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Lundbeck Financial statements for the full year 2025

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Transcript

Speakers:

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Thomas Gibbs

Michala Fischer-Hansen

Charl van Zyl

Good morning, everyone. Welcome to our Full Year 2025 Earnings Call. Of course, it's my pleasure to really present to you our outstanding results. It's been, again, another record year for Lundbeck in 2025 and it's really underpinned by very strong fundamentals, very much underpinned by our Focused Innovator strategic path. You will hear me say a lot about the results very much in the sense of it is not by chance but by clear intent that we are delivering these outstanding results.

If we can go to the next slide, please. So, of course, our discussions today are containing forward-looking statements which, of course, are subject to change. Let's go to the next slide, please. And here I would like to take a moment just to pause and reflect on the last two years of our Focused Innovator Strategy. There is so much to say about this transformation that Lundbeck has gone through, but I have to say I am really proud of the progress that we have made.

Again, it is not by chance but by clear strategic intent that we see these very strong results. If you recall, our Focused Innovator Strategy is very much about growth, innovation, and funding. When I speak about growth, you would have seen over '24-'25 that we have had double-digit growth across our strategic portfolio, which allows us in a way to extend our growth also into 2026.

Secondly, when you think about innovation, we made the acquisition of Longboard that bolstered our late-stage pipeline, but we have truly seen a transformation of this pipeline over the last two years with the position we are in now with five to six mid-to-late stage assets that are really the growth engine of the future of Lundbeck. And it's a pipeline that is characterized by first-in-class or best-in-class molecules.

The third foundation of our strategy is really the funding, the largest capital reallocation that the company has undertaken, and it has allowed us to fund the growth and the pipeline and keep us in a flexible financial position to continue that journey into 2026.

If we go to the next slide, I'd like to focus further more on 2025. And truly, it was an outstanding and a record year for Lundbeck. Again, our intent was to focus on investing in our strategic brands, but also in our pipeline. On the growth level, we have seen that continuation of the double-digit growth on the strategic brands being at 19% in 2025, underpinned by stellar growth in Vyepti of 59% and also stellar growth for Rexulti at 23%.

As you recall, we also made very clear moves in 2025 around sharpening our commercial model to focus on 12 key markets and allowing us to work with partners across 27 markets, again, allowing us to focus our efforts on where we can play to win and grow very strongly as we go also into 2026.

When you think about the pipeline, keep thinking about the fact that we are building strong diversification of this pipeline, building a strong position in neuro-specialty and also in neuro-rare. When you think about neuro-specialty, of course, Vyepti is a growth engine in the U.S. and in Europe, but also soon to become a growth engine with the filings that we have done in China, Japan, and Korea to truly make this a global launch for Lundbeck.

You will also in the first quarter receive results on our anti-PACAP PROCEED trial that will further enhance our position in the space of severe preventative migraine. When we think about neuro-rare, we think clearly about bexicaserin, of course, the Longboard acquisition that is very much in this Phase III and in execution of the clinical program, and so is amlenetug in its fast enrollment also in MSA. Both of these are really high unmet need areas where we can see the opportunity very strongly in the Phase III results.

Then we will talk a bit more today about further elements of the pipeline in the mid-stage, our anti-ACTH in Congenital Adrenal Hyperplasia as well as Cushing's disease and you will hear more about that from the pipeline discussion later today.

Fundamentally, the funding that you see is a continuation of the first two years of our Focused Innovator Strategy where we will continue to be disciplined around our capital reallocation in this range of 1.3 billion to 1.5 billion that we are freeing up to create that flexibility for us to invest in growth and also in innovation.

Therefore, we are guiding today very much in a position of strength from '24 to '25 going into '26 with revenue growth of 5% to 8% and adjusted EBITDA between 4% to 12% with that spread also taking into account a strategy of investing in the pipeline as we see the triggers unfold in 2026.

So with that, let me just introduce the other speakers for today on our agenda and you will hear a business update from the team as well as a portfolio update and of course the financial results in more detail.

So with that, it is my pleasure to first of all start with the business update and hand over to Tom Gibbs, our Head of the U.S. Thank you, Tom.

Thomas Gibbs

Great. Thank you, Charl. As Charl just mentioned, we are pleased with our commercial performance for 2025, which is headlined by strong growth of Vyepti and accelerated growth of Rexulti. Please turn to the next slide and I will first review the performance details for Vyepti.

Vyepti delivered strong and sustained growth for the full year 2025, and we expect this to continue in 2026. This performance has been powered by continued strong growth in the U.S. and supported by robust adoption of Vyepti in prioritized ex-U.S. markets including Canada, Italy, France, Spain, and Germany.

Vyepti global net revenue for 2025 was DKK 4.476 billion, and this represents 59% growth over the same period last year. Net revenue for Vyepti in the U.S. was DKK 3.908 billion, growing 58% over prior year.

In the U.S., our focus has been to make purposeful investments in our patient-centric model supporting Vyepti through our disciplined capital reallocation program that Joerg will speak to later.

We will continue to make incremental investments in 2026 to elevate the impact of our execution informed by our advanced analytics capability and this includes a sales force expansion as well as optimized direct-to-consumer advertising.

We expect to sustain the market-leading demand growth by driving depth and breadth of prescribing and continued positive momentum in new patient starts supported by high written-to-infusion conversion ratio and best-in-class patient persistency.

In Europe and International Operations, significant work is being done preparing for the launch of Vyepti in Asia. And if approved, we see this region as a significant opportunity to drive further growth for Vyepti. Next slide, please.

Now moving on to Rexulti. Rexulti continues to perform well and deliver consistent growth propelled by continued strong progress within the AADAD segment in the U.S. Reported revenue was DKK 5.745 billion, increasing 23% for the full year 2025 versus prior year.

Importantly, revenue growth in the U.S. was driven by strong underlying TRx demand delivering 24.2% growth in 2025 compared to 2024. Rexulti AADAD volume is becoming

increasingly important to overall Rexulti brand growth, and we expect this to continue through 2026 and beyond.

AADAD monthly TRx volume has increased 725% versus pre-indication baseline, and the AADAD contribution to overall Rexulti demand has grown to 24.4%. Importantly, the 65+ segment now contributes 34.8% or more than one out of every three Rexulti TRx claims based upon the most recently available claims data.

The team in the U.S. is continuing to focus on the levers to drive continued growth for Rexulti informed by our margin return on investment analyses. As you may recall, we reallocated a portion of our DTC advertising for AADAD to expand our sales footprint and this is mainly in the primary care segment.

The first wave of the expansion of our multi-specialty sales force team was deployed during 3Q 2025, and we are encouraged by the early results. The second wave is ongoing and we expect to be fully deployed during first quarter 2026.

Overall, we are pleased with the momentum of Rexulti demand exiting 2025 despite an increasingly competitive market and evolving policy landscape. TRx demand in fourth quarter 2025 grew 24.2% versus fourth quarter 2024.

Precision execution across the marketing mix, including our expanded sales team in primary care is expected to reinforce the long-term growth for Rexulti and help address increased competition. Michala, over to you.

Michala Fischer-Hansen

Thank you, Tom. Let's turn our head to the Abilify franchise performance where 2025 was another year of solid growth momentum for the franchise, growing at 10% versus last year overall, now at DKK 3.776 billion.

If we look at the U.S. first, the Abilify franchise delivered a 9% growth compared to the year before and that was also resulting in a gain of 1.1 percentage point market share. Importantly, as the U.S. is transitioning from franchise maximization to conversion maximization, Asimtufii continues to be a key growth driver with an encouraging 22% NBRx weekly conversion rate.

If we turn to Europe and International Operations, the franchise delivered 10% growth versus last year. This was driven by continued launches of Abilify Maintena 960mg which is now launched in a total of 27 markets across Europe and International Operations. We continue to see strong conversion rates across our key markets, with several markets surpassing 20%.

Across the markets, we also continue to see encouraging conversion rates from other orals and atypicals in LAIs that are outside of our Abilify Maintena franchise. Looking ahead, conversion maximization remains a critical strategic focus, and with regards to generic competition for Abilify Maintena 1M in Europe and International Operations, we expect to see generics in the market in Q2 of 2026.

Next slide, please. If we turn to the 2026 outlook, as Charl said, we are pleased to see that despite the pressures from generics that we expect, the strong performance of our strategic brands reinforces our confidence in updating our 2026 growth outlook where we are pleased to guide a 5% to 8% revenue growth in constant exchange rates.

Let me unpack that for you. In 2026, we expect to see headwinds from increased generic pressures on Abilify Maintena and Brintellix, the reprioritized resources with the Takeda agreement in the U.S., as well as emerging competition on Rexulti. This is outweighed by a continued strong performance of Vyepti, Abilify, Cipralex, and Rexulti.

2026 will also reflect in-year commercial adjustments that impact on our reported revenue growth. As mentioned by Charl, in December 2025 we implemented a sharpened commercial model where we introduced 27 partner-driven markets. These partners will receive a commission fee of 25% to 30% of our revenue, which will reduce our net revenue compared to 2025.

In addition, as part of the transition to the partner model, the partners are building up inventory in the market, which is expected to amount to approximately DKK 500 million positive revenue impact in 2026, which would be a one-time effect for this year.

When adjusting for the partner model impacts, we are encouraged that our underlying performance is expected to be at 6% to 9% underlying growth reflecting strong fundamentals as a result of the strategic decisions we have taken in 2024 and 2025.

Specifically for our guidance for '26, as stated, we are pleased to guide a 5% to 8% constant exchange rate revenue growth for 2026, which is driven by our continued strong brand execution and our accelerated capital reallocation towards high-value opportunities globally. Joerg will come back to this in his section.

With this I conclude the performance section and hand over to my esteemed colleagues Maria and Johan for a portfolio update.

Johan Luthman

Thank you, Michala and Tom. It is great to see the continued very strong commercial performance throughout the full year '25. Maria and I will take you through the portfolio update.

Overall during '23 and '24, we paved the way for the pipeline to go through critical value inflection points in 2025 with positive data emerging from several early-stage projects. This means, as you heard from Charl, that we can with confidence say that we will have five to six mid-to-late stage assets in the pipeline by end of 2026 for six to eight indications.

From an R&D perspective, 2025 has been a solid year of execution and progression. We have continued to advance our research pipeline with innovative assets, with highly innovative and strong programs entering into development. I like to highlight that we initiated a strategic partnership with Contra marking Lundbeck's first entry into oligonucleotide-based medicines.

As I mentioned, maturing the Phase I portfolio has triggered several programs to progress towards Phase II starts during 2026. At the same time, we have executed well on our late-stage development programs as well as continued critical brand support primarily for Vyepti.

In early-stage development, we have made extensive use of focused Phase Ib exploratory proof-of-concept studies, allowing us to generate patient data and progress programs with strong biological and clinical validation. As you have seen in the last two quarters, this has led to data supporting progression of our D1/D2 agonist 996 in Parkinson's disease and our CD40L blocker 515 in thyroid eye disease to Phase II initiations.

Next is our anti-ACTH mAb 909, now with the INN name asedebart. Maria and I will return to asedebart in a few minutes. For late-stage programs, 2025 marked the year executing on our two Phase III programs, bexicaserin and amlenetug, with progressing recruitment and continued health authority interactions.

In Q4, bexicaserin was granted breakthrough designation in China for DEE, and amlenetug received fast track designation with the FDA as well as orphan drug designation in Japan. Also during 2025, we completed enrollment in the PROCEED Phase IIb trial.

Finally, turning to our strategic brands, for Vyepti, we have now completed the Asia filings based on the SUN programs

in 2025 with submissions in China and Japan in Q4, completing the global rollout of the program.

On Vyepti, we also continue to generate strong data on efficacy and effectiveness in severe migraines. Overall, this reflects a year of discipline and generally very successful pipeline progression.

Next slide, please. Our pipeline progression is underpinned by strong scientific momentum. During 2025, Lundbeck maintained broad engagement across the scientific and medical community with many medical conference attendance and 114 scientific presentations and several high-impact publications in peer-reviewed journals.

This level of activity is not just about visibility; it enables continuous external dialogue and validation of our science with clinical and academic experts. Importantly, this momentum continues in 2026 with strong presence planned at several medical conferences.

Let me showcase some of those. For AD/PD here in Copenhagen, we will present Phase I data for our D1/D2 agonist 996, with further data being presented at the MDS meeting. Also at AD/PD, we will present the design of the innovative approach in the amlenetug pivotal program.

For AAN, we have four programs presenting data: Vyepti including new data from the INFUSE real-world evidence study in prior anti-CGRP treatment failures; bexicaserin data from its Phase II PACIFIC trial; and amlenetug expert input in what would constitute a clinical meaningful effect.

Finally for 222, our anti-PACAP mAb, we will present data from two Phase I trials. However, much more importantly for 222, we will present the PROCEED Phase IIb headline results at the American Headache Society meeting as well as later in June at the European Academy of Neurology.

Since Lundbeck in recent period has obtained very encouraging data in neuroendocrinology for the CD40L blocker 515 and asedebart, we will showcase our emerging presence in this space at the ENDO conference in June.

As promised, we will now turn over to speaking more about Asedebart. Maria.

Maria Alfaiate

Thank you. As Johan just outlined and Charl mentioned in his opening remarks, our pipeline is progressing with increasing clarity, focus, and value inflection. Asedebart is a strong illustration of that strategy in action.

Asedebart represents one of our most differentiated first-in-class programs moving forward with a clear scientific

rationale and a well-defined development path. Asedebart is an anti-ACTH monoclonal antibody designed to address the root cause of cortisol and androgen excess. This mechanism directly differentiates it from existing therapies that focus on downstream hormone control rather than disease modification.

We are advancing asedebart in two rare endocrine indications: ACTH-driven Cushing's syndrome and Congenital Adrenal Hyperplasia. Together, these indications represent more than 80,000 patients globally, currently underserved, and share a common prescriber base enabling efficient development, regulatory alignment, and future commercial leverage.

Importantly, we have already secured orphan drug designation in CAH in both the U.S. and EU, reinforcing the regulatory attractiveness of the program. From an unmet need perspective, the rationale is clear. In ACS, patients lack targeted disease-modifying options and are often exposed to complex polypharmacy with significant safety limitations.

In CAH, currently approved treatments provide suboptimal disease control and rely on chronic glucocorticoid exposure with well-known long-term risks. Asedebart's differentiated profile positions it to create value across different stakeholders.

For patients, it offers the potential for improved tolerability in ACS and superior efficacy in CAH. For payers and reimbursement authorities, meaningful differentiation on key outcomes supports reduced total cost of care. For healthcare professionals, it enables a simpler, more predictable approach to long-term disease management.

For Lundbeck, solidifying our ambition in neuro-rare diseases supporting long-term pipeline and value growth. In summary, consistent with the pipeline progression Johan described, asedebart perfectly exemplifies how we are advancing focused, high-impact assets with clear differentiation, regulatory momentum, and significant upside potential.

For a more detailed look into one of these indications, I will hand back to Johan.

Johan Luthman

Thank you, Maria. Next slide, please. With that unclear medical need as defined by Maria, let me show an example of the strong data we obtained for asedebart, in this case for Congenital Adrenal Hyperplasia.

In CAH, chronic ACTH elevation drives adrenal overstimulation, leading to excess production of androgens and their precursors. Current treatments primarily rely on glucocorticoids, cortisol replacement, which represses ACTH indirectly, but as you heard from Maria, often with the cost of long-term overexposure associated complications.

By directly targeting ACTH, asedebart is designed to intervene upstream in the disease pathway, reducing adrenal overstimulation and downstream hormone excess at its source. This provides a clear, strong biological rationale. 17-hydroxyprogesterone, 17-OHP, is a precursor in the production of cortisol.

When cortisol production is hindered by CAH, the body produces excess of 17-OHP in the adrenal glands and gonads, and thus elevated 17-OHP is a diagnostic biomarker for the indication.

In an ongoing multi-site, open-label, multiple-dose trial in patients, we could demonstrate effective engagement of the ACTH pathway. As you can see, following an infusion of asedebart, at 24 hours there is a 90% to 98% reduction of 17-OHP from baseline.

We also looked at androstenedione, or A4, a key marker used to monitor treatment efficacy and disease control. Like 17-OHP, we see reduction in A4 following asedebart infusion ranging from 65% to 90% compared to baseline. These pharmacodynamic effects provide a strong reason to believe in the potential of asedebart to address core disease drivers in CAH.

From a safety perspective, asedebart was well tolerated with no serious or severe adverse events reported. With this data set, we can now conclude the Phase Ib part of the ongoing Phase I/II study and move into the Phase II part of the study.

Next slide, please. Finally, let me place this in the broader pipeline context. In addition to CAH, we also have data for asedebart in a similar Phase I/II open-label study in Cushing's disease. Cushing's is a condition caused by ACTH-secreting pituitary adenomas, leading to excess cortisol production by the adrenal glands.

We have now very encouraging Phase Ib data to be presented at ENDO, supporting progressing asedebart to Phase II for this indication. Together with our CD40L blocker 515 in thyroid eye disease and our D1/D2 agonist 996 in Parkinson's disease, we have three assets across four indications progressing towards larger Phase II trials.

As mentioned already, 222 headline results from PROCEED Phase IIb is a near-term catalyst and if positive, the program holds potential to expand our migraine efforts into a franchise with addition of a novel mechanism of action product.

In conclusion, while progressing our current Phase III programs, we are progressing several additional first-in-class and sometimes first-in-indication programs supported by clinically validated biology, building a solid mid-to-late stage pipeline. With this, I'd like to hand over to Joerg.

Joerg Hornstein

Thank you, Johan and Maria, and please allow me a few opening remarks before we turn to our key figures. Over the past two years, we have executed within a very clear financial framework: prioritizing growth behind our strategic brands, accelerating innovation, and funding this through disciplined capital reallocation. This focus is clearly reflected in our results.

From a growth perspective, we delivered strong double-digit revenue growth in '24 and '25, exceeding expectations and underpinned by exceptional performance from Vyepti and Rexulti. This has translated into a strong gross profit growth providing operational leverage allowing us to both expand margins and step-up investment where it matters most.

This is why we enter 2026 with confidence and a clear strategic intent. We have strong commercial momentum, a sharpened operating model, and a significantly strengthened mid-to-late-stage pipeline with several key milestones ahead including PACAP. From a financial standpoint, this supports both our growth outlook and the guidance ranges we have provided.

With that, I will now turn to the financial performance for '25 and our guidance for 2026. Next slide, please. Revenue reached DKK 24.6 billion growing 13% at constant exchange rates driven by strong momentum across our strategic brands which grew 19%, predominantly reflecting accelerated growth in Rexulti and Vyepti. The adjusted gross margin was 87.5% impacted by a reservation fee related to a manufacturing contract for amlenetug.

Sales and distribution costs decreased slightly by -2% to DKK 7.7 billion reflecting the execution of the Focused Innovator Strategy alongside disciplined resource allocation and capital reallocation.

Administrative expenses reached DKK 1.5 billion corresponding to a slight increase of 4% at constant exchange rates in line with expectations. R&D costs

increased by 10% reaching DKK 4.9 billion mainly driven by the continued progression of our Phase III programs for bexicaserin and amlenetug and a maturing mid-stage pipeline.

The increase was partially offset by the MAGLi impairment loss recognized in '24. Other operating expenses reached DKK 969 million primarily reflecting an impairment loss of a non-strategic production site in Italy for around DKK 600 million and commercial restructuring costs of around DKK 400 million related to the transition of 27 markets to a partnership-led model.

Adjusted EBITDA grew 24% at constant exchange rates mainly driven by the strong performance of our strategic brands. Adjusted EBITDA margin expanded to 32% up 3.2 percentage points reflecting our strong performance in '25, continued disciplined capital reallocation, more than offsetting the R&D cost increase from the acquisition of Longboard Pharmaceuticals and the shift to a more mid-and-late-stage R&D pipeline.

Next slide, please. EBIT rose 59% to DKK 5.3 billion driven by higher gross profit and lower sales and distribution costs. This performance was partially offset by higher R&D costs and other operating expenses associated with our commercial restructuring and an impairment loss of a non-strategic production site as earlier mentioned.

Net financials reached an expense of DKK 788 million mainly due to higher interest costs related to the new debt obtained in connection with the acquisition of Longboard and unfavorable currency effects, especially from the U.S. dollars. Our effective tax rate was 28.9% compared to 15.5% in '24. '24 was positively impacted by the reversal of a provision related to the U.K. tax audit that was closed with no adjustments. The increase in '25 in the effective tax rate to 28.9% is driven by two non-recurring items in Q4.

The primary driver was a non-deductible impairment related to the planned divestment of our manufacturing site in Italy, combined with the finalized outcome of a U.S. advanced pricing agreement adjustment that had a larger tax impact than previously expected.

Looking ahead, we are guiding an effective tax rate of 20% to 23% for '26, reflecting the absence of these one-off items and a more stable tax position following the APA finalization. Net profit increased by 2% to DKK 3.2 billion and adjusted net profit increased by 5% reaching DKK 5.2 billion again reflecting strong performance and capital reallocation,

partially offset by higher financial expenses and income expenses.

In line with our dividend policy, it is proposed to pay out a dividend of DKK 1.15 per share, which is an increase of 21% compared to '24. The proposed dividend corresponds to approximately 36% of Lundbeck's net profit and 30% of net profit adjusted for the impairment loss for our manufacturing site in Italy.

Next slide, please. Cash flow from operating activities was in line with EBIT performance reaching DKK 5.5 billion reflecting strong EBIT growth and a significant working capital improvement. Keep in mind that the change in working capital in '24 was highly impacted by around DKK 2.8 billion of acquisition-related transaction and settlement costs.

Cash flow from investing activities was an outflow of DKK 611 million reflecting the purchase of intangible assets and property, plant, and equipment, whereas '24 again was highly impacted by the acquisition of Longboard. Cash flow from financing activities was an outflow of DKK 6 billion mainly driven by the repayment of the loan facility used for the acquisition of Longboard, partially offset by a EUR 500 million bond issued in Q2 to refinance the loan facility.

Next slide, please. An essential part of Lundbeck's Focused Innovator Strategy is our capital reallocation program through which we have taken a number of deliberate decisions to support funding for growth and innovation.

During '25, we increased our level of ambition and continue to operate with a high degree of discipline maintaining our target of freeing up approximately DKK 1.3 billion to DKK 1.5 billion by 2027 as communicated last year. Importantly, we have been able to absorb the Longboard costs while still expanding margins in 2025.

The capital reallocation program is built around several strategic pillars spanning both value creation and efficiency initiatives. These have been successfully executed across '24 and '25, providing strong financial flexibility and a solid foundation as we enter 2026.

One key pillar we acted on in the fourth quarter is our production model optimization. As part of this, we have initiated a plant divestment of a non-core production site which will further reduce complexity and streamline our manufacturing footprint.

In summary, we have more than delivered on the commitments we made 2 years ago during our Capital

Markets event and remain firmly on track to achieve our mid-term targets.

Next slide, please. Let me now turn the focus on the outlook for 2026 where we expect to deliver another year of profitable growth building on the strong momentum we achieved in '25. For 2026, we are guiding a revenue growth of 5% to 8% at constant exchange rates. This guidance is underpinned by continued strong underlying growth across our core portfolio, particularly our key brands, which remain the primary drivers of value creation.

As explained by Michala, there are a couple of one-time effects impacting our '26 revenue. While the sales from the new partner markets are reduced by the partner commission fee, this decline is partially offset by a one-time inventory impact of approximately DKK 500 million in Q1 2026.

This impact is specific to '26 and relates to inventory buildup within the partner channel and is not expected to be a recurring driver of revenue growth. Excluding these one-time effects and restating '25 on a comparable basis, our underlying revenue growth would be in the range of 6 to 9%.

Turning to profitability, we are guiding adjusted EBITDA growth of 4% to 12% at constant exchange rates in 2026. This range is driven by strong gross profit growth reflecting again continued momentum in Vyepti and Rexulti. At the same time, we are increasing investment in R&D to support long-term growth.

With several critical clinical trial initiations and readouts planned during '26, especially PACAP, our guidance therefore assumes a wider adjusted EBITDA margin range. The wider range still points towards margins within our mid-term guidance.

And with that, I would like to hand over back to Charl.

Charl van Zyl

Thank you, Joerg, and thank you to the entire executive leadership team for these outstanding results. I will make a few closing remarks on the next slide, please.

So you have seen clearly from us the 2-year window of where we have put some of the fundamentals in place that allow us to now extend our growth very clearly into 2026 with very clear priorities.

We are extending our growth as we have said with clear focus on our strategic assets, but fundamentally you have also seen a transformation in the pipeline that allows us to really bring those five to six mid-to-late stage assets further into their cycle of development, allowing us to continue in

our strategic path of developing them for the long-term success of Lundbeck.

So we enter into 2026 really from a position of strength with a very clear strategic path. And as I said, these results are not by chance, but really by clear strategic intent and choices we have made that allow us now to enter '26 in this very strong position. So we want to open it now for your questions and I will hand it back to the operator.

Operator

We will now begin the question-and-answer session. Anyone who wishes to ask a question may press star and one on their telephone. You will hear a tone to confirm that you have entered the queue. If you wish to remove yourself from the question queue, you may press star and two.

Questioners on the phone are requested to disable the loudspeaker mode while asking a question. Anyone who has a question may press star and one at this time. The first question comes from Charles Pitman-King from Barclays. Please go ahead.

Charles Pitman-King

Good morning, guys. Thanks for taking my questions. Two from me, please. First question just on Rexulti growth dynamics. I was wondering if you could provide a little more detail on how you are thinking about the potential impact of the IRA listing Rexulti from '28 ahead of the '29 LOE?

And coupled with that, just I know it is super early, but if you are able to comment at all on the initial impact from J&J's Caplyta on Rexulti's growth trajectory? I'm just wondering can MDD and schizophrenia keep growing and into that '28 kind of erosion timeline now?

And then just secondly on M&A. Back in November, Lundbeck pursued a potential acquisition of Avadel. So just wondering if you could provide some thoughts more on the potential commercial opportunity within the narcolepsy space that you saw, what the rationale behind your approach was for that asset. And just thinking about kind of the future BD and the rise of M&A activity at the end of last year, how you are kind of viewing the market today and what therapeutic areas you are most interested in pursuing? Thank you.

Charl van Zyl

Thank you, Charles, and I will - before I hand to Tom to speak more about Rexulti, just one word to say on Rexulti is that, you know, what you've seen and what we are guiding is very much as expected and also planned in our strategic outlook for the brand. But I think Tom can talk more to that and then I will come back and speak about M&A. Tom?

Thomas Gibbs

So thanks for the question, Charles. Just first off on the IRA, based upon the established role Rexulti has as a treatment option for many Medicare patients with MDD, schizophrenia and AADAD, Rexulti did meet the criteria for selection of the IRA price setting in 2028. I think it is important to note that this was aligned with our expectations.

I think it is also important to note that since approval in 2015, Rexulti has treated over one million patients across all these indications. Lundbeck and Otsuka are committed to ensuring as many patients as possible have access to Rexulti and will formally enter into the CMS process. Because the negotiation process is just at the beginning, it is too early to really comment about our expectations related to the impact of the IRA.

But what I will say is that we believe Rexulti is and remains a key growth driver for Lundbeck and our focus remains on driving growth of this brand. And I think this was evident as you said in the fourth quarter. Overall TRx demand growth, and this is in the fourth quarter of 2025, so it is really important as we think about the exit momentum was 24.2% versus the same period last year. That is 16.6% growth in MDD and 63.8% growth in AADAD.

So overall demand in fourth quarter 2025 is similar to what we saw throughout the year. As it relates to Caplyta, I think it is also important to note that there is so much unmet need when we think about mental illness, additional products are welcomed for patients. Again, it is very early to look at the impact of Caplyta, but I think Caplyta from their perspective is probably doing a pretty good job.

But I think it is important for us to understand where their source of business is coming from. If you look at their source of business for MDD, 26% are coming from anxiolytics, 25% from SSRIs and SNRIs, 12% from mood stabilizers and 10% from generic atypicals. If we look at Rexulti specifically, it is 1.5%. So even within the context of a new competitor as you can see, Rexulti is still growing strongly within MDD, but most importantly across the overall franchise.

Charl van Zyl

Charles, to talk about M&A again, I think the example you raised of Avadel is the normal process that we go through in bolstering our innovation. We keep looking externally in our M&A BD strategy in this notion of the string of pearls like we have spoken before, where we look at opportunities that can either strengthen our positions we have.

So we often look at them through the lens of the neuro-rare space or neuro-specialty where we can have synergies with our existing pipeline or our sales organization to build

sufficient scale. In the case of the space of sleep disorder, I mean this is of course one of the spaces that we keep looking at. We also have some early programs that we will speak more about later in the year that would be in this space of sleep disorder, but it is not the only space that we are looking at. So thank you for your question.

Charles Pitman-King

Thanks very much, very clear.

Operator

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

Xian Deng

Thank you very much. Xian from UBS. Thank you for taking my questions. Also two please from my side. First one maybe just to follow up on Charles's previous question regarding M&A. So just wondering you also have this year moving four of your programs into Phase II, but in the meantime, you also made the bid for Avadel last November, but then in the end didn't increase a bid further so you didn't have the deal in the end.

So just wondering if you could maybe help us to reconcile your strategy in terms of R&D considering, both internal and external opportunities please. Is that kind of you mainly look at external for the late stage while developing, prioritizing internal for early stage or any color on that, that would be great? So that's the first question.

The second one is on Rexulti please. So understanding the underlying trends from TRx, everything looks great, but still this quarter you have a 9% miss versus consensus. So just wondering is there any stocking patterns that we should be aware of, if yes, I wonder if you could quantify that please? Thank you.

Charl van Zyl

Good, let me start with the M&A topics. So first of all, I think to just emphasize further what I mentioned, it is an ongoing process of how we build a sustainable pipeline. So we look at this through the phases of Phase I, II and III and of course how do we create more optionality long term. So we have a full pipeline, which is a great thing. We are investing in that pipeline, but we will not be agnostic to looking at other innovations that are coming from outside.

If they are more interesting, have more potential than what we have, we will make some of those choices and trade-offs in the pipeline. So from that perspective, yes we really look across the range and we feel that it is very much part of how we will build the long-term sustainability of Lundbeck by looking both at the external environment that supplements exactly what we are doing also internally to build a

compelling pipeline. Good, then the second question we go to Tom.

Thomas Gibbs

Thanks for the question, Xian, and I'm glad we can clarify this for you. I said overall as we talked about TRx demand growth exiting the year was 24.2% and we saw strong growth across both of our key indications. I think some of the mechanics to help close the gap between what was reported for revenue and the underlying demand I think are twofold.

One is there's one less shipping day this year and I think it's important to note that we only ship to the three big wholesalers on Mondays and Tuesdays. Basically when you have one day missing, in one day we will ship one-third of the orders for the day and then two for the week and then the second day we will ship two-thirds of the orders for the week.

So I think that's a dynamic that's worth noting. And then secondly as we look at inventories, we exited the year for inventories at the low end of our normal range and I think it's those two dynamics that will help bridge the gap for you.

Xian Deng

Thank you very much. Just wondering the last part you mentioned the inventory low end of normal range. This is relating to the wholesalers, right? Not your inventory?

Thomas Gibbs

Yes, it's the wholesalers. We're just quoting the days on hand for wholesalers.

Xian Deng

Got it. Thank you very much.

Operator

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

Kirsty Ross-Stewart

Morning, thanks. Kirsty Ross-Stewart from BNP. Two questions from me. So on the broad R&D expense range, understand that PACAP progression is a key swing factor. So can you talk to your thoughts on probability of success here, especially in light of the positive HOPE data that we've already seen and outside of that progression decision, are there any other kind of moving parts that we need to be aware of?

You've mentioned the Phase II starts, but I think we already knew that they were moving to Phase II. So can we assume that those are incorporated into the bottom end of the guidance and if there's anything else just contributing to that broad range?

And then a second question on asedebart, the anti-ACTH interested on your perspectives on the Phase II data that we saw from Crinetics in CAH in January this year, which

showed good reduction of ACTH production and how you see this asset from a competitive perspective and how your antibody approach is differentiated versus the Crinetics molecule atumelnant? Thanks very much.

Charl van Zyl

Kirsty, just a very quick question before I hand to Johan on the views on PACAP. I mean overall from an R&D perspective, yes, it is one of the important investment triggers, but of course you know that we also have bexicaserin and amlenetug in Phase III. So these are also sizeable investments that we are making to complete these studies and so from that perspective, we have sort of a healthy pipeline to fund which is reflected also then in the range of R&D spend that we see.

But I think Johan, you want to make comments on your views of what you think you can say at this point on PACAP and then maybe on your thoughts on Crinetics?

Johan Luthman

Thanks Kirsty. Obviously, you'd like to know some details on PTRS and how we view this, but we'll get the data soon and we'll take a look at it. There are, of course, prior information and if you believe in priors, there is of course the HOPE trial. And then recently in June I believe last year, Lilly presented data from their very early terminated program in 38 patients that showed also an effect.

So there is of course overall encouraging data in the field and now we just need to expand this with a much wider dose finding range and we'll see what kind of data we'll get. So you can draw your own conclusions based on that basically.

For Crinetics, yes, we were happy to see that data. It's a good validation that the pathway is really to be addressed and you can see effects. I'd like to remind you that Crinetics works with the ACTH receptor blocker, MC2 receptor blocker.

So it's at the adrenal gland stage, so it's further down in the biology, which means that they don't cover all the different aspects of the overproduction in the system. Here we have the ability with this mechanism to have a broader symptomatic effect across different adrenal hormones that are hyperactive in this condition. Great data, but we believe we can have even broader effect with this molecule.

Kirsty Ross-Stewart

Thanks very much.

Joerg Hornstein

Then just going forward, I think what we again guided for was the range of DKK 5.5 billion to DKK 5.9 billion for '26 and that principally encompasses bexicaserin and amlenetug and also the advancement of anti-PACAP and

anti-ACTH. I think on the rest of investment, that's always dependent on milestone outcomes.

Operator

The next question comes from the line of Tobias Berg Nissen from Danske Bank. Please go ahead.

Tobias Berg Nissen

Yes, hello. I have a question on Vyepti here. It's been a very solid '25 with accelerating growth over the last three quarters. I'm just wondering if you can quantify some of the growth drivers for '26. You have lifted the persistency ratio quite significantly over the last few years. Are you hitting the ceiling here?

Also if you can give some insight into the dosing mix and what you expect here in exit '26 and also perhaps on expected approval and first time sales timing for the APAC region, both Japan, China, and South Korea? Thank you.

Charl van Zyl

Thank you, Tobias. Let me ask Tom to comment more on the growth drivers for the U.S. but just to emphasize that this is of course a key asset of investment for us both in the U.S. and in Europe. Then we have filed in Asia and so expect to see more of the sales impact on Vvepti in Asia more in '27.

But I think Tom, you want to just talk quickly about your insights on '25, how it carries forward to '26.

Thomas Gibbs

Yes, thanks for the question and as you stated, we're pleased with the progress that we're making on Vyepti. As we think about the key drivers for growth, it all starts with new patient starts. That's where our focus is and new patient starts by being able to drive Vyepti further up the treatment paradigm to be used earlier in treatment.

And then within that context also to make sure that we're maximizing the written-to-infusion ratio as part of our patient-centric model. As it relates to the 100 milligrams versus 300 milligrams, for the most part we saw that allocation between 100 and 300 milligrams pretty stable over the course of 2025.

We expect that to continue, but we will also say that the majority of patients are on 300 milligrams because the observation from clinicians is that you see improved efficacy for the 300 milligrams for most patients.

Tobias Berg Nissen

Perfect, Tom. Thank you. I'll jump back in the queue.

Operator

The next question comes from the line of Alyssa Larios from Leerink. Please go ahead.

Alyssa Larios

Hi, everyone. Thank you for taking the question. This is Alyssa on for Marc Goodman. I was wondering if you can

give us a little bit more color on how the partnership model is expected to impact total revenue for Vyepti and Rexulti?

And also related to the one-time inventory build. Should we think about the impact as being more front-loaded in the year or will there be some inventory stocking spread across the quarters as some of the international partners come online? Thank you.

Charl van Zyl

Alyssa, could I just clarify your last question? We didn't quite get a clear line there.

Alyssa Larios

Yes, so related to the 1x inventory build, is that going to primarily be seen in Q1 or will there be some stocking across the quarters as well?

Charl van Zyl

Very clear. Michala, do you want to comment on your thoughts on how that's going?

Michala Fischer-Hansen

So first of all with the partnership model, as you know, we have the provision we need to or the commission we pay the partners as I explained and then we have the one-off effect of inventory which we expect to be a Q1 and it relates specifically to partners needing to build up safety stock in the markets so it's a technicality so to speak of them taking over the distribution of our products in these markets.

In terms of our expectations, I think you asked about our expectations for Rexulti and Vyepti in the partnership markets and we don't guide specifically at brand level but generally of course our expectation is that the partners will be able to continue to deliver with the momentum we've seen when we had the business in our own hands. So we expect to see that that will continue.

Alissa Larios

Okay. Thank you very much.

Operator

The next question comes from the line of Alexander Moore from Bank of America. Please go ahead.

Alexander Moore

Hi, two from me. One on Abilify Asimtufii. Slide 8 shows conversion to two-monthly continuing to increase in Europe and International Operations. I just wondered if you could give any color on what your conversion rate assumptions are factored into the full-year guidance?

And then secondly just one on pipeline. Slide 36 highlights potential benefit of little to no monitoring requirements with bexicaserin. I wondered if you could just give any color on what monitoring is currently included in the Phase III DEEP SEA and DEEP OCEAN trials? Thanks.

Charl van Zyl

Thank you, Alexander. So, Abilify conversion ratio. Do you want to start, Michala, with that?

Michala Fischer-Hansen

So generally as I stated for EIO or Europe and International Operations, we see an average of 19% and of course what you have to bear in mind is that we're launching at different times, so not all markets have launched at the same time and that of course also impacts the conversion rate as it progresses. But when we look to '26, we expect this to continue and as I also mentioned, we expect to see generics in Q2 where we previously expected to see them earlier so of course that also gives us a chance to convert more patients. So we continue to focus on that.

Charl van Zyl

Tom, on your views on the US?

Thomas Gibbs

Yes, well, I think if we look back over the course of the last two years with Abilify Asimtufii, our focus has really been on franchise maximization and we've been able to grow our market share over the past year for the franchise 1.1 share points to 24.9. I think as we look into 2026, our focus is really going to be moved from maximizing franchise to conversions and we have seen some good momentum in NBRx's with the latest week we saw a 22% conversion rate and our expectation and ambition continues to be to exceed the conversion rates of the other benchmarks in the LAI marketplace.

Charl van Zyl

I think the question from Alexander, Johan, is on bexicaserin Phase III, what are the end points, what are we monitoring?

Johan Luthman

Yes. First of all, it's a trial in what we call DEE, which is the broad, broad indication across all developmental encephalopathies. We have two trials as you know, DEEP SEA and DEEP OCEAN. What we're monitoring is of course how we are progressing with the trials.

In terms of progressing with the global rollout, we are doing well. We have now activated all sites across the world but remember we started a trial during early 2025 and it's been a gradual rollout of the trial. What we're monitoring in terms of blinded data in the trial, we're very careful with that.

We have some monitoring of data acquisition and we know that we get the right kind of populations in at the front door, that we have a good balance between various parts of the DEE spectrum and we're doing well on that. There are little differences in enrollment between the two trials.

In Dravet Syndrome it is more challenged but that is a standalone trial and the balance is good across the whole system. In terms of medical monitoring, we have good views on what's going on so far with the patients.

No concerns there what we've seen so far and as you know, we are out of the box of having to have cardiovascular

monitoring with this mechanism. So that is a big benefit for trial sites. But that much I can say and we're looking forward to try to wrap up the randomization during the year.

Operator

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

Charl van Zyl

Yes, so thank you again for joining today and again I want to reiterate the very strong position we are in from the last two years of our Focused Innovator Strategy. We are of course very confident as we enter into 2026 with another strong year of performance ahead of us. So thank you again for joining today.