Lundbeck

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Transcript

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Charl van Zyl

Thank you, and welcome to our earnings call for the first nine months of 2024. Of course, I really thank you for joining today. And needless to say, I'm really proud to present these results, which are further validation of our focussed, innovative strategy, which allows us to raise the lower end of our full year guidance.

But before we go to the results themselves, let us go to the next slide. So, from a disclosure perspective, the forward looking statements of today's discussion do include statements that are subject to change. And also, the next disclosure I would like to make is also to the agreement between Longboard and Lundbeck that is subject, of course, to closing of the tender offer to be completed.

So if we go to the agenda, the next slide, please. So I'm really pleased to have the management team join me today here. So we have our two geographic presidents, Tom and Michala, who will talk about our geographic performance, respectively. We have Johan, who will give us an update on R&D. And we have Joerg on the financial update and outlook for the full year.

So then, if we go to the next slide, which is really what I would like to share as a high level summary of our results that we have shared with you today. And put some context around these results, because this is really, for us, an important milestone and further validation of where we are travelling for the mid to long term. This is also consistent with what we shared with you during our Capital Markets event, and it shows, again, that we are executing well against our plan that we've laid out.

The first to say is that revenue is growing at 13%, and when we look at that specifically, also driven very much by our strategic brands, which are growing at 21%. And this is 74% of our revenue today falling in the Strategic Brands category.

Vyepti is leading that charge with 67%, and of course also Rexulti with 16%, especially driven by the AADAD indication. We have also seen major steps forward in the pipeline, which Johan will refer to a bit later. But the SUNRISE trial is another strong outcome for us that further supports the value proposition of Vyepti and will lead the pathway towards future launch potential in some of our Asian countries.

And we also see major advances also with Amlenetug into phase three. And of course, the advance of Bexicaserin into

the phase three programme that is started by Longboard. So overall, these results, in a sense, and where we stand with the first nine months, give us that confidence that we can now raise the lower end of our full year guidance, as we have disclosed today in our press release.

So with that, let's go more specifically into the performance at a geographic level. And it's my pleasure to hand over to Tom and Michala to take us through those results. Thank you, Tom.

Thomas Gibbs

Great. Thank you, Charl. And hello, everyone. As Charl mentioned, we are very pleased with our commercial performance during 3Q 2024, which was driven by 21% growth of our strategic brands. This growth was headlined by Vyepti. Next slide, please.

Vyepti delivered strong results during the quarter. And this performance has been fuelled by accelerating growth in the US and supported by the continued stream of launches and robust adoption of Vyepti in prioritised European and international markets, including Canada, France, Spain, Germany, and the UAE. Vyepti global net revenue for the third quarter 2024 year to date was DKK 2.116 billion. And this represents 76% growth year over year. Net revenue for Vyepti in the US was DKK 1.858 billion, and this represents 66% growth over 2023.

Importantly, we are beginning to see meaningful contribution to global sales by ex-US markets with Vyepti now available in some 29 markets. These markets are exhibiting strong anti-CGRP market growth, and Vyepti continues to gain meaningful market share across these markets. Ex-US sales will receive a significant boost if approved in Asia, based upon the positive SUNRISE trial results, which will be discussed by Johan later in the presentation.

I want to focus a moment on the US. Over the past year, we've worked very hard to refine our speciality commercial model to support Vyepti through a patient centric focussed ecosystem that appropriately supports the patient throughout their patient journey.

We are continuing to see accelerating demand by driving depth and breadth of prescribing and continued positive momentum in new patient starts. Higher written to infusion conversion ratios and increasing patient persistency. Weekly market share during September hit an all-time high in the US of 9.4%. And this compares to 6.8% in January.

Next slide, please. Rexulti continues to perform well,

propelled by the continued strong progress of the AADAD launch in the US. US TRx growth during the third quarter of 2024 accelerated to 20% versus prior year. Global reported revenue increased 16% through third quarter 2024 versus prior year. And revenue growth during third quarter 2024 accelerated to 22% versus third quarter 2023.

Now, we're pleased with the strong demand growth observed across all priority markets. The majority of the volume growth is driven by the US, and this is particularly attributed to the AADAD launch with 361% monthly volume growth when we compare August 2024 monthly TRx demand to the pre-launch baseline.

Rexulti AADAD volume is becoming increasingly important to the overall Rexulti growth, and we expect this to continue through 2024 and beyond. AADAD contribution has grown to 17.5% of the total TRx demand for the brand, based upon the most recently available data, and 22% of new to business prescriptions. We expect AADAD overall contribution to the brand to exceed 20% by year end.

The AADAD launch has also had a positive halo effect on the overall brand, with Rexulti achieving all time market share high last week of 2.32%, and this compares to 1.97% in January.

And looking at the most recent TRx data as of October 25th 2024. Overall rolling four week TRx growth has accelerated to 17% compared to February, with improved execution across the broader marketing mix.

I will now turn the presentation over to Michala to discuss performance of our other strategic brands. Michala.

Michala Fischer-Hansen

Thank you, Tom. Good afternoon, everyone. I'm very pleased to join you here to share some of the results we see for both Brintelix and Abilify, the Abilify franchise.

If we start with Brintelix, then we have a strong performance once again across the key markets. Overall, we are seeing 14% growth versus last year, and now the brand is at DKK 3.58 billion for the first nine months of the year.

We continue to see strong momentum in Europe and international markets, where Brintelix has grown 17% versus last year. We see Europe growing at 17%, which is driven by Spain at 27%. But also in international markets, we see a 17% growth, with China growing 36%, and Japan growing 21%.

If you look at the volume MAT growth over the last 12 months, you can see that we continue to exceed market

growth in the key markets, with Japan at an impressive 32% MAT volume growth.

When we look to the US, you can see a strong and robust performance in sales, with an 8% growth at DKK 1.134 billion, versus last year. And this is mostly driven by favourable gross to net comparisons.

Move to the next slide, please. When we look to the Abilify franchise, we also see a solid performance, with all markets contributing to that performance. The franchise delivered double digit growth versus last year at 10%, and is now at DKK 2.618 billion for the first nine months of 2024.

We have the US growing at 15% versus last year, which is driven by Abilify Asimtufii conversions that now represents 15.2% of the NBRx for the franchise, and 10.6% of the total volume. Encouragingly, we're also seeing that we have increasing conversions from the oral aripiprazole.

In EU and international markets. We had 8% growth versus last year, now at DKK 1.626 billion. And we see, again, strong performance across most of the markets worth highlighting, Spain, Canada, and Australia. And we continue to see a strong volume growth versus the market in key markets, as you can see on the right graph.

We launched Abilify Maintena 960 in Europe, as you may recall, we got the approval from EMA earlier in the year, and it's now rolled out in 11 markets since June of 2024. It is still early days, but the performance is in line with our expectations. And importantly, the feedback from our customers is very encouraging.

With that, I hand over to Johan.

Johan Luthman

Thank you, Michala. And also, thank you, Tom. It's great to see the strong momentum in our key brands. So, let's turn the page to some further information on R&D. The year continues with a very strong progression in R&D, with a set of exciting molecules in research. Progressing towards clinical introduction and advancement of early and mid-stage innovative development programmes, as well as important data delivered on our key strategic brands.

However, before I go into those programmes, I'd like to add to Charl's comment on Longboard. The company recently initiated a pivotal Bexicaserin trial in Dravet Syndrome, called DEEp SEA. That trial is now joined by another trial called DEEp OCEAN, which studies a mixed population of developmental and epileptic encephalopathies, with Lennox-gastaut syndrome patients included.

Returning to Lundbeck's development pipeline. I'd like to highlight that we are currently running three proof of concept trials, all with first in class molecules. The most recently started PoC trial is in patients with moderate to severe thyroid eye disease with our CD40 Ligand binder 515. If the enrolment goes well, we can look forward to readout by mid-2026. This trial joins our anti ACTH antibody programme that is already underway with two proof of concept trials.

Following the varying caching data we obtain in the multiple system atrophy trial amyloid with our alpha synuclein antibody, Ameletug, we have been very busy with external data presentations, KoL interactions on the programme, while also progressing towards pivotal programme start. We have, during the fall, concluded interactions with key regulatory agencies, which were critical, given that this is a first time registration programme for this indication.

After those consultations, we have finalised the trial design, and we are in the race to start up a pivotal trial called MASCOT. Similar to AMULET trial, the MASCOT trial is highly innovative, with key readouts utilising Bayesian progression statistics.

Concerning our branded programmes, we have obtained additional market approvals for Rexulti in AADAD, including through the access pathway that covers countries such as Australia.

Moving on, I'd like to provide some more details on the Vyepti SUNRISE trial readout that we had two weeks ago, a pivotal trial with Asian markets in a so-called SUN programme. The US and European approvals for Vyepti were based on the pivotal promise one and two trials, with the market access programme deliver, also in Europe. This was further supported by the relief trial that demonstrated very fast onset of action in migraine symptoms.

However, at the time the Asian programme started, there were practically no information from migraine prevention trials in Asia. So the SUN programme was initiated with a small, spearheading trial called SUNLIGHT in chronic migraine patients with medication-overuse headache. This trial had a high proportion of Chinese participants. We had the readout of the SUNLIGHT trial in 2022, showing a convincing numerical advantage of Vyepti, but insufficient separation from placebo.

Other essential learnings, including the types of patients being enrolled, with this highly informative data at hand match with the emergence of competitors trial data. We could adapt the ongoing, larger, pivotal SUNRISE trial in

chronic migraine. The sample size for that was adjusted up, as well as implementing stringent screening inclusion monitoring. This trial included larger cohorts of patients from various Asian countries, most notably China and Japan. These optimisations paid off, and we're happy to say that the SUNRISE trial met all its endpoints.

We have now also obtained data from this open label extension part of SUNRISE performed in a Japanese cohort. The SUNSET data reconfirms nicely the long term, sustained effects of Vyepti that we have seen in other studies in chronic migraine patients. The SUNSET study also adds critical positive on job participation, quality of life readouts.

Next slide. The SUNRISE trial included 983 patients on either 100 or 300 milligram Vyepti doses or placebo, with the primary readout at week 12. In the middle graph, you see monthly migraine days reported. On the primary endpoint, monthly migraine days over weeks one to 12, there was a reduction of 7.5 migraine days following the 300 milligram dose and 7.2 days for the 100 milligram dose.

In addition, the trial demonstrated significant efficacy on all secondary endpoints and quality of life endpoints on both doses for Vyepti. Also, no new safety signals or safety concerns were seen, confirming the safety programme we've seen in the past. Thus, the SUN programme data nicely confirms the strong data we have on Vyepti across different trials in various geographic regions. Adding to the already strong value positioning we have in migraine prevention treatment.

Next slide, please. In China, we have the opportunity to make innovative treatments available in selected pilot zones, such as Hainan and Great Bay Area. This pilot initiative is purely non promotional and is aimed to make treatments available to patients with high and urgent medical needs.

In 23, a hospital in Hainan obtained approval to make treatment with Vyepti available, which was based on the US approval. And this year, approval was given in the Great Bay Area based on Vyepti approvals in Hong Kong and Macau. With this early availability in pilot zones, we have the opportunity to create medical awareness and to obtain critical information on real world use.

Now, with the SUNRISE data, the next step is to expand access for migraine patients across mainland China through filing in 2025. Before end of next year, we also expect regulatory submissions to PMDA in Japan and other Asian

markets. For this, I would like to hand over to Joerg.

Joerg Hornstein

Thank you, Johan. Very pleased and great to see the progress we're making in R&D. Before I go into the results, I'm also very pleased with both our year to date and Q3 results. And as Charl earlier said, growth in strategic brands is even further accelerating. We grew 21% year to date and 25% Q3.

Next slide, please. Our revenue for the first nine months of 24 grew 13%, driven by accelerated growth of our strategic brands of 21% with significant contribution of Vyepti and Rexulti, mainly in the US, which overall represents nearly 70% of the overall strategic brand growth.

The adjusted gross margin was 88.5%, decreasing 80 basis points, primarily driven by higher raw material and manufacturing costs, predominantly in H1 of this year, which is partially offset by favourable volume and mix effect. This is an impact already anticipated and in line with our guidance, around 88 to 89% of an adjusted gross margin for the full year.

Sales and distribution costs increased 10% to 5.7 billion, reflecting mainly the continued investments in sales and promotional activities in Rexulti and Vyepti in the US, including the PTSD preparation for Rexulti, as well as the global rollout of Vyepti.

Admin expenses increased 19% to 1.1 billion, primarily driven by higher legal costs investment into Lundbeck's strategy implementation, as well as higher personal costs as communicated in the last quarter. Exclude the effect of the higher legal provision, then underlying administrative expenses actually increased 11%.

R&D costs increased by 36%, reaching 3.4 billion. Driven by, first of all, a 547 million impairment loss that was recognised in R&D costs. If you take that out of the results, you actually see that underlying R&D costs increased by 14%, reaching 2.8 billion. And that is mainly driven by the investments in anti-PACAP and in our anti-alpha-synuclein antibody.

Adjusted EBITDA increased by 12% as a result of the strong revenue growth driven by performance of strategic brands. The adjusted EBITDA margin was 31.6%, representing a decrease of 90 basis points, primarily due to increased cost of sales driven by higher raw materials and manufacturing costs due to inflation. The higher R&D costs and unfavourable currency effect, and if you, in principle, only look at the negative effects impact year to date, then this

basically constitutes a decrease of 60 basis points on the margin alone.

Next slide, please. Our EBIT increased 4%, reported 12% at constant exchange rate, growing in line with the underlying operation and performance, also benefited by lower amortisation of product rights. This growth was mainly offset by impairment losses due to the negative market readout that I referred to earlier in Q3 24.

Net financial expenses were 54 million. Equivalent to a decrease of 63%. The positive development is mainly driven by development and interest income, due to underlying change in net debt cash position and offset by unfavourable net currency effects.

Our effective rate dropped significantly to 16%, down from 23.5% in the period last year, mainly due to a reversal of an uncertain tax position relating to 283 million that was closed in Q3 of this year, and related to a previous audit in 2011.

Net profit increased by 18% to 2.6 billion, and adjusted net profit and EPS increased by 8% to 3.9 billion, and DKK 3.94, reflecting the adjusted EBITDA performance, the positive net financial result and the lower effective tax rate.

Next slide, please. The cash flows from operating activities in the first nine months of 24, we present an inflow of 4.48 billion, compared to an inflow of 3.2 billion in the same period last year. The operating cash flow reflects the continued solid EBIT performance, further impacted by higher adjustments for non-cash items, amounting to 2.3 billion. And that increase predominantly due to the impairment loss of market project and the amortisation of product rights.

You see favourable changes in working capital amounting to 752 million or a reduction in 57% in the first nine months. For 24, which is mainly driven by the lower inventory build-up, mainly due to the completion of the fixed batch quantity supply agreement with Sandoz in September last year.

The cash flow from investing activities were an outflow of 346 million, principal driven by CAPEX investments in the first nine months of 24, compared to an outflow of 362 million in the first nine months of 23. The cash flows from financing activities were an outflow of 808 million in the first nine months, compared to an outflow of 2.1 billion, primarily driven by a lower debt due to the repayment of the revolving credit facility in 23. But it's offset by higher dividend payments in 24.

The first nine months of 24, ended with the net cash position

of 4 billion, compared to a net debt of 46 million in the first nine months of 23, effectively deleveraging the company ahead of the foreseen closing of the Longboard acquisition.

Next slide, please. We have raised the lower end of our financial guidance for 24, and also reflected the impact of the foreseen acquisition of Longboard and the other relevant financial information. The revenue guidance has been narrowed to 12 to 14% growth at constant exchange rate, and adjusted EBITDA has been narrowed to a growth of 17 to 20% at constant exchange rates.

The outlook for 24 remains confident on performance in Rexulti, Vyepti demand in the US, as well as higher Brintelix, Trintelix demand in Europe and Asia.

Please keep in mind that we have communicated approximately 550 million of integration transaction costs tied to the foreseen acquisition of Longboard. We have the majority will be incurred in Q4 2024 and adjusted for. We also updated some of the other, let's call them, soft guidance parameters to reflect the following changes. R&D costs increased to 4.4 to 4.6 billion to reflect the market impairment of 547 million. We expect higher net financial expenses between 50 to 100 million, predominantly due to the depreciation of the dollar in the third quarter of 24.

The negative hedging effects are now expected between negative 20 to negative 45 million, compared to previously negative130 to negative 155 million. Furthermore, the effective tax rate has been updated to reflect the reversal of the uncertain tax position, and our net cash position is now projected to be a net debt position between 12 to 13 billion due to the foreseen acquisition of Longboard. And with that, I would like to hand over back to Charl.

Charl van Zyl

Thank you, Joerg. And let me make some concluding remarks, if we can go to the next slide, please. So, again, as I opened up the call, we're really confident and proud of these results, because it really is showing, again, the path we're following towards our focussed, innovative strategy at Lundbeck. And today's results is another proof point on that journey.

And to, again, remind you, a lot of our focus in the strategy is around growth, mid-term, and long term. And when I talk about mid-term today, strategic assets are growing at 21%, which is essentially 74% of our portfolio growing at this rate, thanks to the great execution of Tom and Michala's organisations.

But also, when we think about long term, clearly the pipeline

is evolving, and the work that Johan is doing around evolving the pipeline, including Bexicaserin, subject to closing, will allow us to be in a position in the mid-term to have four programmes that could be in phase three. So clearly, also creating that pipeline for the long term growth potential of Lundbeck.

And underpinning all of this is a very disciplined capital allocation reallocation programme to remain within the corridor of our adjusted EBITDA guidance that we also disclosed during the Capital Markets event. So, again, great performance in the third quarter, and of course, a strong pathway towards our full year guidance, as we have discussed today.

So with that, it's time for questions and answers, and I would hand back to the operator.

Operator

We will now begin the question and answer session. Anyone who wishes to ask a question may press star and one on their telephone. You will hear a tone to confirm that you have entered the queue. If you wish to remove yourself from the queue, you may press star and two. Participants are requested to only use headsets while asking a question. Anyone who was a question may press star and one at this time. The first question comes from Marc Goodman from Leerink. Please go ahead.

Marc Goodman

[Inaudible 00:28:00] talk about this amlenetug trial and if there's going to be a global study? Do you expect all of the different [inaudible 00:28:09]? And do you think that this one study might be enough [inaudible 00:28:15]?

Charl van Zyl

Marc, that wasn't a very good line, but I think I understood that you wanted to know more about the Phase three programme of Amlenetug. That we had the timeline.

Marc Goodman

Exactly. [Inaudible 00:28:34].

Johan Luthman

That's the question. [Overtalking 00:28:41].

Charl van Zyl

Let's go for that. Thank you, Johan.

Johan Luthman

Thank you for that question. The MASCOT trial, as they call it now, is, as I said, ready designed. And we are very imminent to start it up. We are saying early next year, but we are really progressing with a lot of preparatory work. I'm not revealing the details here in terms of doses or number of subjects. We will communicate that later.

But I think it's a well-designed study pushing the limits, of course, for a new indication. And I think we had really good interactions with several regulatory agencies. So we're pretty confident that in at least some jurisdiction, we will be

able to deliver data that if it's positive, it will be sufficient for drug approval.

What is important to note, it's one trial. It's not two pivotal trial. One trial is enough for this indication.

Charl van Zyl

Hopefully, we answered your question, Marc. If we can go to the next question.

Operator

The next question is from Xian Deng from UBS. Please go ahead.

Xian Deng

Thank you so much for taking my questions. Two, please. The first one for Johan, please. Just wondering, maybe I could try to push my luck a bit more on the MSA stage three trial. Just wondering if you're able to let us know what was the primary endpoint? Are you still going to be using the slope and the last analysis? And just wondering if you could maybe highlight what were the actual key differences from the phase two and phase three trial design, that would be great.

And the second one is just wondering, in terms of thinking about the next year's cost, moving parts. I understand this is going to be too early to guide for 2025, but just wondering if you could maybe remind us about the key moving parts in R&D and SG&A, and especially, how should we think about the R&D step up next year? Please. Thank you.

Johan Luthman

So maybe I can start, and then maybe Joerg can fill in with the costs. I can comment briefly on that. So, obviously, in this business, you don't like to change too much between phase two and phase three. So we try to preserve as much as possible between the two studies. That means that the primary endpoint is based on a Bayesian progression model.

There are different views in the world in terms of which design of [unclear 00:31:15] you like to use, and that's more in the analytical part. We can be adaptive with that part. But basically, what you should look forward to here is something that has many elements from the phase two trial, including the slope analysis, the Bayesian progression model for primary endpoints. The trial will start in the US, Europe, and Japan. For the finance…

Joerg Hornstein

I'll take the guidance question. I think it's, first of all, a little bit too early to give a guidance for 2025. Clearly, we continue with… What we said during the Capital Market event was we are disproportionately allocating funds towards our two most strategic brands for Rexulti in the US. They're driving year to date revenue, and that's going to continue also in the next year.

And, of course, we'll invest into our progressing timeline and also the integration, hopefully, on the foreseen closure of Longboard. But I would like to refrain a little bit from further guiding into 25 at this point in time.

Xian Deng — Thank you.

Operator — The next question is from James Gordon from J.P. Morgan. Please go ahead.

James Gordon — Savings. So you said at the CMD that you're now going to get an adjusted EBITDA margin above 30%. And subject to Longboard closing, that would put some costs up. So you need to make some significant savings. Where are we on those savings in terms of things like taking out promotional costs in some smaller countries? Are you already making those savings, or were you already going to see some benefit from that, even in Q4? And do we get a savings announcement with more detail at some point, maybe in conjunction with full year results? Or just each time you update us, there's just going to be a bit more SG&A taken out? So how should we think about the saving and the communication around that?

And then the second question, Rexulti for PTSD, we're less than 90 days from the February 8th for PDUFA, and I haven't seen anything about an Ad Comm. So does that suggest that we're not having an Ad Comm which is going to be smooth sailing into the decision? And given that, are you already spending on launch prep in Q4? Because it looks like it's a straightforward approval now.

Charl van Zyl — Yes. So maybe the first question, James, I'll also ask Joerg to add. But we are undergoing these programmes today to further look at how we reallocate capital. Part of that will be in our guidance in 25 as well, once we have completed that process. So I don't think we can add specific numbers to you today. But, Joerg, if you would like to add anything more.

Joerg Hornstein — I think, James, you had the same question to me on the Capital Market event, and I said, of course, some of these initiatives are also a structural nature. And I would say we are overall, in terms of progress on the transformation initiatives, very well on track. But I would probably see a contribution a little bit more from the second half of next year onwards. But we'll keep you up to date as part of regular earnings release.

Johan Luthman — On the PTSD regulatory process, I can comment a little bit. First to remind you that PDUFA date is 8th of February, so we're getting close to it. Obviously, we are logging along with the process with FDA. There has been no remarkable

changes in that process in the journey so far. It's an FNDA. So, obviously, there is a lot of safety data from other indications, and we have a big package for this molecule in indication as well. So there are several elements of the review that are probably pretty straightforward. Preclinical safety, etc..

The clinical portion of the NDA review often comes quite late, but I'm sure they are into that part already, and we haven't got any challenging questions on this. Are we getting an Ad Comm? FDA has the right to ask for that at any stage during the review process until basically the PDUFA date. So far, we haven't heard anything about it. And at the validation, when they accepted the filing, they said nothing about it.

James Gordon — Thank you.

Operator — The next question comes from Manos Mastorakis from Deutsche Bank. Please go ahead.

Manos Mastorakis — Yes, hello. Thank you for taking my question. So, on Brintelix in Japan, and also the SUNRISE filing. Initially, I was thinking that it seems there's no particular urgency in filing, but then you talked about raising awareness in those markets. Is that the reason why you're pushing back almost a year, the actual filing? As in, is this related to the commercial readiness? Just give a little bit of colour there.

And also, it seems that there was not much of a positive reaction following the positive announcement. So what is it that the market is really missing about that? Yes, that's it, pretty much. Thank you.

Johan Luthman — So you had something about Brintelix at the beginning? I'm not sure. Was that a comment on Brintelix and the shift, or…?

Charl van Zyl — Yes, I think the comment is probably on the good performance in Japan. Maybe you want to comment on that, Michala.

Michala Fischer-Hansen — Yes. No, I think your question is, I heard, was basically, is it because we don't have a rush with Japan because Brintelix is performing so strongly? And you're absolutely right, Brintelix is doing incredibly well in Japan, and as in many other markets. But I'll let Johan comment on the timeline.

Johan Luthman — Yes. So, Brintelix, if I may add, we have a two year extension now through the paediatric programme, so we have a longer runway in Japan. So that's good. And the product is doing very well in Japan.

But going to your question about SUNRISE, why are we

filing in the later part of 2025? That's because of several reasons. We're lining up very different elements of the programme here. We need, of course, to analyse specific Japanese populations, and we have PK studies, so you have to build a certain file. But it also relates to the CMC filing, etc., and the different manufacturing processes for Vyepti. So that's why we like to build a package that is very comprehensive and will be a package that is long lasting for the market.

Manos Mastorakis — Thank you. Very clear.

Operator — The next question comes from Charles Pitman-King from Barclays. Please go ahead.

Charles Pitman-King — Hi, guys. Thank you very much for taking my questions. Firstly, I was just wondering if you could give us a little bit more detail on the progression of your conversion for the Abilify portfolio. What proportion of patients that are switching away from branded Maintena [? 00:38:38], switching to Asimtufii, and how many are potentially switching over to other products? That's the first question.

And then the second question, you mentioned the gross to net adjustments impacting 3Q 24. I was wondering if you'd give us a few more details on those and how we should think about those as far as recurring impacts going forward. Should we think about this as a 3Q event going forward?

And then just a very quick clarification to your comment on slide 20 and your guidance referring to it as soft guidance parameters. Can I just make sure, are you admitting that there's a potential to end up outside this range, or are you allowing for uncertainty with the relation to Longboard closure? Thank you.

Charl van Zyl — So let's take the first question, Tom, on Abilify switch potential. Yes.

Thomas Gibbs — So, thank you for the question, Charles. Overall, as Michala spoke to, the Abilify LAI franchise in the US continues to deliver solid growth as an overall portfolio. Net revenues grew 15% through three quarter 2024 versus the same time a year ago. I think it's important to note that this growth for Abilify LAI franchise is driven by the continued uptake of Abilify Asimtufii, which now contributes 11% of the overall Abilify LAI franchise. And this has resulted in a market share growth of 2% for the Abilify LAI franchise.

Now, to your question, I think it's important that we note that we are starting to see greater conversion of Asimtufii outside of Abilify Maintena. Right now, we're seeing the conversion trends for Abilify Asimtufii. They're encouraging because

we're seeing a declining percentage of conversions coming from Abilify Asimtufii, and almost half of all conversions now are directly coming either from oral atypicals or naive patients.

Charl van Zyl — There was a follow on question on gross to net.

Thomas Gibbs — Oh. So as it relates to gross to net, I think we're speaking to Trintelix for the US. I do. I do not see these as continuing over time. These will be declining. What the gross to nets are, its favourable comparison as it relates to lower Medicaid as a part of the overall payer mix, which will even out over time, and we don't see that as recurring.

Charl van Zyl — Yes. And thank you, Tom. And Charles, just to be very clear, I think what Joerg was referring to are the other financial information. So relevant information on slide 20, but maybe not a reference to a soft guidance. We are very firm on our guidance based on what we said today. But I think it was just for completeness to share also the other relevant financial information. So hopefully that clarifies that point.

Charles Putman-King — Makes sense. Thank you so much.

Operator — As a reminder, if you wish to register for a question, please press star and one on your telephone. The next question is from Mattias Haeggblom from Handelsbanken. Please go ahead.

Mattias Haeggblom — Yes, thanks so much. Two questions for me, please. Firstly, reading the SEC filings with background of the merger related to the proposed acquisition of Longboard, it became even clearer that the breakthrough designation for Bexicaserin, issued by FDA in July, was a driving force for Lundbeck's willingness to hike the offer substantially from its opening offer. So can you perhaps expand with regards to the importance of the breakthrough designation in light of risks and uncertainties with drug development, not least in neurology?

And then secondly, could you remind me how much is left on the balance sheet related to the Abide assets? Thanks so much.

Charl van Zyl — Thank you, Mattias. And Johan can comment in a second. But there's two drivers, breakthrough designation, but also the willingness from the FDA on a much broader label in the broader population. Those are two big value drivers that came from the end of phase two meeting. But, Johan, do you want to comment on that?

Johan Luthman — Yes, I think that's pretty much it. It's a unique breakthrough. Designation has not been given before. And this is an area

with many smaller indications and a few bigger ones, [unclear 00:42:56]. And then in August they were even slightly bigger. So, this is the first time to really have this go at a broad label for all these epilepsies. And the breakthrough designation shows how committed FDA is to do something here, but it also adds value to a product like this.

Joerg Hornstein — And I think I take the question regarding how much of our Abide Therapeutics platform is still in the books, and that's around 1.3 billion.

Mattias Haeggblom — Thanks so much.

Operator — The next question comes from Lucy Codrington from Jefferies. Please go ahead.

Lucy Codrington — Hi. Thank you for taking my question. Just a few left. Sorry if I misunderstood. But in terms of the changes you made for the SUNRISE trial, in terms of the stringent screening criteria, is there likely to be any limit to the label as a result of those changes, or were these just fairly minor?

And then just secondly, is China a market where you might look to partner for commercialisation, or is this something you wish to do alone?

And then just with regards, probably more broadly, for the guidance and the remainder of the year, if you could just outline some of the key pushes and pulls, given consensus are already at the top end, if not above. So where we might be wrong, I guess. And then with that, the R&D side of things, just to confirm that it does include some Longboard costs, assuming it all goes through. Thank you.

Johan Luthman — Yes, I can start with the SUNRISE changes. No, I don't want to leave you with any impression whatsoever that this is a limitation in label, what we did here. It was truly operational, I would say. Prevention or margin is a new indication, really new indication, in China. And the diagnostic rate for chronic is often with very few years on diagnosis.

And in the SUNLIGHT study, we had a fairly high degree of males, and that was unusual. So we started really to just put in very, very clear guidance for the sites to do the right diagnosis. It's really the experience with the population, the trial site's experience with the population. So there was no rewriting of the inclusion criteria by itself. But it's a better inclusion of the right patients. So if anything, it could strengthen the label that really got the typical migraine patient.

Joerg Hornstein — Maybe I can high level touch on some of the drivers. I think

it depends a little bit how you construct your models. But if you work and try to reconcile reported numbers, that's of course, a difficult exercise, because we look here at Q4 at a bit of a different currency set up, as we had in basically the last quarter of last year. And basically it's difficult to compare. You also have probably around 93 million of favourable hedging impact last year. That is, of course, significantly different this year as before, also given the other relevant information. So currency plays for a bit of a reason.

I think on the underlying drivers, we are very pleased with the trajectory performance of Rexulti and Brintelix. And as we said earlier, specifically on the US Brintelix and Abilify, we've seen a bit gross to net favourability. We don't see that continuing into Q4. And I think overall, if you look at mature brands as well, year to date performance is pretty much in line with what we guided all year long. And if you suddenly see a bit of deviation, then this is minor, because Q3 was in principle, triggered quite a bit by a few price increases we've seen in some high inflation markets. So that's where I would leave it.

Michala Fischer-Hansen — And, Lucy, thank you for your question on China. Let me start by saying that we are obviously very pleased with the very strong results that SUNRISE has shown. And, of course, next is the regulatory process which starts. In terms of how we wish to go to market, it is simply too early to speak to that at this stage. But for sure, China represents a significant market and a very interesting market for us. So more on that at a later stage. Thank you for the question.

Lucy Codrington — Thank you.

Charl van Zyl — I see no other questions at this point.

Operator — Ladies and gentlemen, that was the last question. I would now like to turn the conference back over to Charl van Zyl for any closing remarks.

Charl van Zyl — Yes, thank you for joining today, and also for receiving your important questions. Again, I want to just reiterate, and hopefully you agree that these are compelling results and strong validation of our path of being a focussed innovator. And again, want to thank you for your attendance today, and look forward to interacting with you again in the future. Thanks again.