Lundbeck

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Transcript

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Joerg Hornstein

Charl van Zyl

Welcome to everyone. Thank you for joining our quarter three earnings call and, of course, also full-year guidance. From the outset, I just want to make a few quick remarks. Again, very pleased, of course, with our strategic progress. We see very strong momentum that continues, and we've made some very targeted investments in Vyepti and Rexulti that underlie that momentum.

If we go to the next slide, please. Of course, what we discuss today is forward-looking statements that are subject to change. We can go to the next slide. Let me just lay out the agenda for today. And, of course, I'm very pleased to be joined here with my leadership team that will take us further into some of the insights that help us to understand better how we are performing and, of course, also transforming Lundbeck for the long term.

Let me start with the results and we take the next slide, please. From a results perspective, again, very strong growth. As I said, from the outset, momentum continues to be very strong for us. We see our growth is essentially faster than what we had assumed. And that's very much focussed on very targeted investments that we have made, choices we've made to our key strategic brands to invest more behind Vyepti and Rexulti.

And you see the result of that with a very strong double-digit growth across both of those brands. On the innovation side, we continue to see very, very strong advancement of our pipeline. We're in a stage where we have five to six mid- to late-stage opportunities that are advancing well. And I would just highlight a few key points, which will be further expanded by Johan and Maria later.

First of all, Vyepti, of course, we are advancing with our submissions and filings in Asia important growth drivers for the future growth of Vyepti. And we are also advancing our anti-PACAP Phase 2B, with expected headline results in quarter one, 2026. As we also build further the pipeline, we see the build of the neuro-rare franchise, with enrolment advancing, of course, with bexicaserin and amlenetug.

And we will also highlight today, more specifically, some of the new elements of the pipeline, specifically our CD40 ligand that really allows us to address further immune modulation. And Johan will talk more specifically about a key programme there. The final pillar of our strategy is really around funding.

And, of course, we have been very clear with you around our very targeted capital reallocation programme that is very disciplined to ensure that we can invest in additional growth

opportunities, but also sufficiently invest in the pipeline for the long-term sustainable growth. And we see very good progress that remains on track. And specifically, the rollout of our commercial model has been a major highlight of the last quarter.

With that, of course, we announce, as we did yesterday, an upgrade to the guidance, based on the very strong fundamentals, based on the very targeted investments we've made behind our key strategic brands that give us confidence on the momentum for the full-year. With that, to take us further into some of the specific elements of our strategic assets, I would like to hand the floor to Tom. Take the next slide, please.

Thomas Gibbs

Thank you, Charl. And good afternoon, everyone. As Charl just mentioned, we are pleased with our commercial performance through the first three quarters of 2025, which is headlined by strong growth of Vyepti and accelerating growth of Rexulti. Please turn to the next slide and I'll first review the performance details for Vyepti. Vyepti delivered strong results during the first nine months of 2025.

This performance has been powered by continued strong growth in the US and supported by robust adoption of Vyepti in prioritised ex-US markets, including Canada, Italy, France, Spain and Germany. Vyepti global net revenue for the third quarter year-to-date 2025 was 3.254 billion DKK. And this represents 57% growth over the same period last year. Net revenue for Vyepti in the US was 2.834 billion DKK, growing 56% over prior year.

I want to focus a moment on the US. We continue to make purposeful investments in our patient-centric model, supporting Vyepti through our disciplined capital allocation programme that Joerg will speak to later. These incremental investments, including our sales force expansion in July of this year and our direct-to-consumer patient engagement, continue to outperform our expectations, driven by precision execution and informed by our advanced analytics platform.

We expect to continue to see market-leading demand growth by driving depth and breadth of prescribing and continued positive momentum in new patient starts, supported by a high return to infusion conversion ratios and best-in-class persistency. Next slide, please. Rexulti continues to perform well, delivering consistent growth, propelled by continued strong progress within the AADAD segment in the US.

Reported revenue were 4.695 billion DKK, increasing 26% through 3Q 2025 versus prior year. I think importantly,

revenue growth in the US was driven by strong underlying TRx demand, achieving 24% growth through the first nine months of 2025, versus the same period in 2024. Rexulti AADAD volume is becoming increasingly important to the overall Rexulti brand growth. And we expect this to continue through 2025 and beyond.

AADAD monthly TRx volume has increased 664% versus pre-indication baseline. And AADAD contribution to the overall Rexulti demand has grown to over 23%. The 65-plus segment now contributes 33.7% for more than one out of every three of Rexulti TRx claims based upon the most recently available claims data. I believe this positive halo effect on overall Rexulti's 65-plus segment truly reflects the full value of the AADAD indication for the brand.

The team is continuing to focus on the levers to accelerate growth for Rexulti, informed by our marginal return on investment quarterly analyses. As I shared with you last quarter, we are applying our Dynamic Resource Allocation-focussed innovator principle to redirect a portion of our AADAD direct-to-consumer funds to expand our primary care footprint to drive greater breadth and depth of prescribing.

The first wave of the expansion of our multispecialty sales force team was deployed during 3Q 2025 and we're encouraged by the very early results. Michala, over to you.

Michala Fischer Hansen

Thank you, Tom. And let's now take a look at the Abilify franchise. Next slide, please. There it is. Here, we continue to see sales progressing very nicely, with 11% growth versus the same period last year now at 2.58 billion DKK. And this is driven by the Abilify two-monthly or the Asimtufii formulation, which is now launched in 24 countries around the world.

The conversion, as you can see on the right side of the slide, from 1M to 2M, is progressing very strongly, where we see 18% TRx share and 20% NBRx share in the US and an average conversion rate just above 17% in Europe and international operations. We further continue to see encouraging conversion from orals at 59% in the US and an estimated 40% conversion across Europe and international operations.

Earlier this year, we saw generic entry of Abilify one-monthly in Australia. And we now have confirmation that two generic versions of Abilify one-monthly has been approved through the decentralised procedure in Europe, as well as in Canada. We expect to see the first launches in the beginning of 2026. Next slide, please.

As previously announced and also mentioned by Charl in the opening, we have recently taken important steps to evolve our commercial model by partnering our commercial operations in 27 markets. This is really a signature project in our focussed innovator strategy and a key pillar. The purpose of the change is to sharpen our focus on our key markets, markets that drive over 80% of our revenue and markets that also represent 80% of the market potential within neuro speciality and neuro-rare.

I'm pleased to share that it is progressing as planned and we're on track to complete the transaction by December 1st. Thereby allowing us to maintain business continuity in these geographies and ensuring continued access to our medicines for the patients. With this critical project, we reduce complexity across the enterprise and we also free up significant capital that we can reallocate across the enterprise into commercial growth and R&D.

It also further allows us to continue to sharpen our focus on our key markets and thereby maximising growth of the strategic brands, ensuring that we have the strong readiness we need for the upcoming losses of exclusivity and, importantly, securing the build-up in preparations for our neuro-rare and neuro speciality model. With that, I'd like to hand over to my colleagues, Johan and Maria, to give you a portfolio update.

Johan Luthman

Thank you, Michala and Tom. It's great to see the continued strong commercial performance. Let us now turn over to the portfolio update from Maria and I. Next slide, please. But let me start with eptinezumab, our brand Vyepti. We are making good progress on the Asian expansion, which remains the key future growth driver for Vyepti.

The door opener for this were data obtained through the SUN programme, in particular, the SUNRISE trial. The SUNRISE trial confirmed the efficacy and safety of eptinezumab in a predominantly Asian population, with results comparable to previous pivotal trials. Importantly, the trial also substantiated a rapid onset of action. Data were reported in full in June at the European Academy of Neurology Congress and are also now published in Cephalalgia in August.

Eptinezumab was filed for approval in Korea in early August, as reported last quarter. We have now also filed in China and the submission in Japan is progressing as planned. In addition, during the quarter, the FDA finished their review and acknowledged the clinical relevance of the previous RELIEF trial. The RELIEF trial demonstrated that when

Vyepti was given during a moderate to severe migraine attack, patients eligible for preventive treatment showed rapid relief of headache, pain and migraine-associated symptoms.

For example, Vyepti demonstrated efficacy within two hours after starting the infusion and led to a median time to headache pain freedom of four hours, versus nine hours for placebo. Also, the treatment reduced the need for rescue medication. The data from the trial are now Included as a third clinical study in the US prescribing information for Vyepti.

I'd also like to mention that we had the International Headache Congress 2025 present a new data from the RESOLUTION open-label extension trial in a very severe migraine population and in the SUNSET extension trial of the Asia pivotal programme, both underlining eptinezumab's sustained efficacy and safety profile.

Taking together these developments highlights how we continue to expand our reach and further document the clinical strength of eptinezumab. Pain within migraine, our PROCEED Phase 2 adaptive trial on the anti-PACAP antibody 222 is advancing very well. And we expect full trial results, as Charl already mentioned, in Q1 2026.

Bear in mind, the PACAP innovation offers a distinctly different mechanism of action compared to blocking CGRP signalling, potentially addressing a broader spectrum of migraine biology. Let me also spend a moment on our alpha-synuclein antibody, amlenetug. As you may recall, based on our very encouraging data we obtained in the Phase 2A AMULET trial, we initiated a pivotal programme by this time last year.

This global Phase 3 trial, called MASCOT, is evaluating amlenetug's potential to become a first-in-class and first-in-indication treatment in MSA. The MASCOT trial is progressing very well, with site activations completed across geographies and strong recruitment momentum. The high interest to enrol in the MASCOT trial is obviously driven by the enormous medical need in MSA.

However, the programme is also recognised for its highly innovative design. For example, applying a Bayesian progression modelling statistical approach suitable for diseases such as MSA. The scientific and medical interest in the programme was indeed something that was observed in the International Congress of Parkinson's Disease and Movement Disorders in October.

In neuro-rare epilepsy, in the bexicaserin, the programme continues to make steady progress. We have now the three DEEP trials approved in all key geographies and site activations are progressing strongly. In addition, the programme recently received breakthrough therapy designation in China, reflecting a strong confidence in its therapeutic potential for patients with developmental and epileptic encephalopathies.

Results for the Phase 2 PACIFIC trial on bexicaserin, they recently published in epilepsy and presented at the International Epilepsy Congress in Lisbon. These data reinforced the durability and consistency of bexicaserin as treatment effect across disease. Overall, the bexicaserin programme sees strong engagement from KOLs, patients and caregiver groups.

In summary, the quarter has seen substantial progress across our late-stage trials, with strong execution and expanding global reach. Next slide, please. Let me now turn to another important event in our early development portfolio, this time on our 515 programme. Our CD40 ligand blocker that's being investigated in thyroid eye disease, TED for short.

We are currently running an open-label, Phase 1B study. At an interim analysis, we have already observed very encouraging data. First, we've seen a notable decrease in antithyroid stimulating hormone receptor autoantibodies. Consequently, we have been able to establish target engagement, as well as proof of mechanism.

Moreover and more importantly, the TED patients also showed a clear reduction of proptosis. As you can see from the graph on the left side, proptosis reached over 2 mm reduction over time, looking at change versus baseline. This extent of change is considered clinically relevant and used as a primary endpoint in registration trials in TED. We have this exploratory study.

We have now not only obtained a clear signal suggesting that 515 is affecting disease-relevant autoantibodies, but also that the CD40 blocker may be efficacious in TED patients. 515 is investigated in TED, based on our understanding of the CD40 biology. The CD40 ligand plays a central role in immune activation and B cell production. By modulating this pathway, 515 may influence inflammatory processes central to disease activity. But it may also affect other changes, for example, fibrotic tissue formation.

More broadly speaking, the recently obtained data on 515 exemplifies how we're implementing our strategy by the use

of smaller Phase 1B patient studies as a determining decision gate before progressing to mid-stage development. As another example, at our Q2 report, we shared information on a Phase 1B study on 996, a first-in-class, oral D1/D2 agonist in Parkinson's disease. That triggered the preparations for a larger Phase 2 trial by start next year.

Likewise, based on the strength of the exploratory study 515 in TED, we are now preparing for next steps. We are, therefore, rapidly progressing into this final Phase 2 trial in TED, also to be started next year. With this, I'd like to hand over to Maria, who will speak a little bit more about the further potential of this programme.

Maria Alfaiate

Thank you very much, Johan. And when thinking about 515, it's important to retain that despite meaningful progress in recent years, thyroid eye disease remains an area of deep unmet need. TED has seen innovation, but not resolution. Up to two thirds of patients experience incomplete or only temporary benefit from existing therapies.

And what was once viewed as a single active phase disease is now increasingly recognised as chronic and relapsing, a condition where long-term immune control is critical. The TED market is growing rapidly, projected to nearly double, from US $2.2 billion today to US $4 billion by 2034. Fuelled not only by greater diagnosis and biological adoption, but by the shortcomings of current care that drive emergence of novel treatments.

Of nearly 2 million people with TED in the US, less than half are diagnosed and about 100,000 moderate to severe patients remain candidates for biologic treatment. The existing options have shown what's possible, but also where the bar still stands. Limited durability, safety constraints and relapse rates that remain high. Even for responders, treatment, burden and risks, from hearing impairment and hyperglycaemia to infusion reactions, do restrict long-term use.

That's why our CD40 blocker represents a true next-generation opportunity, a first-in-class mechanism designed to intervene upstream in the immune cascade, offering the potential for safer and more inclusive disease control. Importantly, TED is just the beginning. CD40 inhibition is a platform opportunity pipeline in a product, with potential across multiple autoimmune and neuro immunologic indications.

With a strong biomarker foundation, and a unique mechanism of action, this molecule positions Lundbeck at the forefront of neuro immunology trailblazing, aiming to

build long-term value across a number of different stakeholders. Value for patients with meaningful, sustained benefit and improved quality of life. Value for physicians, with confidence in safety and durability.

And a broader eligibility for payers and healthcare economies, with reduced relapse and surgical burden, delivering long-term savings. And ultimately, value for Lundbeck and its shareholders by delivering clear differentiation, multi-indication potential that drives enduring value. And to take us through the financial results and outlook, I would like to now hand over to Joerg.

Joerg Hornstein

Thank you very much, Maria. From a pipeline of a product to read out of strong financials. It was another strong quarter for Lundbeck, as we continued to deliver solid performance with double-digit revenue growth the first nine months of 25, reflecting robust operation and momentum. Vyepti and Rexulti remain standard performers, supported by disciplined execution and efficiency gains.

Adjusted EBITDA margin reached 33.8%, underscoring our disciplined capital strategy that balances future investment with near-term delivery and maximised returns through focussed efficient capital deployment. Reflecting the stronger momentum of Vyepti and Rexulti, driven by additional investments, allows us to raise and narrow for full-year guidance for this year.

But let's move to the next slide for a deeper look at the financial. Revenue reached 18.5 billion, growing 14% at constant exchange rates, driven by continued strong performance across our strategic brands, which grew 20%. The adjusted gross margin was 87.8%, driven by the effect of costs related to a manufacturing contract for amlenetug.

Sales and distribution costs increased slightly, about 2%, to 5.7 billion, reflecting the redeployment of resources after the US Trintellix divestment and our continued investments in Vyepti and Rexulti in the US. Admin expense is unchanged and in line with expectations. R&D costs increased by 2%, reaching 3.4 billion, mainly driven by the continued progression of our Phase 3 programmes for bexicaserin, amlenetug and the maturing mid-stage pipeline.

The increase was partially offset by the MAGLi impairment loss recognised in the third quarter of 24, in the amount of 540 million. Adjusted EBITDA grew 22% at constant exchange rates, mainly driven by the strong performance of strategic brands. The adjusted EBITDA margin expanded to 33.8%, up 2.2 percentage points, reflecting strong operating leverage and continued disciplined capital reallocation.

Next slide, please. EBIT rose 58% to 4.9 billion, driven by a higher gross profit, reversal of the Vyepti provision for inventory obsolescence. This performance was partially offset by commercial restructuring costs and prior year impairment losses. Net financials reached an expense of 773 million, mainly due to unfavourable currency effects, mainly from the US dollar, and higher interest costs related to the new debt obtained in connection with the acquisition of Longboard.

Effective tax rate was 22% and in line with expectation. And net profit increased by 26% to 3.2 billion, while adjusted net profit and EPS rose by 10%, reaching 4.3 billion, reflecting the strong EBIT development, partially offset by higher financial expenses. Next slide, please. Cash flow from operating activities was in line with EBIT performance, reaching 4.6 billion, partially offset by higher prepaid tax payments, reflecting expected full-year income.

Cash flow from investing activities was an outflow of 409 million, mainly related to investments in property, plant and equipment. And last but not least, cash flow from financing activities was an outflow of 5.3 billion, mainly driven by the repayment of the loan facility used for the Longboard acquisition and the dividend payment to shareholders in March 25th. And this was partially offset by a €500 million bond issuance in Q2 to refinance the Longboard acquisition.

Next slide, please. On November 11th, we raised our full-year revenue and adjusted EBITDA guidance at constant exchange rates, reflecting continued strong year-to-date performance and positive momentum across the business. Revenue growth is now expected at 13% to 14%, up from 11% to 13%, driven by stronger than expected demand due to additional investment for Vyepti and Rexulti in the US.

Both brands continue to deliver robust growth across key indications. As Michala alluded to, we now expect generic entry for Abilify Maintena in Europe in 2026. Adjusted EBITDA growth has been upgraded to 22% to 25%, from 16% to 21%, reflecting the solid top line performance and the successful execution of Lundbeck's capital reallocation programme, which continues to enhance operational efficiency and profitability.

Our delta between constant exchange rates and reported rates remains, for 2025, as previously guided, around 1.5 percentage points below the growth. And adjusted EBITDA, around 1 percentage point below CER growth. The dollar FX rate has moved sideways between Q2 and Q3, but is, of course, substantially below the beginning of the year and

the average FX rates we have seen in 2024.

Which, for the time being, we foresee carrying over into 2026 in our future FX hedging level. Overall, a very good quarter and outlook for 25, reflecting the additional upside achieved by targeted investments and cost discipline. And with that, I would like to hand over back to Charl for final conclusions.

Charl van Zyl

Thank you, Joerg, and thank you to the team. Let me make a few closing remarks before we open for questions. If we can have the final slide, please, as a summary. First key takeaway for you is we are in a much stronger position than we were one year ago. We are advancing very strongly on our strategic path through very clear focus on growth, on innovation and on funding.

And we also see, across the quarters, as we have also, again, demonstrated today, we're very clear in our focussed execution of our strategy and, of course, very confident also in our mid-term guidance that we have provided. And our focussed innovator strategy, as a final reminder, is there to drive sustainable long-term growth for Lundbeck into the next decade. With that, I would open the floor for questions.

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 in the queue. If you wish to remove yourself from the question queue, you may press star and two. Questioners that are on the phone are requested to disable their loudspeaker mode while asking a question.

Anyone who has a question may press star and one at this time. The first question comes from the line of Charles Pitman-King from Barclays. Please go ahead, sir.

Charles Pitman-King

Hi, guys. Thanks very much for taking my questions. One quick question, please, on FY 26, just trying to think about the expected bridge to margins, given the divestment of your rights in non-core regions and this doubling down on the Brintellix Abilify erosion expected over next year. I'm just wondering, directionally, how we should be thinking about that, given the strong operational leverage which Vyepti and Rexulti should offset it with.

I'm wondering specifically if you could just touch on your thoughts around where FY 26 consensus is, including the FX headwind implied with your current hedging levels, just anything given a 3Q versus 4Q. But just having you give us direction would be really helpful. And then just secondly, a quick question on Vyepti. Given the label update, just

wondering if you could give us an idea of what the implication is of this for your formulary discussions, given Lundbeck has been aiming to shift Vyepti earlier in the treatment paradigm for migraine.

And just maybe the split of current use in the various lines of treatment that you see today versus recent quarters. Thanks so much.

Charl van Zyl

Thank you, Charles. And why don't we start with Vyepti and then we can go to your question on 26? Johan, do you want to do?

Johan Luthman

Thank you, Charl, for that question. We have submitted an sNDA for review. And this was ending up with a label update, as you understood. Which is very, very important because it includes one more study, study three, as it's called, the RELIEF study, which really verifies the very early rapid onset of action. But it's still under the umbrella of the original label, the indication label.

But it gives us data to promote and support the use in acute, ongoing migraine in prevention paradigms. But Tom can answer a little better how we can leverage on this.

Thomas Gibbs

Sure. Thanks for the question, Charles. We see this commercially as an element that enhances the overall clinical value proposition of Vyepti to really further strengthen what the perception is in the marketplace of having superior efficacy. And we continue to work hard to drive Vyepti earlier in the treatment paradigm. And we're seeing some good progress in that direction.

Joerg Hornstein

Let me take the two. I think the first one is, of course, it's a little bit too early to give a full-year guidance for 26. I think, overall, we provided mid-term targets until the end of 27 of a revenue CAGR of mid-single digit. And that's basically in the guidance we currently still see valid. In terms of Abilify Maintena, this is something that will impact us next year.

But it's also for us finding out a little bit more of the details of what are the assumptions country by country and also the expected erosion curve. And I think if you look into the effect out of the COM partnership project, then I think as we provided with the press release, we see probably an impact of around 650 million of capital that we are freeing up. On your question regarding hedging levels, we hedge our foreign currency exposure forward-looking 12 to 18 months.

In principle, we are nearly fully hedged also for 26. I think the best indication I can give you is to take the current FX level of the Danish krone versus dollar. Also, as the, you can say, average hedge rate for 2026.

Charles Pitman-King — Understood. Thank you.

Operator — The next question comes from the line of Kirsty Ross-Stewart from BNP Paribas. Please go ahead.

Kirsty Ross-Stewart — Hi, there. Thank you for taking my questions. It's Kirsty Ross-Stewart from BNP. Just firstly on Abilify, you're calling out the 30% share of Abilify Maintena in several European markets. Just interested to what extent you believe this has potential to even grow a little bit in Q4 before you see a generic impact in 2026.

And maybe just some colour on your experience this year in this quarter in Canada, where you saw a greater generic erosion than you expected. And just a bit of detail on where that erosion came from. Was that from the patients on Asimtufii only or did you also see a decline in Maintena prescriptions as well?

And then on the TED asset, just interested to see how you're thinking about the value proposition and positioning for the CD40. Are you thinking about this as a Tepezza-like offering high efficacy? But then they obviously are played by a few tolerability issues or more like a position that the FcRNs and IL-6s are going after, which is the lower efficacy, but improved tolerability.

And related to that, are you pursuing a sub-q formulation with this asset, like the other late-stage pipeline assets here? And just a very quick clarification, if I may, as well. One of your early slides says about the Asia filings for Vyepti coming in Q4 2026. I just wanted to confirm if it is indeed 2026 or Q4 2025. I just think we're expecting that by the end of this year. Thanks very much.

Charl van Zyl — Thank you, Kirsty. I think the question on our views on our assumptions on LOE, certainly the Canada learnings and then also how you think about Abilify. Michala, would you…?

Michala Fischer Hansen — Yes. Thanks, Kirsty, for the question. Let me see if I can take it one by one. On Abilify, you asked about our expectation for the rest of the year. And, of course, we continue to see, as I showed, strong conversion rates with the two-monthly formulation, both in the US and Europe International. And we expect to continue to see that also into next year, which, of course, helps us protect the franchise.

And when we talk about the Brintellix Canada erosion, actually, the erosion has been as expected, but it happened slightly earlier than we had anticipated. You can see the curves happened as, of course, there's both an erosion in volume and there is a price impact immediately at launch. And the curves have followed our expectations.

But as I said, they just happened a little bit earlier. Of course, in terms of forecasting the erosion curves, you see both the dynamic on price, also across Europe, and then you see a volume curve. And then, of course, the Brintellix gives us some learnings. We're here dealing with Abilify. It is an injectable. It's across both vial and pre-filled syringe.

There are a few more dynamics at play here. And then, of course, you have the multitude of countries with different dynamics as well that will also have an impact on the erosion curves per country.

Charl van Zyl — Johan, do you want to talk about TED?

Johan Luthman — Yes. First of all, let me emphasise the data I showed today were in acute TED. And as you may be aware, there are two distinct conditions, acute and chronic. And the chronic one is the second one people look into. And that's obviously when the acute inflammation is down and the progression of the disease has ceased. What we're aiming for here is to continue to evaluate this drug in both acute and chronic.

Which is very fundamental also because the mechanism of action is, as I mentioned, maybe also reaching into fibrotic tissue, which could have an effect on the proptosis. Yes, the higher efficacious drugs come with side effects and tolerability problems that are pretty severe. And we have no evidence from the CD40 cluster that would be a liability.

In our study so far and in other people's studies on this mechanism, they have really seen a very beneficial safety profile. You're obviously right. Tolerability is going to be important. In terms of efficacy, yes, we're looking for the chronic part. But our data are actually quite encouraging. We'll see what they can get in terms of more than 2 mm, because that's the key one on reversing the proptosis.

Too early to tell. Lastly, you talked about sub-q. And that's something we eventually will explore. It is in IV right now. Next step is a more extensive dose response study in TED, chronic and acute. And through that, we can explore whether we can push the limits of this drug to get sub-q.

Charl van Zyl — Thank you, Johan. And we confirm submissions in Asia as Q4 2025?

Johan Luthman — Yes.

Charl van Zyl — Thank you.

Operator — As a reminder, if you wish to register for a question, please press star and one on your telephone. The next question comes from the line of Marc Goodman from Leerink. Please go ahead.

Alyssa

Hi, everyone. This is Alyssa on for Mark. Thank you for taking my question. I'm curious for the bexicaserin programme, are you collecting any data that might give an indication on any cognitive benefit over time or other kinds of developmental endpoints that might give an indication on cognition? Also, have you given any guidance on when we might expect top-line data for that programme?

And then finally, the restructuring that was recently announced, you said in the press release, it will begin to commence in November. I'm wondering when we'll start to see the full impact of the restructuring, if it will be a slow ramp over the next few quarters. Thank you.

Charl van Zyl

Johan, would you comment on bexicaserin?

Johan Luthman

Yes. I can start with your question on cognitive benefits. That's a really, really great question. First of all, we're not seeing bexicaserin as a true disease-modifying mechanism. And some people look for cognition more with a longer-term disease modification. But it's a symptomatic modification that eventually can lead to improvements. Cognition is notoriously difficult to measure in children of different ages.

That's clinically something you don't put high on your readout. Of course, we are going to look at those things eventually, but that's not the main part of the programme.

Operator

Second question, top-line readout.

Johan Luthman

The other readout. As I said, the trials are progressing as we expect. And I think we have communicated our expected readout. And we have not changed on that timeline projection.

Charl van Zyl

Thank you, Johan. Michala, you want to talk about, our commercial operating model?

Michala Fischer Hansen

Yes. Thank you for the question, Alyssa. Essentially, the business will transition to the partners. By December 1st, we will be fully transitioned over. And, of course, we have been working for the last many months on planning for this and been in close dialogue with the partners. And therefore, of course, we expect that there will not be a slowing. It will basically be that we continue operations as we did before.

As we also mentioned in the press release, several of our employees will transition to the partner that is ongoing. Those processes are ongoing and not completed yet. But given that, of course, also it is our clear expectation that this will transition over and there won't be as such an impact on the ongoing business.

Joerg Hornstein

Maybe I will just add that, in terms of our restructuring cost

perspective, we have fully recognised 360 million of one-time costs in our Q3 figures.

Charl van Zyl — Thank you.

Alyssa — Thank you very much.

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

Lucy Codrington — Hi. Thank you for taking my questions. A couple on the pipeline, please. Just in terms of Rexulti for Alzheimer's agitation, obviously, we have the upcoming readout of Cobenfy in Alzheimer's psychosis. And I just wanted to get a better understanding of the overlap between those two conditions. How well are they differentiated? And is there any potential overlap between the two when it comes to treatment?

And then related to that, in terms of the primary care rollout, just so I can understand this, is this targeting primary care physicians in a bid to make them more comfortable? My understanding would be that a primary care physician might be more comfortable refilling an anti-psychotic rather than doing the initial treatment. And is the aim to try and improve that initial prescription from a primary care perspective with an antipsychotic?

And then secondly, on amlenetug, any read across from the recent failure of Takeda and AstraZeneca's alpha-synuclein antibody that was reported this quarter. I know it had taken a long time for that study to read out. So perhaps no surprises. But just any insights you might have on the differentiation between the two. And then finally, on Vyepti, and forgive me if I've totally misunderstood the market here, but do you actually have an idea, are all patients treated with the Vyepti infusion network?

And if not, what proportion are? And do you have an aspiration of what proportion you would like to eventually get treated within the network? Thank you.

Charl van Zyl — Thank you, Lucy. I think we start with the Rexulti question related to Cobenfy and indication.

Johan Luthman — Obviously, agitation and aggression, that is the Rexulti indication, is a much broader term. And sometimes you can see psychosis as the brother of agitation, but it's more specific a symptom. I'd like to just emphasise that with Rexulti, we're seeing a set of effects that are strongest in the most bothersome symptoms of agitation, aggression. And those bothersome symptoms are not generally psychosis. Those are other symptoms, physical or non-physical.

Verbal abuse. Spitting is part of this. And pushing and shoving. We have a very, very strong profile on a broader set of very troublesome symptoms that drive caregivers to, quite frankly, often give up the care. Psychosis is a subset where you have, as you know, hallucinations, etc. That is less playing out, but it can lead to aggression. That's why they're related to each other.

Charl van Zyl — Primary care focus on Rexulti?

Thomas Gibbs — Sure. Thank you for your question, Lucy. As you may or may not know, we have really defined three targets for our AADAD sales force, primary care physicians, psychiatry, and neurology. If we look at our current market contribution, over 60% of prescriptions are coming from primary care, about 25% from psychiatry and the remaining from neurology.

Based upon what we're seeing in the marketplace, the rollout of our expanded sales force will have 80% of our physicians will be targeted within the primary care segment, and they will be called on both for AADAD as well as MDD.

Charl van Zyl — Thank you, Tom. The question on amlenetug and our views on the mechanism of action differentiation.

Johan Luthman — Thank you for that question. It's the MedImmune AstraZeneca molecule that Takeda had in collaboration. The readout is quite limited impact on how we view our own programme amlenetug. And let me explain a few reasons why. Our amlenetug molecule has an active clearance mechanism, an antibody or something called an FCN.

And FCN is active with amlenetug, which actually enhances the clearance of the debris, meaning the different seeds of alpha-synuclein through microglia and macrophages. And the Takeda AstraZeneca compound does not have that. There's a very, very distinct and different mechanism. Also, the Takeda molecule has a shorter half-life and some other characteristics, some safety monitoring that they had in the trial, which we don't have.

But I think the key, key one is really that the mechanism is clearly distinct. And if you have some read-through from the Alzheimer's field, you know those drugs that made it to the market have active immune clearance through the innate immune system, meaning an FCN that is active.

Charl van Zyl — Thank you, Johan. The VIN network in Vyepti?

Thomas Gibbs — Yes. Thank you again for the question, Lucy. We have continued to drive more and more patients through the Vyepti infusion network because we think the patient

experience is a better experience based upon higher conversion rates and even best-in-class persistency rate. If we look back in 2023, only about 12% of our patients were going through the Vyepti infusion network.

That number is approaching 30% now. And we expect to continue to drive greater and greater percentage of the business through that channel.

Charl van Zyl — Thank you, Tom.

Lucy Codrington — Thank you.

Operator — We have a follow-up question from the line of Charles Pitman-King from Barclays. Please, go ahead.

Charles Pitman-King — Hi, guys. Just one quick follow-up. Wondering, just given the progress on tariffs made over the course of this year and MFN agreements through large cap pharma and the US administration, I'm just wondering what your thoughts are in terms of trying to quantify any tariff risk in 25 or 26, but also what your outlook is for the potential impact of MFN on Lundbeck's business?

What are you expecting? Are you expecting to have to negotiate with the administration? Or do you expect 232 tariffs to impact more broadly and no opportunity for avoiding those tariffs through a deal? Thank you.

Charl van Zyl — Thank you, Charles. First on tariffs, of course, it's more complex from a supply chain perspective. We also have a partnership with Otsuka. But as things stand now, year-to-date, we have had no impact on tariffs in our current 2025 numbers. And, of course, we keep monitoring it very closely. Understanding perspectives on different deals being made between geographies to better quantify to 2026.

But at this point, it's not possible for us to fully quantify that. On the most favoured nation part, we, of course, keenly watch the deals that are being made and monitor the progress there. But at this point, it is too early for us to comment on any impact that might have on our business today.

Charles Pitman-King — Understood. Thank you.

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 — Again, thank you for joining, of course, today. Appreciate your questions. And look forward to meeting all of you very soon. And also, of course, for our next engagement on the full-year results. Thanks. Thank you again.