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Transcript:
Financial results and business update Q1 2023

Date & Time:
10 May 2023 at 13.00 CET

Operator: [00:00:00] Welcome to Lundbeck's financial statements for the first three months of 2023. For the first part of this call, all participants are in a listen only mode. Afterwards, there will be a question and answer session. To ask a question, please press five star on your telephone keypad. Today I'm pleased to present Deborah Dunsire, President and CEO. Joerg Hornstein, Executive Vice President and CFO, and Johan Luthman, Executive Vice President of Research and Development. Speakers, please begin.

Deborah Dunsire, CEO: [00:00:35] Hello everyone, and welcome to our first quarter update from Lundbeck.

Deborah Dunsire, CEO: [00:00:39] Next slide, please. You've seen our forward looking statements a number of times, so we'll move right through because we have a lot that's exciting to talk about on the next slide on Q1 performance.

Deborah Dunsire, CEO: [00:00:52] First and foremost, this is the highest revenue quarter ever in Lundbecks history with sales at 5 billion. That's an 11% in constant currency revenue growth, 15% reported. The strategic brands we'll talk about in more detail. But we're delighted with the progress that Vyepti is making. The strategic brands generally have grown extremely well, 19%, and now make up 65% of the global revenue. And we've seen in aggregate double digit growth across all the regions of the world. So, it's great to see that performance in every corner of Lundbeck. We also have had a phenomenal first few months in our R&D pipeline achieving an approval for Abilify Asimtufii right on time on the PDUFA date. We had a very strong outcome from our advisory committee, together with Otsuka on agitation in Alzheimer's disease. And of course, today is the PDUFA date. But we don't have any news for you yet. We are very excited, and Johan will talk more about our PACAP results from the HOPE trial as a positive proof concept in phase II.

Deborah Dunsire, CEO: [00:02:11] Next slide, please. So, just focusing on the strategic brands here, you can see that they're growing well all across the world. The US up 21%. International markets and Europe both up 17% for the strategic brands. And you can see that all the brands are delivering on growth. And our mature brands have been quite remarkably resilient with only a -1%.

Deborah Dunsire, CEO: [00:02:38] Moving on to the next slide. Looking at Vyepti in the US. US demand continues to be strong, and we are seeing an 87% growth Q1 '22 to Q1 '23 as our share in the preventive market continues to grow up to 5.8% volume market share right now. Growth coming from both existing prescribers and new prescribers, and we're seeing an increase in the number of Vyepti loyalists. We anticipate strong continued growth in the balance of the year.

Deborah Dunsire, CEO: [00:03:17] Next slide, please. Of course, we've been enjoying the rollout of the launches globally and we're seeing a good uptake in the markets that we launched last year. Canada is now at 8.8% in its fourth month, Switzerland at 9.7 in its 10th month in terms of volume market share. And we've had five launches already in the first months of the year UK, France, Austria, Indonesia and most recently Spain, but also have ten more markets to look forward to in 2023. And I just want to point out how excellent the execution has been against getting these approvals so that we can launch quickly into all countries.

Deborah Dunsire, CEO: [00:04:04] Next slide, please. Brintellix/Trintellix. There's good growth of the brand, up 7%. Europe is growing incredibly strongly with superb performance, particularly in the GP sector in Spain and Italy really driving that performance. International markets, the growth is Brazil and Canada continuing to grow and Japan being a standout with an achievement of a 12.7% market share. Trintellix new to brand prescriptions have reversed a declining trend and are now growing as a new brand in the US. I think the refocused efficacy messaging and the strengthened field force targeting and execution together with our partner Takeda, are contributing to that.

Deborah Dunsire, CEO: [00:04:55] Next slide, please. Rexulti, as you know, this is mainly driven by the US and MDD continues to be the main growth driver. Many have

asked is AAD driving the growth? No, not yet. MDD is really that continued driver and we've seen it's really driven by strong execution in the field together with a very effective DTC campaign. We are making rapid advancement in preparing for our launch in agitation and Alzheimer's disease.

Deborah Dunsire, CEO: [00:05:31] Next slide, please. Abilify Maintena is also growing strongly. Some of our markets have already achieved over a 30% market share. Of course, our biggest growers are the US, Italy and Canada. Abilify Maintena is demonstrating the strength of its profile as it is in many markets, outgrowing the atypical LAI market. So, with that, I'm going to hand over to Johan, who's got lots of good news to talk about.

Johan Luthman, R&D: [00:06:02] Thank you, Deborah. The first quarter this year has been very news rich for Lundbeck with several positive R&D events. This is obviously the culmination of several years of efforts, but it has indeed been a very intense spring. As Deborah already mentioned, we saw the approval of Aripiprazole extended release for once every two months injection. The product comes as ready to use long acting suspension for intramuscular use. The NDA had a PDUFA date on April 27th and I will come back to the US approval in a subsequent slide. This new product has also been submitted to Health Canada with a supplement to a new drug submission so called SNDS mid-August last year. We anticipate an action date this summer in late July. Abilify has also been submitted as Aripiprazole in the European jurisdiction, EMA, and the submission was accepted on June 22nd and the intended indication is for maintenance treatment of adult schizophrenia patients. The review process has essentially been encouraging and proceeded to the last stages. However, reaching that stage of the review, it became clear that the submitted approval path was not applicable for our type of submission. Thus, solely due to a CHMP procedural objection, the application must be withdrawn. This is entirely unrelated to product quality and safety. The MAA for the product will be resubmitted as soon as possible, using a path that should be appropriate for completing the EMA review. We expect that timelines are going to be somewhat shortened this second round and have a current estimate for H1 '24. Another key event was of course the advisory committee discussion the sNDA for Brexpiprazole for the proposed treatment of agitation associated with dementia due to Alzheimer's disease. I will come back to that as well. Brexpiprazole for the treatment of agitation in Alzheimer's disease was also recently submitted in Canada, with Health

Canada accepting the SNDS for review in April. We expect the review to be concluded by Q1 '24. Then I would say finally, we have now closed the recruitment into the two trials, 71 and 72, that are exploring the efficacy and safety of Brexpiprazole in combination with sertraline in post-traumatic stress disorder. Since the last patient was recruited already, we will obtain the headline results in H2 this year. Well, then we also had very encouraging positive outcome of the Anti-PACAP 222 phase II proof concept HOPE trial that investigated antibody in migraine prevention. I will also get back to that in more detail. I just like to add a few notes on some of the other early development programs in our anti-alpha-synuclein 422 program that is right now in the PoC trial called AMULET. We obtained so-called Sakigake designation in Japan. Sakigake is a drug designation that aims to provide easier access to novel advanced treatments. Thus, this is another testament to the pioneering aspects of this program. We have also started dosing the first participants with congenital adrenal hyperplasia, with the anti-ACTH monoclonal antibody 909. Congenital adrenal hyperplasia is a genetic condition that affects the adrenal glands and leads to high levels of androgens, which also have CNS infections.

Johan Luthman, R&D: [00:09:50] Next slide, please. So, we got the approval of Aripiprazole extended release for once every two month injection by the FDA by the end of last month. For the indication of treatment of schizophrenia and adults, or for Maintena's monotherapy, treatment of bipolar disorder in adults. Thus, the same population of treatment as Abilify Maintena. But naturally for a therapy that will be lasting double time after intramuscular injection. The basis for that approval was a large, robust 32 week pharmacokinetic bridging study that evaluated multiple doses in patients with schizophrenia and bipolar disorder. The bridging doses 720 and 960mg were identified by a solid combination of generating robust experimental data with excellent PK modelling. The efficacy of this product naturally builds on the adequate and well-controlled studies of the Abilify Maintena program.

Johan Luthman, R&D: [00:10:47] Next slide, please. I promised more words about the advisory committee meeting for Brexpiprazole in agitational Alzheimer's disease. The priority review of this program included a meeting on April 14th by the AdCom, a joint group of the Psychopharmacological and CNS and PNS AdComs. The AdCom discussed at the end three questions presented by FDA to them, the overall benefit risk assessment population of patients with ad whom the benefit risk of Brexpiprazole

appears acceptable. And finally, whether sufficient data available to allow identification of a population which benefits the drug treatment and outweighs the risk. And that was really the voting question which you heard was in 9 to 1 supporting the data package. Indeed, the outcome of agitation Alzheimer's disease for Brexpiprazole is a great testament to the solid data generated throughout the program. I just like to highlight the minor set of the data, but the critical set since it relates to improved patient and caregiver outcomes from the Cohen-Mansfield Agitation Inventory scoring done in the study. As you can see in the table, there are several important readouts that relate to patient and caregivers, which all show a positive effect of the treatment, such as hospital admission falls and psychiatric burden on caregivers. We are very much looking forward to the evening or probably tomorrow morning since the PDUFA date is today, as you heard from Deborah. If approved, Brexpiprazole will not only be the first treatment for Alzheimer's disease agitation ever in the US, but the first ever approval of a treatment for any symptoms related to behavioural and psychological symptoms of dementia. So, if approved, this will be a critical addition to current treatment for this devastating disease.

Johan Luthman, R&D: [00:12:46] Next slide, please. Now I'd like to turn over to something completely different. On April 19th, we announced a positive readout of the first in class anti-PACAP monoclonal antibody in the HOPE trial. I have been in this industry for many years, but it's not often you get the pleasure to be part of such a critical readout. Science is hard to convert into therapies, but occasionally you get rewarded for the efforts. Thus, we were very pleased to see the very robust readout in this proof concept clinical trial. The positive headline results for 222 is a breakthrough for a new mechanism of action in migraine prevention. Just a few words on the molecule 222 is a humanized IgG1 antibody against the receptor ligand PACAP, which is known to act through at least three different receptors. The PACAP biology is quite broad, but one of its action is as a potent vasodilator. Therefore, the PACAP biology provides a new approach to migraine prevention with potential in other pain indications as well. The HOPE trial studied prevention of migraine in episodic and chronic migraine patients and not helped by 2 to 4 prior treatments. As the primary readout, we looked at change from baseline in the number of monthly migraine days at week four. 237 patients were randomized a little more than we expected, so randomization went very well, in 2:1:2 split, using a high dose and a low dose and placebo.

Johan Luthman, R&D: [00:14:17] Next slide, please. The trial showed a statistically significant effect with p value below 0.01. Reduction in the number of monthly migraine days for patients treated with 222 from baseline to week four, as I mentioned. Moreover, which is important 222 was also well tolerated in this study. These findings bring an important new possibility for migraine. Despite the availability of effective therapies such as anti-CGRPs, there is still a large unmet medical need for migraine prevention therapies. So, the outcome of the trial brings new hope for patients with severe migraines.

Johan Luthman, R&D: [00:14:58] Next slide. So, this result, of course, from PACAP adds an opportunity for Lundbeck to further build the migraine franchise. As we mentioned earlier, we also shown the possibility of subcutaneous administration of this drug. So, this may lead us to complete the molecules potential for other pain conditions as well at some stage. So, this is our pipeline and how it looks today. Apart from the programs I mentioned, I like to say that we have made good progress in several other programs. As one example, 966, our D1/D2 agonist program in Parkinson's disease is progressing well to conclude this phase one this year. With a solid data set so far, giving it a potential to progress into phase II proof concept studies already next year. Generally, our R&D organization has been fully transformed and we have now full programs even in development within our four chosen biological clusters for innovation. We are also stringently using biomarkers in our early development programs for go or no go decisions and for paving the way into later development. And also, our research pipeline is fundamentally reshaped with several highly innovative programs. Programs that I hope to be able to talk more about one day. To conclude, Lundbecks R&D has lately shown great ability to deliver on our late stage LCM for our brands. But maybe more importantly, we have shown great progress in advancing our mid-stage pipeline and continue to add strong programs into our very early stage pipeline. With that, I'd like to turn over to Joerg.

Joerg Hornstein, CFO: [00:16:36] Thank you very much, Johan. As Deborah said, we start the year with the strongest revenue quarter Lundbeck has ever delivered. The plus 15% of reported revenue growth is driven by a constant exchange rate growth of 11%, mainly coming from the strong underlying performance of our strategic brands with FX and hedging, both contributing 2% respectively. The positive effects and hedging impact are driven by predominantly the increase of the US dollar compared to the same quarter

last year. Our gross margin is 1.3 percentage points lower actually, compared to '22 negatively impacted by the additional amortization of product rights related to the EU approval of Vyepti sales milestone achievement, as well as by the provision for Vyepti inventory obsolescence of 101 million booked in Q1. And I think that's why it's so important to also look at our adjusted gross margin, because if we adjust for this provision as well as for the amortization and depreciation linked to sales, the adjusted gross margin in Q1 is actually higher by 1.5 percentage point reflecting the positive sales volume development in the quarter. Sales and distribution costs grew 17%, with a constant exchange rate of plus 15%. The increase is driven by higher promotion and sales costs, predominantly for the continued rollout of Vyepti, as well as launch preparations for Rexulti AAD, but also to an extent due to the normalization of activity levels in Asia following the return to pre COVID pandemic levels in comparison to Q1 '22. R&D costs in Q1 declined by 15% or -14% at constant exchange rates, primarily impacted by lower project costs related to completion of phase III and phase IV studies. I think timing in R&D projects has of course an impact as well, which is why I will later, when we discuss our full year guidance, reiterate our expected R&D costs to remain broadly stable in '23 in comparison to last year. All of these factors contributed to an EBITDA growth of plus 35% overall, with a constant exchange rate growth of plus 31%, contributing to an increase of the EBITDA margin by 5.1 percentage points compared to last year. You remember we introduced an adjusted EBITDA and if we look here at we basically grew plus 43% or 39% at constant exchange rates because we adjust for the provision of the Vyepti inventory obsolescence.

Joerg Hornstein, CFO: [00:19:28] Next slide, please. Our EBIT grew 41% overall or 35% at constant exchange rates. Overall, we improved our margin by plus 4.4 percentage points. Our net financial expenses decreased for the quarter by a -264 million to actually a -83 million. The lower expenses are mainly driven by actually three factors. The first one is the non-recurring 278 million fair value adjustment of the CVR to our shareholders in Q1 '22, which was triggered by the Vyepti EMA approval, and the zero interest impact compared to a -21 million impact last year due to significant increases in the general interest rates and lower debt levels. And the last factor that partially offset this development was actually a higher currency impact of around 73 million driven by the dollar decline we've seen in the quarter. The effective tax rate has increased to 23.5% compared to last year's 22%. And that's in line with the full year expectation reflecting the reduced deduction from the Danish R&D incentive. Net profit

increased by 114% to 880 million, and adjusted net profit increased by 34% to 1.4 billion. The adjusted EPS growth is in line with the underlying performance when we adjust for the fair value adjustment of the CVR and the corresponding tax effect.

Joerg Hornstein, CFO: [00:21:04] Next slide, please. The cash flow from operating activities landed at an inflow of 378 million in the first quarter of '23, compared to an outflow of 205 million last year. The Q1 '23 operating cash flow is of course a reflection of the strong EBIT performance, further benefited by higher adjustments for non-cash items of 623 million, which are driven by A) higher amortization in Q1 '23. B) the provision for Vyepti inventory obsolescence, but negatively impacted by higher changes in working capital of 1.3 billion, which are mainly driven by the increased receivables driven by higher sales and the increased inventory in Vyepti, which is related to the inventory build-up due to the fixed term manufacturing agreement with our external CMO that expires in mid of this year. The cash flow from financing activities was an outflow of a -955 million in the first quarter compared to an inflow of a positive 699 million in the same period last year. This is primarily driven by the continued repayment in '23 of the last part of the loan in '22 that was connected to the payment of the CVR to shareholders and the higher dividend payment in '23 connected to the improved net results in '22. Our net debt position continues to develop favourably and lands at 2.5 billion in Q1 '23 compared to a 5 billion at the same period last year. Maintaining the leverage at 0.5 for the rolling four quarters, continuing our progress of deleveraging the company.

Joerg Hornstein, CFO: [00:22:56] Next slide, please. We maintain our full year guidance on revenues for '23 with a range of 19.4 to 20 billion, despite a significant currency headwind since November 22nd, which formed the basis of our original guidance. As previously communicated in February, we will focus on adjusted EBITDA from the first quarter of '23 onwards in order to provide an improved and more consistent assessment of the underlying business performance of our company. Reflecting this change and adjusting EBITDA with a provision for the Vyepti inventory obsolescence of approximately 300 million, the EBITDA guidance is updated to adjusted EBITDA guidance for '23 with a range of 5.1 to 5.5 billion. I think if you look on the right hand side, our housekeeping items and overall assumptions on revenues and profits underpinning the guidance remain mostly unchanged. But important to note is the following. The end of March, exchange rates were considered for reconfirming the

guidance. We see continued solid growth of our strategic brands with a strong momentum for Vyepti. We expect positive effects from hedging of around 130 million for the year. Amortization of product rights is expected at approximately 1.6 billion. And the R&D spent guidance remains unchanged, expecting an annual spend in the range of last year despite the lower spend in Q1 '23. And last but not least, as previously mentioned, the provision of 300 million for Vyepti inventory obsolescence is reflected in the guidance for '23 whereof 101 million have actually been recognized in Q1. And with that, I hand over to Deborah.

Deborah Dunsire, CEO: [00:24:44] Thanks, Joerg. So, finishing up, it's great to continue to deliver that very solid financial performance with the revenue momentum being strong, driven by the strategic brands. We've made that shift to adjusted EBITDA reporting starting this quarter. Continuing to drive those brands is a key focus for us as we drive the Vyepti global rollout. Building with ten more markets to come on the top of five already launched this year. There's a lot to do in the US as we gear up the launch of Abilify Asimtufii and look forward to the approval and then subsequent launch of agitation in Alzheimer's disease for Rexulti. We have been working hard for a long time on the pipeline and it's great to see the momentum coming through with the positive phase II proof concept results for a new mechanism of action, anti-PACAP or our 222 molecule. And of course, we look forward to the PTSD headline results in the second half. You hadn't mentioned it, but I'd also like to just reiterate that we also see that forward movement in our research pipeline and our early development portfolio as we move forward. Lundbeck is firing on all cylinders, and we're committed to deliver sustainable, profitable growth into the future. So, with that, I'll stop and take your questions. For questions. We're joined here today, in addition to Johann and Joerg. With me, I have Jacob Tolstrup, Executive Vice President of Commercial Operations, who you know very well, and Thomas Gibbs, who is our EVP for the US, who's newly joined Lundbeck in February. So, we open for questions.

Operator: [00:26:34] Thank you. If you have a question for the speakers, please press five star on your telephone keypad. To withdraw your question, please press five star again. We will have a brief pause while questions are being registered. The first question is from the line of James Gordon from JP Morgan. Please go ahead. Your line will now be unmuted.

James Gordon, JP Morgan: [00:27:03] Hello, James Gordon, JP Morgan. Thanks for taking the questions. Firstly, just on PACAP, so you had a static phase II, a headline. Where might we see more detail about that? And was it a static benefit for high and low dose? And could you also talk about next steps in terms of clinical development? Should we assume you need to do another phase II, or could this go straight into phase III? And when could a product like this actually potentially hit the market? And then just a clarification the tail performance maybe. So, it looks like the key area where you did better than the market expected this quarter was on the tail, the older products. And was there anything exceptional or how much of it was exceptional or is this a good run rate for the rest of the year for the non-strategic brands? The other bit of the business, please.

Deborah Dunsire, CEO: [00:27:46] Thanks, James. Johan is going to dive in first and then Jacob will take the question the mature brands.

Johan Luthman, R&D: [00:27:52] Thanks, James. I understand many people are eager to hear more about what we have seen in this study. We have only had the data for a few weeks, so obviously we need to digest and we're looking at data as we speak here. We will present this at some conference, but we have not announced when and how that will be, but we hopefully will do that during the coming year. And that's what I can say. We're trying to get the data out as soon as possible, but we also need to be able to digest it a bit ourselves. Yes, the doses, we have not gone in so much detail. We talked about the headline data being positive. As you heard, it was a low and high dose used. We're very pleased overall with the results and it behaves very nicely. And that's why I call this a very robust proof concept. So, without revealing really the different doses, what we report here is primarily on the primary outcome, which was the high dose where we had most of the subjects. But obviously we are looking at the lower dose and have a very good understanding about the drug's mechanism of action really working throughout the tested doses. In terms of next development steps here, obviously with this in your hand, you like to be able to move fast. You also like to do the right thing. This is a scientific proof concept. It's nothing more. We've shown that the drug works. I think it's robust enough to believe in that readout. Then we have to carefully consider how we bring this forward. But as I mentioned before, it's a very big medical need still in migraine. Many patients are not served well with current therapies. And if you look at analogues in the past, there is always a room for a new drug. And how we'll position

that is a matter for decisions later on. We'll come back how the phase II, phase III or whatever we'll do will look like.

Deborah Dunsire, CEO: [00:29:56] And those decisions will determine time to market. So, we won't comment on that at this time. Jakob.

Jacob Tolstrup, CCO: [00:30:02] Thanks, James, for the question. I would say in general, we have a good, mature business that is relatively sticky around the world. But of course, what you're seeing in this quarter is better than we also anticipated internally. So, it's a lot of moving parts for that part of the business. I would say in general, we are benefiting from some inventory stock builds in certain parts of the world, pricing effects. So, I would say the quarter is unusually good, but in general, we have a good portfolio here. When it comes to Lexapro, there are sort of two bigger moving parts. One is that we now have generics on the market in Japan. We have 11 generics there. So, going forward, you will see Lexapro being impacted by that in our numbers. On the other hand, we see Lexapro growing in China and for the rest of the world, it is a I would say, a flat or slowly declining Lexapro business. So, a lot of moving parts, but the quarter is unusually strong.

James Gordon, JP Morgan: [00:31:11] Thank you.

Operator: [00:31:15] Thank you, James. The next question will be from the line of Martin Parkhøi from SEB. Please go ahead. Your line will now be unmuted.

Martin Parkhøi, SEB: [00:31:26] Martin Parkhøi from SEB here. I would like to ask that question because I think that you have downplayed the estimates of the portfolio for as long as I can remember, but I will keep that as a comment and take a couple of questions. Firstly, on the Rexulti, how can you be sure that the development you've seen so far this year is not a positive spill over effect from the presentation of the aggregation data? And then secondly, what should we actually think about Abilify? The two month version will just be a complete cannibalization of existing sales of Maintena, or do you think that this can be added? Will you actually report it as two separate products or will you just report it to the one product? And then a final question the adjusted EBITDA for the rest of the year, of course, we have a very strong start to the

year, so there must be some weaker quarters coming implied by your guidance. Can you maybe talk a little bit about quarterly phasing?

Deborah Dunsire, CEO: [00:32:40] Okay. Lots of questions, Martin. I think Thomas going to take the first one on Rexulti. But what I'd just preface that with is we wish that physicians responded to every piece of good new data immediately. Never seen it happen. But over to you, Thomas.

Thomas Gibbs, EVP: [00:32:58] Thanks for the question, Martin. As we look at the Rexulti business, the best way to be able to measure the potential utilization within the AAD space is looking at subnational data with IQVIA. What we have seen is the percentage of utilization 65 and above has been about between 12 and 14%, and it's been stable over time. So, at this point in time, we do not see that there has been any inflection based upon the positive AdCom that was that occurred last month. We've also looked at claims data, although there are some challenges in terms of trying to discern the diagnosis, we don't see much there either. So, we believe that this is upon approval, a significant opportunity.

Deborah Dunsire, CEO: [00:33:48] And we've guided over time. Don't expect a light switch like uptake. This is a market that needs to be built. Talking about Abilify Maintena and Abilify Asimtufii, is it a straight cannibalization? Over to you, Thomas.

Thomas Gibbs, EVP: [00:34:04] So when we think about Abilify Asimtufii. I'm excited about this opportunity as it expands the long acting injectable franchise for Abilify. And the way that I see this is that we're going to continue to be able to differentiate Abilify long acting injectables based upon the molecule, based upon the sustained efficacy in bipolar and schizophrenia. And then this additional dosing opportunity provides greater flexibility for HCPs to determine what is the right interval of dosing for the patient, whether it be one month or two. So, I see this as an opportunity for us to grow the franchise and be able to retake and become the fastest growing LAI in the marketplace.

Deborah Dunsire, CEO: [00:34:50] Thanks, Thomas, over to you, Joerg, on the adjusted EBITDA for the rest of the year.

Joerg Hornstein, CFO: [00:35:03] Coming back to your question, I think in general, we don't really guide by quarter, but of course you can see that we had very strong revenues and they travelled through to the bottom line in Q1, as expected. We had the benefit of probably a bit lower R&D costs than we originally estimated. But also, in comparison to Q1 last year, Q1 last year was extremely high at the same time. So, what we're guiding forward is to basically say don't bet on that underspend in R&D and also see, of course, that if we talk about ADD and to simplify that, these are costs, we are also phasing into over the coming quarters. So, overall, we reiterate our guidance.

Martin Parkhøi, SEB: [00:35:59] Thank you.

Operator: [00:36:01] Thank you, Martin. The next question will be from the line of Michael Novod from Nordea. Please go ahead. Your line will now be unmuted.

Michael Novod, Nordea: [00:36:13] Thank you very much. It's Michael from Nordea. Two questions. So, not talking about sort of the light switch on and off for Rexulti in AAD, if you could give a bit more detail to how fast you can sort of ramp marketing, how fast you potentially plan to do DTC if that's appropriate in this indication as well. Just for us to get a feeling of when could we sort of start to see the potential effects materializing besides just a normal interest for new product in the market? And then secondly, any updates to the anti-TAU monoclonal antibody would be appreciated. So, a lot of discussions both on this mechanism and others in recent time. So, I just want to see, is this moving forward at all or is this something that sort of will leave the pipeline at some point in time? Thanks a lot.

Deborah Dunsire, CEO: [00:37:06] Okay. Thomas, would you like to start on?

Thomas Gibbs, EVP: [00:37:09] Sure. Thanks for the question, Michael. As I look back, I think the team has been working very hard in terms of preparing for the launch of Rexulti for over a year now. And I can tell you that the team is ready for positive news as we think about the readiness. There are two key elements that I'm looking at. One is sales force readiness. And as we look at our target audience of about 36,000 physicians, both on the Otsuka side as well as the Lundbeck side, we are fully ramped up from a sales force point of view to be able to effectively call on that target universe. The second element, which I think is going to be important, is really mobilizing

caregivers to be able to accelerate presentation of their loved ones to physicians. And in doing so, there's going to be two parts to that. First is going to be an unbranded DTC campaign, which will be launched shortly after approval, and then it will follow with a branded DTC campaign later on in the year.

Deborah Dunsire, CEO: [00:38:14] And I think what that means for us, Michael, in terms of what you said about phasing of costs, you know, we've just brought on the sales force there in training the branded DTC, the medical conferences. So, I'd say that it grows over time in the year. And then if you're asking about how fast does it start to impact in the marketplace, I'd say we see that it will have a positive but more limited impact on the growth in Rexulti this year. It really accelerates next year and it's moving very strongly in '25. Next is the anti-TAU. That's Johan.

Johan Luthman, R&D: [00:38:57] Thanks. I think you've been asking about this molecule a few times, and we are also asking ourselves sometimes what we should do with this molecule. You know, this space is extremely hard to navigate, and I think one should be careful to have too much read through. From the amyloid therapies to TAU. Every antibody approach, every proteinopathy is unique and there is high risk in this field. We actually have had this in the pipeline for a long time because the study is active, the program is active, but we just completed enrolment in the phase I target engagement study. Yes, that took a long time. It was a phase I study that was struggling a lot during the pandemic is also enormously hard to find Alzheimer patients as volunteers into these kind of studies. And we were, quite frankly, struggling operationally with the trial sites. We did some really good work at the end here with a person located in New Jersey helping to finish up the studies. What we'll get out of that study, the phase I study, is target engagement data. Is the drug doing what it is supposed to do? That will not still trigger further development. We really have to think through what we'll do in this space. And it's primarily, as you know, for Alzheimer's disease, which is a big beast to take on. And with really no external information supporting that approach, we do this very carefully. So, I think you will hear more about us saying it's post, it's been in the pipeline until now because the study was active.

Deborah Dunsire, CEO: [00:40:35] And I think it's great that we finished it accrual what we've always said about that is it that we like the antibody. We like the structure of the antibody, the epitope binding. But we would certainly not go ahead on our own, and with

Johan's deep knowledge in the field we certainly wouldn't be going ahead until we feel we've got the right approach for TAU. And that's not clear, as Johan just said.

Martin Parkhøi, SEB: [00:41:07] All right. Thanks a lot. Appreciate it.

Operator: [00:41:12] Thank you, Michael. The next question will be from the line of Vinit Agrewal from Citi. Please go ahead. Your line will now be unmuted.

Vinit Agrewal, Citi: [00:41:23] Hi, Vinit from City. Thanks for taking my questions. Just a couple of them. First, I was just wondering if you could share what was the price and volume mix to the growth in Q1, especially interested in strategic brands of the 19% growth? If you could quantify the contribution from pricing and what was this like last year? And then second, on gross margin, how should we really think about gross margin going forward? In the last quarter, I think you spoke of improvement for Vyepti. Is the Q1 gross margin representative of the benefits realized from that or is yet to flow through the gross margin and it can expand further from here?

Deborah Dunsire, CEO: [00:42:15] Over to Joerg.

Joerg Hornstein, CFO: [00:42:17] Thank you very much. I think in terms of the price volume split, we don't necessarily provide the exact numbers, but it's fair to say that this was mostly demand driven. And I think if I hope I understood your question the gross margin correctly, I think the adjusted gross margin we are seeing for Q1 is probably also a good indicator for the quarters to come. We really established this key figure to really take the noise out that we have from approximately a third of our cost of goods sold is amortization of product rights. 50% of that is dollar. So, we got a lot of questions in the past in terms of if the dollar would increase or amortization would increase as it does relate to the Vyepti EMA approval or certain sales milestone achievement. We always get the question of what the variability in your gross margin is. I think this we take out now by bringing the adjusted gross margin number in, and that probably is a good indicator also for the quarters to come.

Vinit Agrewal, Citi: [00:43:34] Okay. Thank you.

Operator: [00:43:37] Thank you, Vinit. The next question will be from the line of Brian Boldshen from Jefferies. Please go ahead. Your line will now be unmuted.

Brian Boldshen, Jefferies: [00:43:48] Hey, thanks for the questions. It's Brian from Jefferies. Maybe just on Rexulti, phase III and PTSD. Could you just talk about confidence in a positive outcome there? And then just remind us on the commercial opportunity. And then on BD, is the messaging still, we're not looking for anything near term accretive given current levels of R&D spend? Thank you.

Deborah Dunsire, CEO: [00:44:16] Okay. So, maybe I'll ask Johan to comment on the PTSD probability and Thomas to comment on the market size.

Johan Luthman, R&D: [00:44:23] Yeah, thanks for the question. We are also eagerly hoping to see the readout, but confidence is hard in an area of this kind because we take the molecule into a new indication. And quite different is a psychiatry indication. It's not even Alzheimer, it's not neurology, it's still psychiatry, but it's a quite different indication. So, we don't have so much prior to build on. What we've seen in the other indications cannot really translate into these indications. But I guess you one flavour, the other flavour I would add is that we did an exploratory phase II before we started these two phase III trials. That was a highly exploratory study that showed that together with the SSRI, the drug seemed to work but was not a premeditated outcome. And it was a reasonable small study, but we thought it was worthwhile with that data, we almost felt obliged to move forward to evaluate this. So, it's quite an open book what we see there. Thomas?

Thomas Gibbs, EVP: [00:45:24] Yes. So, as we think about PTSD, we know that it's a large patient population prevalence about 6%. But we also know that the diagnosis and treatment rates are quite low. So, as we think about sort of the magnitude of what the opportunity would be, I think it's going to be less than AAD but probably more than what we see in schizophrenia.

Deborah Dunsire, CEO: [00:45:47] Great. And on the BD side, I think what we've said is that we look across the different phases of the portfolio and we look at different types of deals, licensing, acquisition, partnership, and so that continues. When we find the right fit for our portfolio, be it late stage and if it is something that is great for Lundbeck,

great for our shareholders, we can deliver a return on. Then we act on it. So, we'll continue to take that position as we look to supplement and build our pipeline from the inside and from the outside.

Brian Boldshen, Jefferies: [00:46:33] Great. Thank you very much.

Operator: [00:46:37] Thank you, Brian. The next question will be from Charles Pittman from Barclays. Please go ahead. Your line will now be unmuted.

Charles Pittman, Barclays: [00:46:46] Hi, Charles Pitman from Barclays. Thank you very much for taking my question. Maybe just the first question on Vyepti. Obviously you've highlighted that you've made further market share gains in the preventative space. I was wondering what further market intelligence do you have or kind of comparative share gains across the industry? And if that's something you can share with us, kind of where are these share gains coming from? Have they been impacted at all by the recent approval of Qulipta? And that would be very interesting to kind of hear more from you on. And then just secondly, on the PACAP, obviously this is only proof concept, but when we're thinking about the commercial opportunity later down the line, could you just outline the key patient market that you would theoretically be targeting here? I mean, why does PACAP significantly differ to the other products patients are currently being treated with? And is the hope that this could be a new first line treatment? And any thoughts around the potential commercial placing for PACAP would be interesting. Thank you.

Deborah Dunsire, CEO: [00:47:42] Great. Thanks for the question. I guess when we think about the migraine market, the question you're asking, it's probably focused on the US. But of course, we've had some good share gains in the markets we've launched in outside the US. I'll start with Thomas and then open it to you, Jacob, to talk about and then Johan, perhaps you can talk about the PACAP.

Thomas Gibbs, EVP: [00:48:03] Sure. Thanks, Deborah. And thanks for the question, Charles. As we think about the progress of Vyepti, we are seeing good growth within the context of new patient starts as well as continuing patients. So, we have seen steady share gains and we have not necessarily seen any slowdown with Vyepti growth as a result of the Ellipta launch. We continue to see good, steady growth. And as we've

talked about, we've taken a first step in terms of our market share relative to Nurtec, where we surpassed Nurtec in the preventative migraine marketplace. And we continue to focus on growing our business.

Jacob Tolstrup, CCO: [00:48:47] Yeah, I can add to that. I think we also talked about it on previous quarters, the brand positioning of where we would like to win with Vyepti. And that's also what we see in the market that we are targeting severely impacted patients. And that's also what we see in the initial uptake. So, many chronic patients that are on Vyepti and once we have proven to physicians that the treatment is as good as we say, and physicians become comfortable and confident about using Vyepti. I'm sure you will also see eventually they will start to move more into the episodic migraine.

Johan Luthman, R&D: [00:49:31] Thanks for the question. I think one should start with what we know. This was a study in prevention of migraine. Pretty traditional population, if I may say so. Episodic and chronic patients. A little more on the severe end. So, this was hard to treat population from the severe point of view. So, that's a good outcome. So, it's obviously showing its worth in prevention of migraine and people that have failed 2 to 4 prior treatments. So, that was the extra tweak we put on this study. So, that's what we know. Then the question is how will this be positioned in the future? Again, I will need to digest this a little bit and think about it more carefully. But I just like to say that this first line, second line, if you look at, for example, Vyepti we have today, it's obviously not the first line. It's something you go to when you have tried a few other therapies. So, I would say this is probably not going in that direction either. But the market will, of course, reshape over the years. This will take a while until it comes to the market. I have analogues here and I talked about this before. For many of those fairly big diseases with big medical need, there is always a new patient for a new drug. And you may say that the new mechanism of action has to differentiate. Yes, it often does. And it does sometimes in surprising ways. The CGRP class and I was part of that journey. We didn't know the indication when this field started. Prevention of migraine was not an indication people talked about when that class started, and we were already far into phase II and phase III studies when that sort of thing surfaced. So, new drugs, new mechanisms can create its own subset of indications. We will learn through the journey. And still there are many patients out there that need would just need another prevention treatment. So, we'll see on this journey where we land with this. But the door

is open to maybe new indications and maybe still a big new good treatment for patients on the prevention of migraine space or in that space.

Charles Pittman, Barclays: [00:51:45] Thanks very much.

Operator: [00:51:48] Thank you, Charles. The next question will be from Michael Leuchten from UBS. Please go ahead. Your line will now be unmuted.

Michael Leuchten, UBS: [00:51:57] Thank you. Two questions, please. Just going back to the switching or flipping the switch on AAD. There is a meaningful amount off label usage obviously of anti-schizophrenia drugs in the setting. Why would that not offer itself as a fast access to market? What would stop a switch dynamic from developing whilst you wait to build the new patient share? And then Johan, there's been some interesting data on alpha-synuclein as an imaging agent coming out of the Michael J. Fox Foundation. Just wondering what your thoughts are around that. Is that something that might help you accelerate your developing program or is that completely independent? Thank you.

Deborah Dunsire, CEO: [00:52:41] Great. Thomas, would you like to step in?

Thomas Gibbs, EVP: [00:52:44] Yeah. So, thank you for the question, Michael. I think you're right. There is a significant unmet need that exists within the AAD market. We do see that about 30% of the patients who are treated are treated with antipsychotics. We also know that many of those patients have an unwanted sedation side effect. So, there is the opportunity to convert those patients, particularly with the first and only approved agent. However, it is going to take time to be able to penetrate that market with our sales force and physicians will also be hesitant just to switch patients that are stable. So, we have to recognize that dynamic. We also have to recognize that about 16% of those patients are in skilled nursing facilities and penetrating that segment will also take a little bit of time as well. So, although we see a very rich opportunity in that patient segment that are being treated with antipsychotics, it's going to take a little time to be able to penetrate and convert those patients.

Johan Luthman, R&D: [00:53:49] Yeah. Thanks for the question about the PET. This is a little dangerous question to give to me because I can give you a 30 minute lecture on

this, but I will try to be short. I have the pleasure, actually, to have been past helping my folks to review some of those tracers. But what's happening now is a breakthrough in the PET field for alpha-synuclein. We have clinical PET tracers now from more than one company that are being tested out. And my key focus is going to have a PET consortium looking at this together. We obviously follow this and discuss with them. Will this be a game changer as the amyloid tracers have been or more recently, also the TAU tracers, when you see Donanemab, for example, from Lilly, we don't know. It's too early. The data we have so far looks strongest in multiple system atrophy. That's really what we're studying, and it looks best in actually cerebellum readouts. So, there is promise there that you could use them for that kind of purpose. But I also like to say that we're using other things in our program. Neurofilament light is something that we also have already been using in the trial, and we will use that as a supportive readout. And neurofilament light is one of the higher validated biomarker for neurodegeneration. And as you may know, it's even been used for accelerated approval for an ALS drug from Biogen recently. So, we're trying to do all these things together. It would be great to have a PET tracer that you could use as the amyloid tracers, but we honestly don't know that yet. If you can expect that kind of what I call brainwash, maybe not the perfect term for it that you see with amyloid tracers with our therapy, but that could be a good way to illustrate that. We are contemplating various biomarkers throughout the program. And obviously the hope is always for an accelerated approval based on the biomarker, but that requires a lot of validation for that particular indication.

Michael Leuchten, UBS: [00:55:49] Thank you.

Operator: [00:55:52] Thank you, Michael. The next question will be from Marc Goodman from SVB Securities. Please go ahead. Your line will now be unmuted.

Marc Goodman, SVB: [00:56:02] [inaudible]

Operator: [00:56:20] I'm sorry, Mark. It seems like your line is breaking up a lot. Can you try to reconnect?

Marc Goodman, SVB: [00:56:26] Reconnect? Okay.

Operator: [00:56:31] Yes. If you reconnect, we will take the next question. The next question will be from Dominic Lunn from Credit Suisse. Please go ahead. Your line will now be unmuted.

Dominic Lunn, Credit Suisse: [00:56:48] Hi. Thank you. Just two follow ups. So firstly, On the R&D spend, obviously down 15% in the quarter and guiding to flat for the year. So, I'm just wondering if you could talk a bit more about the cadence of that rise through the rest of the year. And essentially I'm just trying to understand what the exit rate is to get a better sense of next year where it looks like something, you know, in the mid to high single digit growth range in R&D wouldn't be too much of a stretch versus a flat this year. And then secondly, just to follow up on PACAP, I think in the past, obviously you said you're considering doing another phase II before going to phase III. But what would be the reason for this? Is this based on size number of patients in the trial? It looks like you did a bit better than you expected. Or is this because there's something else that you'd be looking to address in another phase II that you didn't look at in the first trial? Thank you.

Deborah Dunsire, CEO: [00:57:39] Okay. So, Johan, do you want to dive in on that?

Johan Luthman, R&D: [00:57:43] Let's take the PACAP first. So, yes, we have, of course, been sort of looking at this quite generically before we have the readout. When you have a readout, you start to reconsider a lot of things. As I said, and I like to repeat that this looks like a very robust readout. So, this is definitely something to build on. However, there are still fundamental unknowns we need to sort out. Like route of administration. I mentioned that we have Sub-Q possibilities. This study was an IV. So, the question is will we translate this into Sub-Q, or will there be a benefit of both or whatever? That's a really good consideration. Vyepti is a great drug. It's an IV drug, so there are a lot of things to consider there. The other one is, of course, what dose to use exactly. So, that needs to be sorted out. Traditionally you do that in a phase II B, but if that will happen, that remains to be seen. As I said in the meeting this morning, because obviously with this in the hand you like to try to speed up, but you don't like to do something stupid with the dose, you don't go into phase III with the wrong dose, not understanding that you have to find the right dose range. And for some regulators, you also like to see non-functional doses, non-active doses. So, we are not ready to tell

whether there will be a phase II B or a phase III, whatever we call it. Call it late development, and we'll do our fastest development plan possible.

Deborah Dunsire, CEO: [00:59:18] Yeah, I think that's a that's a great summary, Johan. Late development, the fastest development plan possible. But I think, you know, one of the things we focused on at Lundbeck is making sure that we get things sorted out in those earlier stages, not rushing into the big late stage and then getting it wrong. And I think you'll see us take the time to make sure we have those questions sorted out. But we are very excited to be able to take this forward. So, we're looking at it up and down to look for the right answers to those questions. Joerg, would you like to comment on the R&D spend?

Joerg Hornstein, CFO: [01:00:02] Absolutely. I think as early as stated, we see R&D costs broadly stable compared to last year. We spend around 3.7 billion last year and I think that's a good indication for this year as well. I think that's as far as we go in terms of guidance, we don't really provide quarterly breakdowns, but of course the underspend we've seen in the first quarter is lower than we anticipated. And in terms of exit rate, again, we don't provide guidance yet for the next year. Let us first deliver on our promise this year.

Deborah Dunsire, CEO: [01:00:41] But I think acknowledged that we are getting ready for, you know, other trials and we're thinking about how we are dealing with PACAP. Biologics, I want to remind you, the preparation expenses are higher as you think about creating drug supply. So, all of those things factor into why we will continue to spend in the rest of the year. And you can't extrapolate the first quarter.

Johan Luthman, R&D: [01:01:05] If I may add. You know, there's also, of course, timing effects on certain contracts and payment or contracts. That's why, as Joerg said, we look at the whole year that's more relevant because there are fluctuations in some big cost contract costs, etcetera, from CROs that come through and they are not lined up evenly during the year. So, that's also a matter for just waiting for the full year.

Dominic Lunn, Credit Suisse: [01:01:33] Okay. Thank you.

Operator: [01:01:36] Thank you, Dominic. The last question for today will be from Mark Goodman from SVP Securities. Please go ahead. Your line will now be unmuted.

Marc Goodman, SVB: [01:01:46] Yes, Hi. Questions were number one on the two month Abilify. Can you tell us what the percent of LAI market is over one month? So, we understand what that opportunity is. Second of all, the lead MAGLi lipase molecule. Can you just give us an update and when we'll see some data? And a third on Trintellix. Just given the recent prescription trends, I'm just curious if you and your partner are increasing advertising and promotion dollars are actually decreasing. Thanks.

Deborah Dunsire, CEO: [01:02:14] Okay. Maybe we'll start with you on the MAGLi program, Johan, and then Thomas can take the two questions on.

Johan Luthman, R&D: [01:02:22] Thanks, Marc, for that question. So, I'd like to start by reminding you that the MAGLi program is a platform of several molecules, and we have also another molecule in phase I that is a more peripherally restricted, it's more going for some pain indications that we're now finishing up the single ascending dose, etcetera. But I assume you're asking about MAGLi 66, which has been our lead molecule for testing more CNS and central active action of the mechanism. We have done a set of phase I B studies. We do what I call let the molecule speak here. We just had a readout from two of those indications that you have seen publicly listed. We have just finalized MS spasticity and PTSD. We're analysing those kind of data, but that will form the basis really for how we will progress with this program, with maybe this molecule, maybe another molecule that we have in preclinical development that also looks very promising. So, we have a set of at least three molecules that we can choose between here moving forward. And as Deborah pointed out, we'd like to do it right. So, unfortunately, this takes a little while. I know it's a while ago we acquired a bite and got access to these molecules, but there is no point in rushing this because it's a really broad and high potential biology, but it needs to be sorted out.

Thomas Gibbs, EVP: [01:03:50] So, thanks for the question. As we think about the evolution of the LAI market, there's a growing percentage of utilization in the greater than one month dosing interval, but right now it's still predominantly a single one month. Predominantly the products that are one month represent about 75% of the total market.

Deborah Dunsire, CEO: [01:04:16] Great. And then the comment there was another question in there on Trintellix.

Thomas Gibbs, EVP: [01:04:23] What was the question?

Deborah Dunsire, CEO: [01:04:25] Marc, ask your question Trintellix again?

Marc Goodman, SVB: [01:04:31] It was related to whether you were increasing or decreasing spending on that market.

Thomas Gibbs, EVP: [01:04:37] So as we look year over year, we see that we're going to continue to promote Trintellix at the level we are right now. Right.

Deborah Dunsire, CEO: [01:04:47] I think what we've seen is the disruption in '22 as Takeda reformulated their sales force and we did some tweaks within ours, that disruption is now settled and I think we've got the field force in place and fully focused on the updated efficacy message and that seems to be impacting on the NBRX trend picking up after basically it had declined last year.

Deborah Dunsire, CEO: [01:05:23] With that, we'd like to thank you all for your questions. Thanks for your attendance today. It's been a great first quarter and indeed first four months at Lundbeck. We're all excited about the outcome for AAD later today. Thank you.