biggest impact that we've seen in 23 is the erosion of Lexapro in Japan, as we've seen generics there, which certainly also had an impact in Q4 on Cipralex sales, as reported. One note here that I think is worth highlighting is that the decline that we see on Cipralex throughout 23, if we did not have the impact from Japan, Cipralex would actually have been growing in 23. So, it speaks to the impact that we've seen on Lexapro in Japan.

Joerg Hornstein

I'm not sure, James, if I got all of your questions regarding SG&A and EBITDA, but as I recall, I think, overall, from a ratio perspective, we anticipate an improvement in our SG&A ratios, which also allows us, basically, to reallocate funds into innovation, as you see in the increased guidance on R&D costs.

The second part of your question was, I believe, the one time effects. And I think, in principle, I would look at Q4, purely if you look at differences between cross margin as a one-time effect. And the best, as I said earlier, is to really look at the indication we're giving forward of adjusted gross margin between 88% to 89%.

Charl van Zyl

And, James, let me just quickly address your question on how, I think you phrased it, as cost cutting, or cost reduction. I would like to just refrain from that. What we're really trying to do here is, when we look at the current guidance for 24, we see very a nice expansion in growth on an EBITDA level. So, we are travelling in the right direction towards the midterm guidance that we set of 30% to 32% by 2026.

What we're really trying to address is can we create flexibility to allocate more to innovation, once we see success in the

pipeline? And I think that's really what we're trying to do. It's not a cost savings exercise, but really, the potential to be flexible, to invest more in innovation, when we see those opportunities come along. So, I hope that clarifies your question there.

Tom Gibbs — And James, I'll finish up with your question, in terms of looking at the contribution index across different indications for Rexulti. As you know, we are now tracking the business, both from an MDD standpoint and a AADAD standpoint. And it's our ambition to be able to continue to grow both segments of those markets.

If we look at the level of contribution of AADAD, what we call spontaneous use, prior to the launch, it was running at about 4%. If we look at the November claims data, the contribution of AADAD is now at about 11%.

James Gordon — Thank you.

Operator — Ladies and gentlemen, that was the last question. I will hand back to Lundbeck for any closing remarks.

Charl van Zyl — Great. I just want to thank everyone for joining the call today. And of course, I want to, again, convey my confidence around how we see the company evolving, and also, as we go into 24 with another strong year ahead for us. So, thank you again for joining us today.

Operator — Ladies and gentlemen, the conference is now concluded and you may disconnect your telephone. Thank you for joining and have a pleasant day. Goodbye.