

Lundbeck A/S
Financial Results & Business Update 9M 2023
8th November, 2023 | 1:00 PM CET

Transcript

Speakers:

Charl van Zyl

Joerg Hornstein

Johan Lutman

Operator

Ladies and gentlemen, thank you for standing by. Welcome and thank you for joining the financial statements for the first nine months of 2023 of Lundbeck A/S. Throughout today's recorded presentation, all participants will be in a 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

Welcome, everybody, and thank you for joining us this afternoon to read out the interim report for Lundbeck for the first nine months of 2023. Of course, I'm really delighted to be here. It's my first 60 days. And I look forward to engaging with you to share the progress we are making in the company.

So first of all, a few opening remarks before we go to the main content. So of course, as I said, it's my first 60 days, and I want to express my clear confidence around the underlying revenue performance of the company that demonstrates our ability to execute very well.

The second opening remark I'd like to make is that obviously, within my 60 days, I've been able to assess our R&D portfolio, and I see clearly a profile that is emerging that gives us some significant opportunities in the future, also to be shared in an Investor Day later in this quarter.

Of course, in my first 60 days, I anticipate that you would have many questions and curiosity around our strategy, but I would like to take some of those questions, of course, later. But I would assure you that we are going through a strategy review in the first 100 days, and we'll be happy to share more with you later.

So let's go to the next slide just to disclose our forward-looking statements. So let's go to the next slide, please. And here, I want to highlight the key points, of course, for the first nine months, again underpinned by very strong performance. And here, what you will see is firstly, on a constant basis, a 9% revenue growth in the first nine months over 2022 and an adjusted EBIT growth of 20%.

What makes me more confident here is that when we look at our strategic brands, which essentially make up approximately 70% of our portfolio, where we're also investing significant SG&A, we see a constant growth rate of 16%. And a lot of that is underpinned by Vyepti, at 81%,

and also Rexulti with its new indication.

You will also hear a bit more later about our pipeline highlights, of course, with anti-PACAP being one of the important milestones with the proof-of-concept data that allows us now to advance into the next phase of our development. We'll also share with you headline results on the PTSD studies that have read out recently.

So if we go to the next slide, please. So what I want to continue to emphasise is really the strong power of our growth related to our strategic brands. What you'll see on the left-hand side is, in essence, the growth we see across all our key geographies. And it's really important to see here that we are growing high double-digit across all the key geographies in our strategic brands, the US at 19%, Europe at 14% and the international markets at 13%. So I'm really pleased at this point with the execution we see that's consistently across all our key geographies.

And the right-hand side, you will also see more a breakdown of this growth also by our key assets. And you'll see a nice balance of our positions across US and the rest of the world in a 50-50 split. But more importantly, in the US, you see strong growth, of course, driven by Rexulti and Vyepti, and in the European and rest of the world, we see very strong growth from Brintellix.

If we now go more specifically into the comments on each of the assets, I'd like to move to the next slide to talk more specifically about Vyepti. And here, I would leave you with three important comments. Of course, 81% growth on a constant basis is phenomenal, and we're very pleased with this progress we're making.

One of the key areas we see it clearly in the US is in inflection growth that we've experienced, and I'll talk more about that in a second. And then of course, in the rest of the world, in Europe, we also see a function of our early launches, where we're rolling out these also across the rest of the world.

But more specific remarks around the US. First of all, of course, I've had a chance to also be with the US team. And what I see is clearly an organisation that is now poised to further maximise this opportunity. We have a strong customer-facing organisation, and we've really built and learnt over the last years how to maximise this opportunity in front of our customers. So that's a really strong foundation that I feel is evident also in the results that we see today.

The second important point to make here is that we see also

an increasing depth of prescribing and also a breadth in terms of new patients that are being prescribed. So this gives us additional confidence that we see a steady uptake also of new patients on Vyepti.

What is most important in the third point is really that through this experience now, we see an emerging position that is seen as one of the most efficacious or most efficacious in the class of severe, preventative migraine. So this is clearly a strong position, which gives us confidence that we can continue to see strong growth in the US also for Vyepti.

It is a global asset for us, so it is really emerging also in other positions in migraine, and we see it as an important vector for long-term growth, also when we think about anti-PACAP in our pipeline that could fuel additional opportunity in the long term. So Vyepti I would position for you clearly as an invest for long-term growth inside Lundbeck.

If we go to the next slide then, some remarks specifically on Rexulti. And again, also here, phenomenal growth, high double digits at a constant basis, at 19%. This is predominantly from the US, and we would see here, of course, an indication expansion, with agitation associated with dementia in Alzheimer's disease, where we see clear early signals of a successful roll-out of the launch.

When we look at this specifically, of course, we have a number of indicators that we will share in the future more in detail. But what we see is a very strong uptake in our target population of 65-plus. And you will also see, as we now go into the fourth quarter, additional awareness that we will generate through our DTC campaign to further fuel that growth we expect for the long term also for Rexulti. And of course, together with our partner, Otsuka, we're investing here to maximise this opportunity for the expansion of the indication.

Then if we go to the next slide, a few comments specifically on Brintellix/Trintellix. So of course, we have a well established asset here, with a lot of years of experience. But despite that, we see very strong growth across the European and international markets, specifically in Europe, to call out here 16% on a constant basis.

And of course, also very strong growth we see in the international markets, in particular, also Japan, where we see very strong performance. And in this essence, we are very targeted, we're very focused with our resource here, and we see a clear response in terms of growth rates for Brintellix/Trintellix.

A few words specifically on the US. Of course, the market is phenomenal in terms of its change as well that we've seen post-COVID, with a greater shift towards primary care and also nurse practitioners. And together with our partner, Takeda here, which, in this case, 80% of the resource is driven by Takeda in the US, we are jointly assessing how we best deploy our resources with this new dynamic. And so our resources essentially is to maintain Trintellix in the US while investing more specifically on Vyepti and Rexulti for the long term

Then if we go to the next slide, and before we go to Johan, I want to make a few comments on Ability Maintena. Of course, here also, very good to see the underlying growth of 11% on a constant basis. This is driven by very strong underlying demand in the long-acting injectables segment. And of course, we come from a very strong position here, with a strong foundation and strong market position. So it's still really phenomenal to see the growth also in this long-acting segment.

So before I hand over to Johan, I just again want to express my confidence around the underlying revenue performance, the strong contribution we see from the strategic assets that make up essentially 70% of our portfolio today. And therefore, we are very confident as we go into the remainder of the year and into next year that we can drive this growth with the strategic assets that we have. And so with that, I'd like to hand over to Johan.

Johan Lutman

Yes, thank you, Charl. It's good to see that you're off at a strong start as our new CEO. So R&D continues to have a very strong year. As we already carried in the Q2 call, we had an extraordinary second quarter, with a rich flow of very important positive R&D events, including two approvals with the FDA, both of those together with our partner, Otsuka. But even Q3 comes with very interesting R&D activities.

One big event this year was obviously the sNDA approval of Rexulti for agitation associated with dementia due to Alzheimer's disease. We have thereafter spent the summer and fall to support the launch of the product in this indication. We have been participating in conferences, for example, the AAIC Conference in July, with the special session on agitation, and we also had many interactions with leading KOLs in the field.

And what we keep hearing is that the approval is really welcome. Given that it came after a 20-year period of no full approval of any NMEs by FDA for the treatment of Alzheimer's disease. More importantly, the interactions with

various leading experts in the field have reinforced how critical it is to have an approved therapy with the devastating agitation symptoms of Alzheimer's disease.

Agitation is part of the behavioural psychological symptoms of the dementia spectrum, a range of major clinical issues for which there has never been any FDA-approved treatments. Specifically, agitation is one, together with aggression, of the most bothersome clinical issues. Agitation is not only a burden to patients themselves, but even more so to caregivers, and it's a critical challenge in their care.

Earlier this week, we were therefore very pleased to see the full publication coming out in JAMA Neurology on this last year's concluded pivotal trial in the programme. The full publication is a nice follow-up to our Late-Breaking News Presentation at AAIC in 2022 and a more complete presentation at the CTAD meeting, December last year. The publication, together with the prior publications from 2020, is providing a very comprehensive view on the drug's performance in this indication.

In addition to the US, we have ongoing regulatory reviews of brexpiprazole for treatment of agitation in Alzheimer's in Canada, with the expected completion by Q1 24. Regulatory review for the indication is also ongoing in Singapore, Australia and Switzerland. Approval in those three countries through the so-called Access Consortium process is anticipated during mid-24.

On September 7, Lundbeck and Otsuka also announced results from their phase three clinical trials of brexpiprazole, studying the potential of the drug in the treatment of post-traumatic stress disorder. This has been to us a much-awaited read-out, given the long and arduous road it has been to complete the two trials. The trials were hard to recruit, and particularly, they were heavily influenced by the COVID pandemic.

One of the trials was a two-arm design, studying 2 mg to 3 mg flexible dosing of brexpiprazole in combination with sertraline. That trial met its primary endpoints on clinician-administered PTSD scale, CAPS-5, by brexpiprazole separating against the treatment arm receiving sertraline only. The second trial, a three-arm design, missed its primary CAPS-5 endpoint. Overall, the safety and tolerability results across these two trials were consistent with the profile of brexpiprazole we observed in other indications.

We are currently in the process of further analysing these results as well as the previous phase two data for the

programme in PTSD. The data from these trials constitute one of the largest data sets ever generated in this indication of PTSD. Also, more importantly, PTSD is a very serious mental health disorder, with a wide range of symptoms, with no new treatment options seen in more than 20 years. It's therefore important we discuss our findings with the FDA to determine next steps.

We also had another FDA approval during the spring for aripiprazole two-month ready-to-use long-acting injectable suspension for intramuscular administration. In that programme, the EMA review progresses well after resubmission in the summer through the line expansion pathway. Our estimate is still for an early H1 24 finalisation of the review. The product is also undergoing regulatory review in Australia and Korea.

In April, we announced a very encouraging positive read-out from the first-in-class anti-PACAP monoclonal antibody FY 2022 in the HOPE trial. The antibody was given as an IV infusion to patients with frequent migraines that had not responded well to two to four prior preventive treatments. Since this is an emerging full development programme for Lundbeck, I'd like to provide some additional context in the next slide.

And the data from the proof-of-concept HOPE trial, together with some phase one experimental medicine data, were revealed at the International Headache Conference in Seoul in September this year. The presentation was very well received by the scientific community. It's not often in R&D that you get the chance to be part of a clinical proof of concept.

And in migraine, this is indeed the first clinical evidence of a new mechanism of action being effective since the CGRP target was shown to work back in 2004. So this is big news for the field. The excitement is exemplified here by a statement by the 21 Brain Prize winner, Peter Goadsby, one of the most eminent scientific leaders on migraine research.

A broader phase 2b programme has been designed and will start in early 24. Key aims of the upcoming trial is to establish subcutaneous efficiency and build a comprehensive understanding of the optimal dose range. Next slide, please.

So we've had several important events during the year so far. We have, however, also progressed nicely across the R&D pipeline, both with brand support and, not least, with our early innovation pipeline. This is facilitated by our transformed R&D organisation, including a very strong

preclinical research organisation.

Since the pipeline is in the coming years set up to deliver some interesting programmes, leading to full development, we think this is timely to reveal a bit more what is happening in our Lundbeck R&D. We will therefore hold an R&D event in London on the 30th, as Shirley has mentioned, followed by a shorter version on December 6 in New York City.

In that event, you will hear about how neuroscience is the right place to be and how Lundbeck is built to profit from this exciting field and deliver leadership. We are already well on our way to build a very interesting, innovative pipeline, and thereby, an even stronger sustainable future for the company. About this, we would like to share more at the R&D event. With this, I'd like to hand over to Joerg.

Joerg Hornstein

Thank you, Johan. Let's turn our attention to the financials. The plus 10% of reported revenue growth was driven by growth of 9% in constant exchange rates, attributed to the robust performance of all of our strategic brands. The negative FX effect is driven predominantly by the decrease of our main currencies, which is more than offset by the positive hedging effect year over year.

The adjusted gross margin, just removing the 312 million impact of the provision for Vyepti inventory obsolescence and the amortisation and depreciation linked to sales, is higher compared to 22 by 1.3 percentage points, reflecting the positive sales development. Sales and distribution costs grew 15% at constant exchange rates, primarily due to expenses for the launch of Rexulti AADAD in the US in June of this year as well as the continuing global roll-out of Vyepti.

Increased administrative expenses in 23 are attributed to digital investments, the CEO transition and an increase in legal provisions of 69 million, related to ongoing litigations, which we are factoring in as an adjustment.

R&D costs decreased by 12% at constant exchange rates, which is not entirely aligned with the guidance we provided in the previous quarter. The main reason for this is that we are seeing lower than expected costs related to completed lifecycle management and phase four activities. Additionally, the transition from early stage to mid-stage for several of our projects takes slightly longer than anticipated.

All of these effects contributed to an EBITDA growth of 9% at constant exchange rates. Adjusted EBITDA, net of effects of the provision for Vyepti or other legal provisions, grew by plus 20% at constant exchange rates, improving the margin by 5.2 percentage points to 32.5%. Please bear in mind that

approximately 2.4 percentage points of the margin improvement in the nine months relate to the lower R&D costs compared to last year. Next slide, please.

Our EBIT grew by plus 21% in reported rates. Also, it carries exceptional costs of 396 million. The increase is reflecting the high revenue growth and strong operating leverage. And please also keep in mind that our EBIT of this year includes a higher depreciation and amortisation of roughly 200 million compared to last year.

Our net financial expenses decreased for the first nine months to 146 million. The lower expenses are mainly driven by the non-recurring fair value adjustment of the CVR in Q1 last year, triggered by the Vyepti EMA approval as well as lower debt levels and higher interest rates.

The effective tax rate has increased to 23.5% compared to last year's 22%, in line with the full year expectations, reflecting the reduced deduction of the Danish R&D incentives. Net profit increased by plus 34% to 2.2 billion, and adjusted net profit increased by plus 27% to 3.6 billion.

The adjusted EPS growth of 27% is in line with underlying performance after adjustments, related primarily to amortisation of product rights, Vyepti provision for inventory obsolescence, other legal provisions related to the ongoing litigation and the fair value adjustment of CVR to former shareholders in Q1 2022. Next slide, please.

The cash flows from operating activities landed at an inflow of plus 3.1 billion in the first nine months of 23, compared to an inflow of plus 2.2 billion last year. The operating cash flow is, of course, a reflection of the strong EBIT performance, further benefited by higher adjustments for non-cash items of 1.9 billion, which are mainly driven by higher amortisations in 23 and the provision for Vyepti inventory obsolescence.

This is negatively impacted by higher change in working capital of around 1.3 billion, driven by a decrease in short-term liabilities from payment of sales milestones in 23, partially offset by lower inventory development, primarily due to the final part of Vyepti inventory build-up that concluded in September 2023.

The cash flows from investing activities were an outflow of 362 million, driven by paid-out sales milestones. Just for your reference, the 2022 number, in comparison, included an outflow of 1.1 billion for the CVR payment to all the shareholders.

The cash flows from financing activities were an outflow of

2 billion in the nine months of 23 compared to an inflow of plus 169 million in the same period last year. This is primarily driven by the now fully repaid revolving credit facility, under which 1.2 billion were drawn last year, and the higher dividend payment in 23, connected to the improved net result in 22.

In the nine months of 23, we have continued to deleverage the company, standing at a net debt position of minus 46 million compared to a negative 3 billion at the same period last year. Next slide, please.

As we are coming closer to the end of the year, we see the strong momentum of our strategic brands to continue and more than offset the erosion of mature brands. Lundbeck therefore narrows its full year guidance range on revenue to 19.8 to 20.1 billion, which is the upper end of the previous range.

Connected to the narrowing of the revenue guidance, allow me to elaborate the following. The strong performance of our strategic brands is complemented by the continued global roll-out of Vyepti as well as the launch of Rexulti AADAD and Abilify Asimtufii in the US in June of this year, while Brintellix/Trintellix is facing lower growth in the US and China and generic pressure in Brazil.

Our mature brands, and especially CipraleX/Lexapro in Japan, Deanxit in China and Sabril in the US, are facing strong generic erosion. The remaining part of the year is expected to show a lower performance compared to the first nine months of the year, which were benefited by timing of shipments as well. Additionally, the full year is expected to benefit from a positive hedging effect of approximately 66 million due to more favourable hedging rates.

At the same time, Lundbeck is raising and narrowing its full year guidance on adjusted EBITDA to the range of 5.6 billion to 5.8 billion. The raise of the adjusted EBITDA guidance is driven by the lower than previously anticipated R&D costs as we see lower close-out costs connected to completed lifecycle management activities. In addition, the transition from early to mid-stage of several of our projects is moved to 2024. With that, I hand over to Charl.

Charl van Zyl

Thank you, Joerg, and also thank you, Johan. So let me leave you with a few closing remarks before we go to the Q&A. So again, what you would have seen here is a very strong underlying growth performance in the mid-term. You see also here very strong confidence around our evolution of our strategic brands, with double-digit growth, and of course, a very strong translation of that also into profit and

adjusted EBITDA.

What you will hear more, of course, also during our R&D day, is an advancing and emerging pipeline that is also very exciting for us. So from that perspective, of course, with my first 60 days here, I am very optimistic around where we're going and how we're seeing the progress inside Lundbeck.

And of course, we're happy to take your questions now, going forward. Before we go to the Q&A, I would also just like to say that I'm joined today also by Tom Gibbs, our head of the US commercial operations, and Jacob Tolstrup, our head of commercial operations for our business outside of the US. And we'll be happy to take your questions now.

Operator

Ladies and gentlemen, 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 your touchtone 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. Our first question comes from Michael Novod with Nordea. Please go ahead.

Michael Novod

Thank you very much. It's Michael from Nordea, Copenhagen. So a couple of questions. First, to marketing dynamics in the US and also scripts dynamics, so maybe this is for Tom in terms of Rexulti in AADAD. So you see this very significant growth trend in 65 years-plus, but we haven't really seen the full inflection in the total scripts. So maybe you can talk a bit about prescription dynamics and how you see this panning out over the next couple of quarters.

Secondly, on commercialisation too, you're talking about perhaps considering Trintellix more so of a very mature brand now in the US. Could it be justified to add more marketing resources outside the US, or will it just be for the products in the US? Yes, I'll start with that. Thank you very much.

Charl van Zyl

So, Tom, would you like to answer the question on the US? And then Jacob, I would ask you to answer the question of Michael on the ex-US opportunity. Thank you.

Tom Gibbs

Hi, Michael, and thanks for the question. I would start out by saying it's still early in the launch for Rexulti AADAD, as we've just debuted our direct-to-consumer campaign on October 9. But I would say the launch is progressing as we expected. From a qualitative perspective, our experience to date does confirm that the AADAD market is a large

opportunity for Rexulti, with significant unmet need in the marketplace.

We've discussed this earlier. We do see the AADAD market as a nascent market that does need to be developed. And Lundbeck, along with our partner, Otsuka, will make the necessary investments to make sure that we maximise this opportunity, both to ensure patients and caregivers can realise the benefit of Rexulti treatment for this highly debilitating disease.

Now, from a quantitative perspective, we're now starting to track weekly TRx data, as you've seen, in the 65-plus cohort as well as patient claims data. Now, the patient claims data does lag by about two months. Both of these data, as we've discussed and as you've seen, suggest there has been a meaningful uptick in this segment, which is having a positive impact on the overall rand. The claims data even suggests a greater impact from the AADAD launch than what we're projecting with the 65-plus TRx data.

I think, importantly, and as we outlined in the presentation, the contribution within the long-term care segment has actually been very robust. And through my lens, it's the AADAD launch that is really propelling the growth of the brand. And if we look at the October data, which I'm sure you've seen, we've seen all-time weekly highs for TRxs, NRxs and BRxs, NBRxs, TRx share as well as NRx share.

Now, as we think about moving forward, we are anticipating to begin to start seeing the impact of our branded DTC campaign. Normally, you see that about eight to ten weeks post introduction, so we should start seeing that in the December timeframe. And we're also looking at implementing a more focused effort in long-term care to maximise the opportunity in this channel, which will begin in early 2024.

Michael Novod

Great.

Jacob Tolstrup

And on Brintellix/Trintellix outside of the US, Michael, to try to answer your question, so we talked about it also in previous quarters. It's been a journey for us, starting with an optimised brand positioning and then, over the past five/six years, have a smaller investment into growth here and there in different parts of the world.

And that work continues, and that is also the benefit that you see coming out now, with the growth rate that we see, I would say especially from southern parts of Europe, but certainly also other markets, including Canada. And the latest smaller investment we did there was recently done in

Canada.

So I would say for my part, it's not about what we cannot do, meaning we don't need to go down in promotional spend in the US to find these additional growth opportunities for Brintellix outside. So it's not an either/or, but we will continue to look for those opportunities outside. And I think we're seeing very good growth rates for Brintellix around the world due to these investments that were done in the past.

Michael Novod

Great. Thanks. If I just may add one short follow-up for Johan in terms of PTSD. So when do you expect to have a meeting scheduled with the FDA, and thereby be able to take the decision whether to try to approach the regulators with the data you have for potential label expansion or not?

Johan Lutman

Yes, we are gathering the data, as I said, and analysing. And I tried to remind you that we also had a phase two trial that's part of this programme. So we have data from three trials that we have to look at. And we do all this combined analysis and separate analyses.

It's very strong, convincing data from the flexible-dose study, so that drives our desire really to have that conversation with the FDA. We are already on track, having those discussions. I don't like to give any dates. And of course, the outcome of those discussions will determine our next steps.

But we are confident we have a strong position to discuss, and then we'll see if they really see the big medical need. As I mentioned, it's 20 years since last a drug was approved in this field, and it's only two SSRIs on the US market. So we're looking forward to those conversations, but obviously, we would have liked to see two positive trials, a smashing success. Now, it was a smashing success in one of them, which makes it a little more complicated in terms of discussions.

Michael Novod

Okay, great. Thank you so much.

Operator

Our next question comes from Charles Pitman with Barclays. Please go ahead.

Charles Pitman

Hi. Charles Pitman from Barclays. Thanks very much for taking my questions. I have just two to start off, thank you. First, to Joerg on R&D costs. I was wondering if you could just expand on the lowered R&D cost expectations for FY 23, and maybe particularly focusing on what the key delays have been around moving 222 and 462 forward. They were originally expected to keep R&D flat year on year. And maybe just what the sensitivity around next year's R&D expense is going to be, and directionally, how should we

think about this increase, year on year, moving forward?

And then just secondly, I know, Charl, you've mentioned you don't really want to talk too much about strategy. But I was just wondering if you could just give us maybe a bit of a background on, following your experience at UCB and previous M&A experience within the neurology section, what specific learnings do you believe that you have from UCB that you would like to apply to Lundbeck here, and how are you considering M&A options and use of cash, and is that something we could hear more about at the conclusion of your 100-day review? Thank you.

Joerg Hornstein

Maybe I'll start off on your financial questions. I think we have to look at a couple of parameters. I think, this year, we're not spending less on R&D. We're spending less on lifecycle-related projects. And that's something we've seen as a development over the past couple of years, that pretty much every year, we are halving the spend. And especially when these trials close out, you usually finalise your reconciliation, and that basically is what drives the favourability in Q3.

In terms of expectations going forward, I think the guiding parameters are, first of all, the mid-term targets that we have set, which is the existing corridor which we are navigating. So I think that's where I would leave it, because I believe it is overall a bit too early to give an indication for next year's R&D spend, and I would hand over to Johan.

Johan Lutman

Yes, thanks for that question. Yes, I think it's important to re-emphasise what Joerg just talked about. We have actually, over the last three, four, five years, had quite a high LCM spend, because we had successor programmes that went all the way to the market. And those were attached with a lot of post-market requirements, paediatric studies, indication expansion studies, line expansion studies, etc. Those are very predictable costs. Those we can really expect to have, and when they will occur.

Now, we're shifting over, as Joerg talked about, to a more dynamic cost structure. And it's in early development. Things are moving much faster. And obviously, it's good for us to invest in this space. We just had a phasing here that was not entirely lined up with various activities.

Going specifically to 222, I'd really like to nail that one. We had a positive proof of concept. That was done with two doses, as you may recall, and a high and a lower dose. Now it's time to really fully explore the potential of this molecule. So we took our time really to make sure that we have really the right design to move forward. So that spend, of course,

will come primarily next year.

Delay? Yes. In terms of the overall programme, not at all. We are de-risking what we will do in phase three. And I'm a firm believer that you should do your job well in phase two before you go into phase three. You like to de-risk that. So overall, we don't see a delay in the programme. But of course, it's a phasing difference here, how we spend money in that particular programme.

Charl van Zyl

So Charles, just a few comments on your question around M&A. But let me start first by positioning in the sense of what we're facing also from an industry perspective. We see clearly, with policies that are changing in Europe and also in the US, that the hurdle for innovation is set even higher. So this area of how companies operate with what is remaining unmet need is important. And I firmly believe that with Lundbeck's history and legacy, that we need to remain in this very focused innovation space.

And so having said all of that, what of course we are disclosing today, and when we think about our strategic brands, we have a strong mid-term growth position. And so when we think about what we're trying to solve for strategically for the company, it's really how we solve for the long-term LoE effect that we see on Rexulti at the end of the decade.

And that's really where we are also focused when we think about our efforts around R&D and around M&A. And on the R&D space, of course, we will reveal more, but very promising areas there that can advance and, if successful, will contribute certainly at the end of the decade to commercialisation.

Now, when we think about M&A, and of course, all companies need to look at organic and inorganic innovation, we do not see the need to do an immediate M&A to solve the short term but really continue to think about the long-term opportunity. And here, we do not necessarily see the need for one single deal that will solve that but really a sequence of deals that make sense for us, that we can digest, that in a sense build on our strength.

And of course, there, we would therefore prioritise deals that are more near-term commercialisation, that might be at a phase three level or entry into phase three, with a view that they can contribute revenue in the second half of this decade, and then obviously into the next decade as well. So we see it more programmatic in our M&A approach, combined with a very strong evolution of the R&D pipeline that will bring us that sustained growth also into the next

decade.

Charles Pitman

Thank you very much.

Operator

Our next question comes from James Gordon with JPM. Please go ahead.

James Gordon

Hello. James Gordon with JP Morgan. Two questions, please, following up on some of the comments just there. So the first question would be about duration of growth, which I think you alluded to already. So where do you now see the company positioned to have growth until, without you licencing anything or having success in the pipeline? Is it having something to address the Trintellix LoE in 2027, or are you confident that you've got growth until 2029 and the Rexulti LoE, and it's solving for the post-Rexulti growth is really the focus? That's the first question, please.

And the second one, also on M&A plans in terms of how big an M&A you're looking at and how you might fund it. So thoughts on potentially using equity. The stock split occurred a couple of years ago. Is the clock ticking to potentially do something big that would involve equity, or is that now not seeming so likely? And how would you feel about funding it the other way, with debt? In terms of leverage, how highly levered would you be comfortable taking Lundbeck to be?

Charl van Zyl

So James, thank you for that question. First of all, I think on the growth dimension, we certainly feel confident, with our current strategic assets we have and the evolution of Vyepti, that we can bridge that growth in the short term with the Trintellix LoE. And of course, we see that slowing down as we go towards the end of the decade. But I think I would narrow that window of growth towards more the 27-28 timeframe.

When we think about M&A, then again here, we are thinking more in the space of... Also as we look at neurology and where it's going and where our area of focus will be, it's in well-defined populations where there's a clear unmet need, so smaller populations where scale is not that important, but really where there's a chronic specialised focus in the market.

So we're thinking more of smaller deals, with again a series of these that have peak potential of maybe €500 million-plus level, that in a cumulative effect can essentially build a growth engine beyond that 29 LoE window. So again, that's how we look at them. And we see them, in a sense, as a way of doing a series of these over the next years that are digestible also from a debt perspective for the company and can build on the existing pipeline we have. So I would leave

it at that but certainly would love to engage more as we build our strategic plan also into the next years.

James Gordon

Thank you.

Operator

Our next question comes from Brian Balchin with Jefferies. Please go ahead.

Brian Balchin

Hey. Yes, thanks, I think most of my questions have been asked. But I've got one on Vyepti. I know, in the release, it says that the ALLEVIATE trial recruitment was halted following a planned interim. So can you just share if that's a good thing or a bad thing? Thank you.

Charl van Zyl

Johan, do you want to take that?

Johan Lutman

Yes, I guess that's for me. Yes, that's clear, that we had an interim. It was a scheduled interim, so it was not mandated by any safety concern, anything like that. Actually, the data in terms of tolerability/safety was very good in this trial. Actually, no, this is a slightly different population, males primarily, and very severe headache. The medical need is enormous.

We did have a scheduled interim, as I said, while we took a look at the data. And we're actually going to reveal more of that at our Investor Day. So you have to be a little patient here. But I can say this much, that it's intriguing data, and it really verifies that this is a strong drug in many ways. And I'll leave it like that, and we'll come back on the 30th if you'll join us.

Brian Balchin

Thank you.

Operator

Our next question comes from Marc Goodman with Leerink. Please go ahead.

Marc Goodman

Yes, hi. My first question is you talked about this over-65 prescriptions. I was wondering if you could quantify it, maybe just tell us what per cent of the prescriptions that you were looking at were actually over 65 versus under, so we can get an idea of just how much it's helped so far, that new indication.

And second of all, Joerg, could you just give us a sense of gross margin over the next couple of years, adjusted gross margin and how to think about it? Would there be much change, or is this what we should expect? Thanks.

Charl van Zyl

Tom, do you want to answer the question on Rexulti?

Tom Gibbs

Sure. Thanks, Marc, for the question. As we have looked historically at the 65-plus cohort, it really had been stable over time through the last several years at about 12% to

14%. Since May, with the increase over the inflection point with the AADAD launch, we have seen that increase over 40% since then.

Joerg Hornstein

Maybe I'll take the question on the adjusted gross margin. Again, we see a very nice development, year to date, that fully reflects the operating leverage due to the strong growth in our strategic brands. And I don't think we give any mid-term guidance on the adjusted gross margin, but I think the current level is a good level to start with.

Operator

Our next question comes from Suzanna Queckbörner with SHB. Please go ahead.

Suzanna Queckbörner

Hello. Suzanna Queckbörner from Handelsbanken. My first question goes to Johan. I wanted to get an update on the alpha-synuclein antibody. Given that you've said that you're expecting headline, top line data in H1 2024, what are the ambitions here, and especially with the next steps, is this something Lundbeck is going to explore alone in MSA, or are you looking to partner? Yes, maybe some detail there.

And then the second question to Charl, now 60 days into your tenureship here. Which of the current pipeline projects do you find the most encouraging and also, especially, in contrast to external expectations?

Johan Lutman

Yes, so I'll start. So thanks, Suzanna, for that question. Needless to say, the asset is in a field where we have high scientific challenges and technical challenges but an enormous upside. But the most important thing here is that it's an enormous medical need. There is really nothing to offer in this space.

MSA has really no optionality in terms of treatments other than it's a fairly rapidly progressing disease and death through a very, very devastating loss of function throughout the body and, at the end, respiratory failure. So we feel it's almost an obligation to go into this field with this great asset.

And we opted to go into MSA first. That's something that we can do, and we would be able to do that throughout the entire programme. It's, as I indicated, soon upcoming in terms of our read-out, and we hope that we designed this in a way so we have a clear-cut yes or no. That is obviously for MSA.

This mechanism of action could also be explored in Parkinson's Disease. Other people are doing that. That is a bigger undertaking. And that's something, of course, we have to consider, particularly if we have a positive read-out in MSA. It's not automatically something that will work in Parkinson's Disease, but then we probably also feel obliged

to explore that.

And that's something we have to think about how we can manage such a broad and still a fairly high-risk programme. So that's all I'd like to say right now. But right now, I think we should look forward to that read-out that's coming during the first part of 24.

Charl van Zyl

So yes, thank you, Suzanna, for your question. Of course, as I said, I am excited by the pipeline, and we'll discuss more of that at the R&D Day. And I'll use the words that Johan normally uses. Let's let the molecules speak and let the data speak for us.

Of course, don't want to single out any of the specific assets right now. But what I've certainly seen and what I'm excited about is the anti-PACAP results. We saw a novel mechanism of action and we know that there's still a huge unmet need in the space of severe migraine. So this is, of course, where there could be an opportunity for really building a stronger migraine franchise in the future.

And as Johan had just highlighted, with alpha-synuclein and MSA, this is breakthrough, and so we really believe, if there is something there, this will be a wonderful opportunity for us as well. But very excited with the pipeline and, of course, more to disclose in the future.

Suzanna Queckbörner

Thank you.

Operator

Our next question comes from Xian Deng with UBS. Please go ahead.

Xian Deng

Hi. Thank you. Thank you for taking my questions. Two, please. The first one is probably for Johan, regarding PACAP. So understanding that you will launch phase 2b dose finding for sub-Q next year, but just wondering if you could give us some timeline for the... When do you think we could know about the pivotal trial design?

And in the longer term, just wondering, where do you think you will most likely position this asset? Are you mainly targeting in the late line, highly efficacious, like Vypti, highly efficacious but probably like a last resort? Or you would also be thinking about maybe putting this... Giving it as sub-Q, you could actually go for a much earlier line, potentially combining with others?

And the second question is regarding to Rexulti launching in AAD. Understanding this is very early days, just wondering if you could give us any more colour in terms of the patient segment. Is this mainly the patients that are actually late-stage, mainly in the care homes and institutions, or you are

also seeing some use in the community setting? And also just wondering, any comments on duration, etc., that would be great. Thank you.

Johan Lutman

Yes. So let me start with the PACAP question. It's a really good question that you're asking, actually two good questions. The phase 2b design is a design that has lots of optionalities, and we will reveal a little bit more how we're going to design that when we launch the trial. But it has different ways of exiting, if I may put it that way. And with some good results coming up early, we could maybe go faster.

But the most important thing that I tried to emphasise before is that we like to go in phase three with a really good understanding about which dose or doses to use. And this is something we also learnt a lot from Vyepti, how critical it is to really establish the dose range for the drug so you have a value position for whatever doses you have.

So that's a little bit how we built it. So there are different possible timelines for that study. I like, as I said, to be very, very swift in phase three, once you establish those very fundamental facts, that sub-Q works and we know the dose range.

The nice thing with migraine, even with the chronic episodic migraine we're dealing with, the trials are fast. Well, we have competition now for enrolment from the CGRP class of drugs, so that may slow us down a little bit. But these are generally fast programmes in migraine, and we know how to execute them. So I think, after we establish this phase 2b, we can look forward to a very efficient phase three.

The question you have about differentiation is something that we honestly don't know yet. Our proof of concept was done in a little bit of differentiation. There were patients that had failed two to four prior treatments, so it was a little bit a test, what they can take. As you may have seen from the presentation at the Headache conference in Seoul, we had very few CGRP patients, so we cannot really say much about whether this is a treatment for people that fail on CGRP.

But the market dynamics are very interesting here. People cycle through, a little bit, different treatments, and there are new treatment paradigms being developed. And remember, we had an IV. Now we're exploring sub-Q. So a lot of optionalities here, that patients are asking for different solutions. And there are also variants, how we can go in early with IV, and shift over to sub-Q.

So there are many possibilities here to build differentiation way beyond just beating, head to head, CGRP. But the biology is very rich, as I talked about, so there is great potential already built in to the mechanism of action to have differentiation.

And often, that is what happens with a new mechanism of action. You discover that they differentiate. And I'd like to remind you, our IV CGRP antibody is differentiated against the sub-Q ones, so we already have, just by ways of manoeuvring the assets, differentiation. So that's probably what I can say at this stage.

Tom Gibbs

So Xian, this is Tom. Thank you for the question. And I answered the question from Marc as it related to the 65-plus cohort with our weekly TRx data. As I said earlier, the claims data, I think, are more representative of how the launch is going. And since you asked questions about patient segmentation, I'm actually going to start quoting some of the early claims data, and this is based upon July data.

If we look at the different patient segments from an age standpoint, the 66 to 84 patients we see up over 55%, about 55% versus launch. And again, this is July data. If we look at the 85-plus segment, that's up almost 310% in the July data. So from a patient segmentation standpoint, you see that those that are more advanced are being treated more prominently than those that are less advanced, which again is not surprising, based upon the dynamics of new product launches.

Then, if we look at segmentation from a channel standpoint, as I said, the long-term care, prescriptions within the long-term care have been very robust. If we look at those data since launch, it's up close to 100%. So once again, you're looking at patient data that's suggesting, as well as channel data, that it's the more severe patients that are being treated now.

And again, that is what's expected, and that's why it's so important, as we think about the launch of our DTC campaign, to be able to push the prescribing for this significant unmet need more into the community setting and for those that are less severe.

Xian Deng

Thank you so much.

Operator

Our next question comes from Manos Mastorakis with Deutsche Bank. Please go ahead.

Manos Mastorakis

Hi. Thank you for taking my question. Hope you can hear me. So I'm just wondering, how long do you plan to continue investing behind Vyepti, or how is that decision going to be

made, moving forward? So as long as you see a return, will you keep backing it with marketing and sales? If you could be a bit more specific on the breakdown of sales and marketing versus distribution component of the spend, that would be very helpful. And in other words, as competition continues to increase, will you need more of an investment? Thank you.

Charl van Zyl

Manos, can I just clarify your question? You're referring to Vyepti in terms of investment?

Manos Mastorakis

Correct. Correct, yes.

Charl van Zyl

So Tom, do you want to comment on our...? As I commented, of course, in the opening remarks, we see it as an investment for the long term, so it remains an important investment asset for us. But Tom, do you want to comment as well?

Tom Gibbs

Sure. Perhaps I'll comment with the US and then turn it over to Jacob more broadly for the ex-US. First of all, when we think about where Vyepti is within its lifecycle, we're clearly beyond the turnaround of Vyepti, and we're really into the acceleration phase. We've grown, as you saw, 73% from a revenue standpoint over prior year, and I think that's representative of the investments that we've made from a sales point of view, from a marketing point of view, with patient activation. There's also from a market access point of view, as it relates to patient experience.

I have been incredibly pleased, quite frankly, to see what the marginal return on investment analyses suggest of those three key levers in terms of driving investments. I'm sorry, driving results. And I think there's an opportunity, quite frankly, to expand our investments based upon the positive return on investments that we're seeing to even further accelerate growth in the US.

Jacob Tolstrup

Yes. Maybe I could just add also for ex-US market. So I think it's important to highlight what Tom is saying. We're still early on. So we've been going for a little more than three years in the US, and for rest of world, we basically just have been launching within the last six to 12 months. So that means that we have several years ahead of us with, I think, very strong growth rates from Vyepti.

And of course, also remember that this is a brand that will live long. We're looking into mid-/late-30s for LoE. So this is a brand that will stay with Lundbeck for a long time, with significant growth ahead, very early in its launch. So I think there will be some time to go before we can start discussing investments and what is needed.

Manos Mastorakis

Thank you.

Operator

There are no further questions at this time, so I'd like to turn over to Charl van Zyl for closing comments. Please go ahead.

Charl van Zyl

Thank you very much. Again, thanks for joining today. As you would have seen, very strong confidence around our growth profile going forward. And we will look forward to engaging with you also during our R&D Day, where we will talk more specifically about our exciting pipeline. So thank you again for joining 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.