

**Lundbeck**  
Q1 2025 Earnings Call  
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Transcript

**Speakers:**

Charl van Zyl

Tom Gibbs

Michala Fischer-Hansen

Joerg Hornstein

Johan Luthman

Charl van Zyl

So, welcome, everybody, to the Lundbeck earnings call for quarter one 2025. From the outset, I want to just make a quick statement to say these strong results of the first quarter are really serving as another proof point of the path we are on in terms of a focused, innovative strategy, confirming very much that the path is very strong for us going forward.

So let's go to the next slide, please. Of course, what we discuss today are forward-looking statements, and, of course, subject to change. Let me then go to the next slide, please. Of course, I have the privilege of being joined by my exceptional team here, who will cover the commercial update but also R&D, the financial update, as well as the outlook for the 2025 period.

So let's go to the key summary slide. And here again, I want to emphasise, as we've been consistent with you on a very clear equity story, which is one of advancing a focused, innovative strategy around three areas, growing the assets we have, growing them well, making sure that we build a compelling, innovative pipeline that will sustain the growth for the long term of the company, sustainable growth, and, of course, funding, thinking through very careful allocation and deployment of our capital to where we see the most opportunities for growth or innovation.

And, of course, I'm really pleased with the first quarter results, which are a strong validation of a lot of the effort and work we've done over the last 18 months to build the path going forward for Lundbeck. Firstly, our total revenue is growing at 16%, and our strategic brands, which now make up 77% of our revenues, is growing at 24%. And, most importantly, two key growth drivers for the long term, Vyepti at 62%, and Rexulti at 28%. So again, a validation of a strong execution mindset of the company, and making sure we focus our investment on where we can grow sufficiently for the mid-term.

On the innovation side, we are advancing the pipeline in the two areas, neuro speciality and neuro rare. And in neuro speciality, anti-PACAP, in its phase 2b, is progressing now to part B, which is the intravenous administration of anti-PACAP. We've also, in the first quarter, focused significantly on the integration and smooth transition of Longboard with bexicaserin, which is now at full speed on enrolment in phase 3, as well as amlenetug, and enrolling according to our plan. And we're also advancing anti-ACTH in congenital adrenal hyperplasia in phase 1b. So, of course, significant ongoing evolution of the pipeline, with more of the late stage phase 3 opportunities emerging.

From a financial perspective, the first quarter results, as I said, is a clear confidence in terms of our underlying performance, the

investment we've made, the operating model that we've established, which allows us to put ourselves in a position to raise the guidance, as indicated on this slide.

So when you think about Lundbeck going forward, here, it's a company with a clear strategic path, one of strategic clarity of where we focus. It's a company that is consistently delivering and executing on what we said we will do, and this is an execution-focused company. And, of course, you also see very briefly here, and as you will hear from my colleagues, it's a company that is in transformation and progressing very well. So with that, I would like to hand it over to my team, and have Tom and Michala comment specifically on the asset performance. Tom, please.

Tom Gibbs

Great, thank you, Charl. As Charl mentioned, we are pleased with our commercial performance for 1Q 2025, and this is primarily driven by 24% growth of our strategic brands. I'll first review the performance details for Rexulti. Next slide, please.

Rexulti continues to perform well and deliver consistent growth. And this is propelled by the continued strong progress within the AADAD segment in the US. US reported revenue increased 29% for the first quarter of 2025 versus the prior year. Importantly, this revenue growth was driven by strong underlying TRx demand growth in the US, with 22% growth during first quarter 2025 versus the same period last year.

Rexulti demand growth accelerated through the first quarter of 2025 in the US, recording record highs in market share, TRx and NRx volume. This demand growth is attributable to continued improvement and execution across the marketing mix, and this includes salesforce execution across the alliance, and optimised direct-to-consumer media mix, and patient affordability programmes. Growth in the US was supplemented by continued strong demand growth in Europe and international operations, delivering growth of 27% versus the same period last year.

Looking forward, we expect Rexulti to be a key driver of growth for Lundbeck, and this growth will primarily be driven by continued expansion of the AADAD franchise, supported by solid growth of our base business and MDD.

Let's take a deeper look at our progress and AADAD. Next slide, please. Rexulti AADAD volume is becoming increasingly important to overall Rexulti brand growth, and we expect this to continue through 2025 and beyond. AADAD monthly TRx volume has increased 472% versus baseline, and the AADAD contribution to overall demand for the brand has grown to nearly 21%, based upon the most recent patient claims data.

Growth is being primarily delivered by expansion of the HCP .

prescriber base growing 374% since launch, to over 11,800 prescribers. Rexulti AADAD market share has grown from 0.67 share points pre-launch to 3.44 share points based upon February claims data. Importantly, we continue to see consistent growth on the non-AADAD side of the business, achieving 11.1% growth when comparing January 2025 monthly claims TRx volume to January 2024. The AADAD launch has also had a positive halo effect on the overall brand. AADAD has fuelled 907% growth in the 65-plus segment when we look across all indications.

The team is continuing to focus on the levers to even further accelerate growth for Rexulti, and this is informed by our margin return on investment quarterly analyses. We are applying our dynamic resource allocation focused innovator principle, and redirecting a portion of our AADAD direct-to-consumer funds to expand our primary care footprint. And this will allow us to drive greater breadth and depth of prescribing.

Let's move on to Vyepti. Next slide, please. Vyepti, again, delivered strong results during the quarter, and this performance has been fuelled by continued strong growth in the US, and supported by robust adoption of Vyepti in prioritised ex-US markets, including Canada, France, Spain and Germany. Vyepti global net revenue for 1Q 2025 was DKK 1.042 billion, and this represents 62% growth over the same period last year.

Net revenue for Vyepti in the US was DKK 916 million, representing 60% growth over first quarter 2024. Importantly, we are beginning to see meaningful contribution to global sales by ex-US markets, with Vyepti now available in some 29 markets. These markets are exhibiting strong anti-CGRP market growth, and Vyepti continues to gain meaningful market share across these markets. Ex-US sales will receive a significant boost if approved in Asia, based upon the positive SUNRISE trial, and we expect to submit for approval by the end of 2025.

I do want to take a moment to focus on the US. Over the past eight months, we have made purposeful investments to refine our speciality, patient-centric commercial model to support Vyepti. We believe our model is a competitive advantage because it enables our team to appropriately support the patient throughout their patient journey. We continue to see accelerating demand by driving depth and breadth of prescribing, and continued positive momentum in new patient starts, supported by higher prescription-to-infusion conversion ratios and best-in-class patient persistency.

Looking forward, we expect Vyepti to continue to deliver strong growth, driven by new patient starts in the US, and expanded usage of Vyepti in all ex-US markets where the brand has

launched. Vyepti remains on track to achieve over \$1.3 billion peak-year sales at peak. Michala, over to you.

Michala Fischer-Hansen

Thank you, Tom. Let's start with looking at the performance of Brintellix in the Q1 25 results, where we see a very strong performance overall, growing at 7% versus Q1 24, and now delivering DKK 1.254 billion. We see a continued strong momentum in Europe and international operations, where we have seen double-digit growth in most of our markets. It's worth highlighting that we have a 17% growth in Europe, which was driven by Spain at 29%, and Italy at 23%, as well as continued strong growth in international operations at 8%, with Japan delivering 12%, and Canada growing at 22%, compared to the same period last year.

In Japan, I'm also pleased to share that, in the month of April, we achieved a significant milestone and now hold value market share leadership in the market for antidepressants at an impressive 22.6% value market share. When we look ahead, we expect to see continued solid demand growth in Europe and Japan. And I want to remind you that we extended our market exclusivity in Japan by two years, now with loss of exclusivity in 2031.

If we look to the US, you can now see the effects of the revised agreement with Takeda, which reflects a lower revenue, but certainly also a higher profitability. And this is a dynamic that we expect will continue throughout the year. I also want to remind you that while we have seen an impressive growth of 22% in Canada in quarter one, we do expect to see generic competition sometime during the year. Next slide, please.

If we look at our Abilify franchise, also here we see a solid performance in Q1 25, growing at 16%, and just now a little above DKK 1 billion versus quarter one last year. In the US specifically, we see an accelerated growth of 18% versus Q1 24. And this has been driven by a Abilify Asimtufii, and with a 1.6% market share growth for the franchise. Encouragingly, we continue to see a very strong uptake for Abilify Asimtufii, with approximately 52% of Abilify Asimtufii neutral-brand [?] patients coming from either oral antipsychotics, other long acting injectables, or naive patients.

In Europe and international operations, we saw growth of 15% versus Q1 24, and the Abilify LAI franchise continued to see strong growth across many markets, also driven by additional rollout and launches of Abilify 960mg, the Asimtufii name in Europe. When we look ahead, we expect to continue to see strong uptake of Abilify Asimtufii, or Abilify 960mg, while we, at the same time, expect a negative impact in Europe from generic launches towards the end of this year.

Let's zoom in specifically on the Abilify Asimtufii or Abilify 960mg performance. Next slide, please. When we specifically look at the performance of our Abilify Asimtufii 960mg, we do see the penetration ramping up very nicely. In the US, Asimtufii growth is now outpacing other LAIs, as I just said, and more than 52% of neutral-brand patients are coming from orals, other long-acting injectables, or naive patients.

When we look at the conversion rate in the US, we see that Asimtufii has had an aggressive conversion rate, now constituting 16% of total franchise in TRx volume. And importantly, we now also see the 20% of the NBRxs, which is a leading indicator of future TRx development, are Asimtufii prescriptions.

As you may recall, we started launching Abilify Maintena 960mg in Europe in June of last year, and we now have the drug available in 18 EIO, or international operations, markets, with Australia launching just here in May. We see a strong increase in the conversion rate, and have seen that both Spain and Finland have actually exceeded 20% conversion rate. The feedback we received from physicians is very positive, and early market research has suggested that around a third of the patients are coming from all aripiprazole.

The rollout of Abilify 960mg continues throughout the rest of 2025 across Europe and international operations markets, as we continue to see our regulatory approvals. That concludes the business update. I'd now like to hand over to you hand to Johan to give us an update from R&D.

Johan Luthman

Thank you, Michala. And thank you, Tom. It's very impressive to see the momentum our key brands, a testament to their strong therapeutic characteristics in the indications we're pursuing. So let us turn the page for our first quarter on 25 from an R&D perspective. Our two phase 3s in neuro rare programmes, bexicaserin in developmental epileptic encephalopathies, and amlenetug in multiple system atrophy, are progressing well, although still at early stages of enrolment in their pivotal trials.

The DEEp SEA and the DEEp OCEAN trials for bexicaserin are active in the US and are gradually starting in Europe, with more countries expected to be coming on board mid-25, including from the Asia region. We are not yet, however, at the time point of the trials where we have a firm validation of the predicted timelines.

Amlenetug, our alpha-synuclein antibody, the pivotal MASCOT trial continues to expand into further geographies, with enrolment expected to be active globally within the coming months. That means that we successfully completed regulatory activities for the trial with all key agencies, a critical achievement for this pioneering, innovative programme.

In addition, FDA has granted fast-track designation in February for the programme, and also in February Japan granted orphan drug designation for amlenetug. With the latter, will have now an orphan drug designation from US, Europe, and Japan. These designations are a testament to the high medical need this programme is aiming to address.

Concerning the FDA application for brexpiprazole in combination with sertraline for the treatment of PTSD, FDA in early January informed about the postponed decision date, and that they'd like to host an advisory committee meeting. After some delay, we now have a communication from the agency that this will be held on July 18th this year. For Rexulti, we're also pleased to have received approval in March for the treatment of adolescents in schizophrenia in Europe.

Turning to Vyepti, eptinezumab, in our last call, I spoke about the interesting life cycle management trial RESOLUTION reconfirming its strong efficacy. Let us now take a closer look at the trial, as we obtained results from the 12-week open-label part of the trial.

In this 12-week double-blind period RESOLUTION trial, Vyepti reconfirmed the strong efficacy seen consistently with the drug. The RESOLUTION results show rapid treatment effects, even in the most severely impacted migraine population, those with chronic migraine and medication overuse headache. As is evident from the right side of the graph, after the dotted line, patients switching from placebo to the Vyepti, when going into the open label period, saw similar improvements to that seen in Vyepti-treated patients during the placebo-controlled period, reaching a similar level of efficacy.

In addition, the 12-week open-label period demonstrated sustained efficacy from onset of placebo-controlled phase to the end of the open label trial. The robust and sustained efficacy seen on the primary end point was also confirmed on all key secondary endpoints in the placebo control, as well as during the open label period. So yet another data set on Vyepti that verifies this strong clinical profile in very severe margin conditions, underlining its best in class profile, not only in CRP area, but overall in migraine prevention treatment. Next slide, please.

Anti-PACAP IV holds the potential to address an unmet medical need. I've already been talking about we're looking forward to the... Sorry. Around last time last year, we moved our next generation migraine programme 222, and anti-PACAP IgG1 antibody in the phase 2b trial called PROCEED. The PROCEED trial is an adaptive trial, exploring different doses and routes of administration, 222 in patients with migraine for whom one to four previous preventive treatments have failed to provide a

benefit.

Also, the PROCEED trial has 12 weeks as the main readout time point, while our previous HOPE trial had a readout at four weeks. Thus, we're aiming to expand our understanding of the molecules potential to the PROCEED trial before initiating a future pivotal programme.

In the first part of PROCEED, we explored a range of subcutaneous doses. In late March, a pre-planned interim analysis triggered initiation of an IV dose-finding part to build on the previous positive HOPE trial. The first patient was randomised to IV administration already in early April. Next slide, please.

I'd like to remind you that the anti-PACAP programme 222 is investigating a new and differentiated mode of action compared to anti-CGRP treatments. PACAP and its receptors are broadly expressed. Moreover, abnormal PACAP signalling is involved in pain sensation, and neurogenic inflammation. Interference with PACAP signalling has therefore potential to affect multiple symptoms of headache disorders. It has also been shown in experimental human studies that PACAP induces migrant-like attacks that differs from CGRP-induced headache. PACAP induces a more delayed migrant-like attack associated with more premonitory effects like photophobia and facial pain.

With these biological and functional characteristics, we have the potential to see a differentiated clinical profile of anti-PACAP, different from anti-CGRPs. In more severe types of migraine, anti-CGRPs have established himself as effective treatments. However, still 30% to 40% of patients do not achieve adequate response, leaving a major unmet medical need. Anti-PACAP IV holds the potential to address this unmet need.

Also, I like to mention that with Vyepi we have a well-established efficacy by IV treatment, and we built an infrastructure in migraine prevention. Future IV anti-PACAP can leverage this established clinical infusion infrastructure. Next slide, please.

I have already been talking about looking forward to be able to hold an Advisory Committee meeting for brexpiprazole, also, in the coming months, we have a better clarity on the progression in our late stage development programmes for bexicaserin and amlenetug, once the trials are fully active globally. Anti-PACAP, as I just spoke about, is enrolling very well in the IV part of the PROCEED trial.

What I'd like to highlight here is more our early pipeline, where we see strong biology supporting our programmes, translating to interesting clinical data. A recent review of data for 909, the anti-ACTH programme in congenital adrenal hyperplasia and Cushing's syndrome, supported progressing towards formal

proof-of-concept evaluations. We're also very pleased to note that regulatory agencies are also seeing a breakthrough potential of this programme, that includes obtaining an orphan drug designation from FDA yesterday for the congenital adrenal hyperplasia indication.

Also for the 996, the oral active D1/D2 agonist programme for symptomatic treatment in Parkinson's disease, we have now a very encouraging data set on so-called Good On time, supporting progressing towards a formal proof-of-concept trial. We are also outlining right now a more clear overall development plan for this programme.

This summer, we are also building phase 1 further by a new chemical entity going into first-in-human initial evaluation. I hope that will be working out, so you will hear more about that programme in the coming years. With that, I'd like to hand over to Joerg.

Joerg Hornstein

Thank you, Johan. Before we go into the key figures of Q1, let me summarise the following. We had a strong start to the year, revenue reached an all-time high, up 16% at constant exchange rates, with strategic brands growing 24% now making up 77% of our total revenue.

Growth was led by Vyepti and Rexulti in the US, and supported by strong demand momentum across our key strategic brands and regions. Importantly, this was not just about revenue. We saw solid underlying demand trends, but volume growth was the primary driver of performance, particularly for our growth brands.

Adjusted EBITDA increased by 24%, and the margin expanded to 34.9%, reflecting strong operating leverage and disciplined resource allocation. We've been able to reinvest through our capital reallocation programme by continuing to improve cost ratios. EBIT was up 33%, and adjusted EPS increased 11%, despite higher financial expenses from the Longboard acquisition, a clear indication of robust underlying profitability.

Let's move to the next slide to look at the financial highlights in more detail. Our revenue reached 6.2 billion, growing 16% in the first quarter of 25 at constant exchange rates, driven by the continued strong performance of our strategic brands, which grew 24%. The adjusted gross margin was 88.9% and was in line with the same period last year. Sales and distribution costs increased 2% to 1.9 billion. The slight increase reflects targeted investments in Vyepti and the normalisation of Rexulti promotion activities in the US, including salesforce expansion. These were partially offset by resource redeployment following the Trintellix US transition and ongoing commercial model optimisation.

Administrative expenses increased 35% [?] to 359 million. The

increase was primarily driven by legal provisions for ongoing litigation, structural investments including Longboard integration, and indexation effects. A proportion of this increase reflects timing increases. R&D costs increased by 19.6%, reaching 1.2 billion, mainly driven by the phase 3 costs of bexicaserin and the anti-alpha-synuclein antibody.

Adjusted EBITDA grew 24% at constant exchange rates as a result of the strong revenue growth, despite continued investments in building the R&D pipeline. The adjusted EBITDA margin was 34.9%, representing an increase of 1.9 percentage points, reflecting strong operational leverage, supported by disciplined capital reallocation, which helped fund investments in R&D and brand growth, while continuing to improve cost ratios.

Next slide, please. Our EBIT rose 33% to 1.7 billion, reflecting the strong revenue performance, solid cost leverage, and lower amortisation of product rights, despite continued investments in R&D pipeline, progression, and structural investments. Net financials reached an expense of 221 million. Development is mainly driven by higher interest costs due to the new debt obtained in connection with the acquisition of Longboard and unfavourable currency effects, mainly due to the US dollar.

Our effective tax rate was 22%, down from 23% in the same period last year. Net profit increased by 15% to 1.2 billion, while adjusted net profit and EPS rose by 11%, reaching 1.5 billion. This growth reflects strong EBIT performance, partially offset by higher financial expenses.

Next slide, please. Cash flow from operations was in line with EBIT performance and offset by higher prepaid taxes, which reflected the expected income for the full year, resulting in total inflow from operating activities in the first quarter of 25 of 632 million. The cash flows from investing activities were an outflow of 111 million, mainly due to purchase of PP&E. The cash flow from financing activities were an outflow of 2.5 billion in the first quarter of 25, primarily driven by the repayment of part of the loan facility for the acquisition of Longboard, and higher dividends paid to shareholders in March 25.

Next slide, please. The performance in Q1 gives us confidence that we are seeing sustained momentum across our strategic brands, particularly Rexulti and Vyepiti, and that our resource reallocation efforts are supporting continued investment without compromising profitability. Based on the strong underlying demand trends and the progress in our disciplined capital reallocation programme, we are raising our full year guidance. We now expect revenue to grow between 8% and 11% at constant exchange rates, and adjusted EBITDA to grow between 8% and 14%.

On a reported basis, revenue growth is now expected to be equal to constant exchange rate, compared to around one percentage point higher previously. Adjusted EBITDA is expected to be around half a percentage point below constant exchange rate, which was two percentage points higher previously. Both changes are due to updated FX assumptions, primarily related to the US dollar.

Our full year guidance is based on exchange rates at the end of March, with the US dollar at 6.9 now closely aligned with our hedge rate of 6.79. This neutralises the prior expected upside from currency, but also significantly reduces our expected hedge loss to around 150 million, compared to 425 million to 450 million previously. We continue to guide for an adjusted gross margin between 88% and 89%, and R&D spend between 5 million to 5.2 billion.

In addition, depreciation, amortisation impairment losses are expected to be in the range of 1.7 billion to 1.9 billion. Net financial expenses are expected between 535 million and 585 million, primarily reflecting the impact of Longboard-related financing. Our effective tax rate is unchanged at 21% to 24%.

We remain mindful of the challenges ahead, particularly the anticipated loss of exclusivity on some of our strategic brands later on this year, including Brintellix, which is expected to face generic entry in Canada, and the continued transition to Takeda in the US. We also expect further erosion in the mature brand portfolio, with a projected mid-single-digit revenue decline. These dynamics remain fully reflected in our outlook and will continue to be closely monitored. With that, I would like to hand over to Charl.

Charl van Zyl

Thank you, Joerg. And thank you to the team for the update. Let me make some closing remarks before we go to questions. So, if we could have the next slide, please. And what you heard from us today is certainly a strong confidence and strong validation of our path towards the focused innovator and the strategy that we follow, strong business momentum that we see across the board, across our key strategic assets and across the geography. So the growth engine remains very strong. And it's a proof point, of course, of the work we've done over the last 18 months to ensure that engine is well funded for this growth. We see the advancement of the pipeline, as Johan had mentioned, but also see earlier pipeline opportunities coming to the fore.

And of course, with this we are, with the confidence we have in the underlying performance, able to raise our guidance and maintain a very healthy financial picture in our capital, with redeployment either to innovation or growth. So, again, strong performance, strong momentum, and strong confidence from the

management team on where we are heading with Lundbeck. With that, I think we can now open it 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 the telephone. You will hear a tone to confirm that you have entered a queue. If you wish to remove yourself from the question queue, you may press star and two. Questioners on the phone are requested to disable the loudspeaker mode while asking a question. Anyone with a question may press star and one at this time. Our first question comes from Marc Goodman from Leerink Partners. Please, go ahead.

Basma Radwan

Hi, good morning. Thank you for taking our question. This is Basma on for Marc. Our first question has to do with bexicaserin. Could you please provide some update regarding the enrolment in both DEEp SEA and DEEp OCEAN trials? And the second question has to do with the phase 1b of the 13909, please. What should we expect about the data that's going to be released? Is it going to be safety data only, or is it going to be some type of engagement data as well? And could you please remind us again how many dose cohorts were assessed in this trial? Thank you very much.

Charl van Zyl

Thank you for the question, Johan?

Johan Luthman

Yes, I'm not sure I heard the second question, but I will try. So, bexicaserin, your question was about enrolment rates, right? And that's why what I mentioned is that we are fairly early stage of the trials. We are just opening up more globally, so this is not a fully global open trial yet. And so we've not reached the stage where you really have solid proof points where you are, but so far, it's going well. We have had a number of regulatory interactions that have also been very supportive. So we're kind of through that phase of the trial, and open up to site activations right now. That's all I can say at this stage.

The second one was about, again, I didn't hear exactly. Did you talk about [overtalking] 909.

Basma Radwan

The 139...

Johan Luthman

Yes, that's a programme we've been actually presenting a little bit before. It's the dual indication programme that is going for both congenital adrenal hyperplasia and Cushing's, and we have data from both populations at this stage. We have mostly had an open-label approach with that study, and we're looking at exploring further doses in a more controlled environment. That will be the next step of the trial. So basically, more referring to a placebo response, building it up.

As I also said, we have an orphan drug designation on it now for congenital adrenal hyperplasia, but the programme is really built

on both indications moving forward. But we have flexibility in the programme going for either of those two indications. In terms of dosage, we're not at the stage where we're talking about the doses, because we're still at an exploratory stage.

Basma Radwan

Thank you very much. That's very helpful.

Operator

The next question comes from Michael Novod from Nordea. Please, go ahead.

Michael Novod

Thank you very much. First one for Johan. In terms of detail a bit more, what you sort of sense being the main topics on the AdCom for Rexulti in PTSD, and also how fast a potential decision can be made afterwards. Because now it's been in the hands of the FDA for quite a long time, so do you think they will be able to act fast following the outcome of the vote?

And then secondly, on the guide, can you try to elaborate a bit more, maybe in actual numbers, how much you actually put in terms of generic erosion? Because if you just take your first quarter and multiply by four, then you get to 13% growth in reported terms. So just to get a feeling for how much you actually put in, how conservative you actually are, and also whether you have already taken some cautiousness in, should there be any thing on tariffs, etc. Thanks a lot.

Charl van Zyl

Johan, do you want to comment on PTSD?

Johan Luthman

Yes. Obviously, the main topics we can expect to be, for the outcome, we can expect the usual two or three questions. Have we demonstrated efficacy sufficiently, the risk-benefit profile? And then, it's obviously a last question about the provability. Those are the general ones. There may be more specific questions. And obviously, in the action meeting, there will be many more topics to discuss. We are basically looking forward to get to this meeting. It's been delayed a few times. In terms of the decision, we have no indication from FDA when and how we can expect a decision after the AdCom. I think they'd probably like to hear the AdCom, and they like to mull over what they get from the AdCom before they reach a decision. So we have no new date for a decision. And as you know, they cancelled the PDUFA date, which was the official approval date in February.

Charl van Zyl

Yes, please, Jeorg.

Joerg Hornstein

[Overtalking] question, Michael. First of all, I think I would not just extrapolate Q1, because, as we've also stated in Q1, you had a you normalisation of inventory levels. That's an effect we would quantify approximately at 150 million that impacted our Q1 numbers. That, of course, is not reoccurring in the following quarters.

I think when it then comes to the outlook, it's mostly around the

three areas we talked about. It's the early, somewhat mid-year, expected generic erosion on Trintellix in Canada. It's basically the generics entry for the latter half of the year for Abilify Maintena and Europe. And it is clearly also the divestment of our Takeda agreement, or basically Trintellix agreement back to Takeda, which fully shifted into royalties. And that of course is on the back of an eroding brand towards the end of this year.

And I think your last aspect was in terms of impact of tariffs on our guidance. We have given a disclaimer that, of course, our guidance focuses on the operating part of our business and excludes impacts from macroeconomic environment. I think it's fair to say that 425 [?] we see from a tariff perspective, so far, not a significant impact.

Michael Novod Maybe just one follow up to Abilify Maintena, what is the status for what you've seen in terms of generic activities, trying to get approvals? What about price listings? Because I guess price listings are extremely important in those markets as well. If you don't have applied for price listing, then it won't happen, at least not in 2025. So can you give an update to that?

Michala Fischer-Hansen I can give an update that the latest we've heard is that it's still at clock-stop with the EMA. So, the regulatory file is still being processed. And in terms of payer activity, I don't have a lot of specifics at this point. But that, of course, also follows a regulatory approval by EMA.

Michael Novod Okay. Thank you very much. Thanks a lot.

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

Manos Mastorakis Hello. Thank you very much, and congrats on the results. So, two, if I may. The first is for Johan. What more can you share about what you've learned so far about the biology or administration of the PACAP molecule, given the outcome with the subcutaneous? And what would you say is the impact on your strategy and investments moving forward? Is that potentially where Vyepti increased investment is coming from? Just give us a little bit of a more high-level impact of the PACAP developments.

And maybe for Charl, I believe you previously said you'd be providing more colour on how the resource allocation programme is progressing. Maybe it's also a question for Joerg, really. But what can you share now, to be more specific, how long is this going to go for, this reallocation programme? How much more room for further improvement in terms of margins do we have? Thank you.

Johan Luthman Yes, I can start with the PACAP question. At this stage, we are progressing with the control studies, so we don't have full

insights into data. This is a switch that was preplanned in the protocol to be able to occur. So it's a usual phase 2a/b trial, where you try to really nail down the doses that are active from the initial very encouraging HOPE trial, which was an IV trial, as you may recall.

So the whole idea here is, of course, to explore subQ dose range and IV dose range. So I actually don't have much more to say. In terms of differentiation, it's a strong, differentiated profile biologically, and, quite frankly, also clinically, as I went through. The translation of that into differentiation against CGRP class or any other class, like with Botox for prevention of migraine is still unclear at this stage.

We have some data for this, and the PROCEED trial, where we look at different populations, and I like to remind you we're looking at people that failed prior preventive treatments. So that's also part to really, already at this stage, look at how the drug performs, which was also the HOPE population. And I think you asked about Vyepti and further...?

Charl van Zyl

Yes, I think, Manos, your question maybe alludes to are we, in a sense, focusing in our investment behind Vyepti, and the answer is no. Vyepti remains well-funded for its growth. And also, the investment we make from clinical development in anti-PACAP remains unchanged. And as Johan said, we will learn more as we read out the phase 2b and enter into phase 3.

Then, I think, Manos, your question was on capital reallocation. As we've always stated, we have, in essence, a target of achieving an ability to have flexibility of around 10% of our capital, so DKK 1 billion to DKK 1.5 billion. And we are progressing very well with that. That's coming from either additional growth or from being very efficient in how we operate. And we see that we have a strong line of sight to be able to bake all of that into our mid-term. And it allows us, of course, as an example, today, to be able to absorb the phase 3 programme of bexicaserin into our P&L and remain within a healthy financial picture.

So I think that gives you a sense that we're executing against it, transforming the company, but also being very mindful around how we redeploy the capital in the best place going forward.

Manos Mastorakis

Thank you very much.

Operator

The next question comes from Xian Deng from UBS. Please, go ahead.

Xian Deng

Thank you. Thank you for taking my questions. Two, please. The first one is I know there are still a lot of uncertainties, but just wondering, what are your initial thoughts on most favoured nation [?] drug pricing? Especially just wondering for Rexulti,

where you have relatively limited European launch, just wondering, I know it's a lot of uncertainties, just wondering what are your initial thoughts on this. That's the first question.

And the second one is for Johan. If just may just follow up on the PACAP question, just wondering, because usually the conversion from IV to subQ formulation is relatively straightforward, the KEYTRUDA, a lot of oncology drugs, stuff that many use reformulation technology which is relatively mature. So just wondering if you could give us colour or any theories of what actually happens, so why the subcu dosing didn't work out as planned? Thank you very much.

Charl van Zyl

So let me start with the first question on, I think, your question around overall policy outlook. Of course, as we are all again stating that today we don't have knowledge that gives us a clear indication of where this will go. We are very focused, as we are with all governments across all countries, to make sure that access for patients is the top priority. But at this point, it's speculative to really quantify what this might mean for us.

And so I think as an industry, we're working closely with all governments to ensure that access for patients to innovation remains unchanged. Johan, do you want to comment on anti-PACAP?

Johan Luthman

Yes, thanks for the question. Let me start by reminding you about the HOPE trial, where we really went out to test whether this mechanism may work. So, we had a high dose, what they call a high dose, which was really hammering the target, very high dose. And then, we had a somewhat lower dose in a smaller group of patients. So that was really us finding whether the biology delivers anything. What we're doing in the PROCEED trial is going down in doses. We're pushing it downwards to see how far we can go down, which is extremely important, particularly for antibody therapies and the cost of goods, etc. So we pressing the margin downwards.

In terms of what happens when you do that, I can only speculate, because, as I said, I haven't seen the data. There could, of course, be other factors playing a role, but dose is one of those factors pressing it down. It's also pharmacodynamics. If you give a drug IV, you have a hit and run, pharmacologically, much more than is subcu. Subcu is a much more delayed way of interacting with the target. So it's very important for us to look at ,basically pharmacokinetics coupled to target engagement.

Because the turnover of PACAP, which is the driver of the biology here, is not extremely well known in migraine conditions, or not even normal in man. So there are many PKPD- related things that we'll find out, hopefully, in the data set. Otherwise, I can speculate, but it's better to get the data, and we'll talk about

it once we have it.

Xian Deng Thank you.

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

Charles Pitman-King Hi, guys. Thanks so much for taking my questions. A couple of quick clarifications. Just firstly, on your condensed statement of cash flows, I've just noticed that there's a little bit less disclosure, so wondering if you're going to be providing expanded cash flow financials, or should we consider this to be the kind of level of disclosure to expect going forwards, for example the breakdown of depreciation, amortisation in your cash flows?

Secondly, just going back to the PTSD question, given the kind of delayed launch time frame, I know previously you were saying no change to peak expectations if you achieve it by the end of 1H, now it likely will be end of July suggests maybe there's a quarter or two further delay to bringing that to market. Does that impact your peak sales expectation for the indication?

And then, on the Brintellix strength, you highlighted the double-digit European growth, what do you credit this rather strong growth to, so many years after its launch? Are you reallocating efforts behind that following the end of the Trintellix deal with Takeda? And can I just double-check that you are expecting generic competition in Japan by the end of this year for Trintellix, given slide nine's market exclusivity extension of two years comment? Thank you.

Charl van Zyl Thank you, Charles, for that question. Let's start with cash flow.

Joerg Hornstein I'm happy to take the first question. Of course, we're, in principle, providing statement of cash flows in the current form, similar to how we've always done it over the past quarters. And that's actually exactly the way how we will also present it going forward.

Charl van Zyl Thank you, Joerg. Tom, would you like to comment on PTSD peak sales, timing of launch?

Tom Gibbs Thank you for the question, Charles. When we look at the PTSD forecast, clearly there will be a delay based upon the AdCom. And once we hear back from the AdCom, we will be able to mobilise our resource and launch, honestly, the next day related to beginning to start commercialisation.

On the forecast, you basically just do a lift and shift as it relates to the peak year sales. And because we're going to be going generic in 2029, we had peak-year sales projected in 2028, and we believe that we can still achieve that number.

Charl van Zyl Can I just build on your comment to remind all of those who have

dialled in that, of course, we still remain with a 50-50 chance of an approval. Although we have an AdCom, it is not in our mid-term guidance, and so this is, of course, to be very clear, how we see this indication, with the outside chance of approval.

The question, then, for you, Michala, was around Brintellix. Your confidence around why it's growing so well in Europe? Of course, I would say the organisation, what you're putting in place. And then, what is the timing on Japan for Trintellix.

Michala Fischer-Hansen

So, thank you for the question, Charles. Let me start with Europe. We continue to see a strong execution of our strategy, which, of course, has a level of going deeper with our prescribers. But also, in some areas, we've expanded into new segments of the prescribers, so that is what's bringing us a strong growth. So a continued strong execution in the marketplace, and investing behind Brintellix to the tune that it is still relevant, given the stage of the cycle.

With regards to Japan, maybe a misunderstanding. The generic has not been intended for Japan this year. We were mentioning Canada, that we expect to see generics in Canada this year. Japan, I can confirm that we have gotten an extension, or indication that gives us a two-year extension, to 2031. So no generics expected for Brintellix in Japan this year. It's Canada. So just wanted to confirm that.

Charles Pitman-King

Perfect. Thank you very much.

Operator

The last question for today's call comes from Shan Hama from Jefferies. Please, go ahead.

Shan Hama

Hi. A couple from me, please. Could you just clarify how you expect Rexulti's performance to develop throughout the rest of the year, particularly in terms of a new goal for Alzheimer's agitation as a percentage of the Rexulti brand? And then, I know you pointed towards strong performance in Alzheimer's agitation and MDD, but are you seeing any weakness or perhaps share-taking in schizophrenia?

And then finally, your guidance raises the EBITDA level, implies potential for EBITDA growth at a higher level to revenue growth for the year. Could you just tell us some of the key levers to achieving the top end of that profit range? Thank you so much.

Tom Gibbs

Thank you for the question, Shan. As we look at Rexulti performance, we're pleased with the progress that we made during the first quarter of 2025, and we expect that trajectory to continue for the rest of the year. As I said, this will primarily be driven by the continued uptake of AADAD, supported by consistent performance for the MDD franchise as well.

As relates to schizophrenia, schizophrenia represents about 8%

of our total business. So it's very, very small. And if we look at source of business for the new competitors that have entered the marketplace, we really have seen a de minimis impact in terms of switches from Rexulti to the new competitors in schizophrenia.

Joerg Hornstein

Coming back to your question, I think, first of all, it's the strong revenue growth that drives the improvement of, basically, 3% increase in our guidance on adjusted EBITDA. Clearly, we have also reflected, I would say, towards specifically 25, a bit of a higher ambition on cost discipline around especially contribution out of a global procurement for growth programme.

Shan Hama

Thank you.

Charl van Zyl

No other questions? So, with that, I assume we can close the call. And want to thank everyone for joining today. Look forward to seeing you very soon.