Lundbeck

H1 2024 Results

21st August, 2024 | 13:00 CEST

Transcript

Speakers:

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Joerg Hornstein - Executive Vice President and CFO

Johan Luthman - Executive Vice President R&D

Charl van Zyl

Welcome and thank you for joining us today on our earnings call. It's my pleasure to be with you and be able to express my confidence around our first half results. Our goal today is to give you a comprehensive update and we look forward to your questions and engaging with you on the full first half results for 2024. And go to the next slide, please. Today will contain some statements, and these are forward-looking statements and are subject to change. Go to the next slide, please.

The agenda here today is my pleasure to be joined with my management team. You will hear from our two Executive Vice Presidents for our geographic operations, Tom Gibbs for the US, and Michala Fischer-Hansen for Europe and international markets. We will also hear from Johan Luthman, who is our Head of Research and Development, and also our CFO, Joerg Hornstein, around the full financial update.

To take us to the next slide, again I want to remind you also of some changes we have announced previously. But it's important for me to also welcome our eighth member to our executive leadership team, Maria Alfaiate, who is heading up our Commercial Strategy for Lundbeck. This is the team, essentially, that will continue to perform and transform Lundbeck for the long-term success of the company. And Maria will bring a lot of capabilities that we need around building our strategic understanding of our therapeutic spaces, as well as the strategy for some of our commercial operations in the future.

If we then go to the next slide, please. And here again, before we get into the first half results, I think it's important that we just, as we have consistently done in the past, to remind you of the strategy and where we are going. And this is less than one year ago that I joined, and we've undertaken the strategic review and developed our focussed innovator strategy. And it's underpinned by three important elements. But firstly, to say it's really important to emphasise that part of our strategy here is to really look at capital reallocation that will allow us to either invest in more innovation or more growth, where we see the opportunities with our existing portfolio.

There are three important pillars to the strategy that I just, again, want to remind you. Our main focus is really to secure long-term, sustainable growth. We want to continue to pivot to lead in innovation in a very focussed way and we are very committed to deliver sustainable profitability, also again against our mid-term guidance that we've given you in the past. And just to emphasise a few quick points. When we talk about secure and stable long-term growth, the most important part here is that we are already making very selected investments in our strategic brands, mainly Vyepti and Rexulti. And the aim here is to advance their growth to allow us to bridge across the mid-term LOE and focus our

efforts on the long-term LOE that we see in 2029. We're also advancing the pipeline, and you'll hear more from Johan on that. But supplementing that is a very targeted approach to business development that builds on our strengths and builds on our capabilities, and really what we call programmatic M&A that will continue to support our innovative pipeline.

As we think about focussed innovation, we have made some specific elements already to progress there. One of them, in a sense, renegotiation of our agreement with Takeda that allows us to reallocate resources more to the growth portfolio of Rexulti in the US. And we are rebalancing a lot of our investments, very much around selected markets, where we believe we can grow more with the assets that we have. And finally, again here our commitment to our adjusted EBITDA of 30 to 32% mid-term is very much in our hands, and we feel confident that we can deliver on that to sustain the long-term success of the company.

If you then go to the next slide, it's my pleasure to be able to present to you such strong results. And I want to take a moment to thank the management team and the leaders at Lundbeck for delivering these stellar results in the first half of the year. We see essentially double-digit growth on our total top line of 10%, and we have seen the confidence in the first half of the year with our underlying performance that allowed us to, as of yesterday, raise the guidance for 2024, again giving us that confidence that our strategy is delivering on what we said we would do.

And in a sense, a strong performance on the strategic brands is evident, as you see in the results. Our strategic portfolio, which is 73% of our current composition of our portfolio, is growing at 19%. Leading the way there is Vyepti, that continues to excel, as well as Rexulti, both at 78% and 13%. Then we have not stood still on the pipeline and we see good advances on the pipeline. As we have mentioned to you in the past, we are seeing in the PROCEED trial with anti-pay cap that that continues to advance in the phase IIb. But you will also hear from Johan more specific elements of the pipeline, specifically areas where we are looking at more neuro rare assets. As we said, this is very much part of our strategic pillar with CD40 in thyroid eye disease, and also anti-ACTH, both in Cushing's and also congenital adrenal hyperplasia. And the alpha-synuclein advancement, with fruitful conversations we've had with the FDA, will advance to our phase III going forward from there.

We are building a diversified pipeline that will allow us to build on that long-term success that we expect to have with this pipeline, delivering long-term growth for the company. With that, it's my pleasure, therefore, to hand over to our two geographic executive vice presidents, to take you through more specific details of our underlying performance. And therefore, I hand over

to Tom.

Tom Gibbs

Thank you, Charl, and good afternoon, everyone. As Charl mentioned, we delivered strong commercial performance during 2Q 2024, and this was driven by the 19% growth of strategic brands. This growth was headlined by Vyepti. We'll go to the next slide, please.

We are very pleased with the performance of Vyepti in the quarter, and this performance was fuelled by accelerating growth in the US and supported by the continued stream of launches and robust adoption in prioritised ex-US markets, including Canada, France, Spain, Germany and Switzerland. Vyepti global net revenues for the quarter were 1.342 billion DKK, and this represents 78% growth year-over-year. Net revenues for Vyepti in the US were 1.18 billion DKK, delivering 68% growth over the first half of 2023. Importantly, we're beginning to see meaningful contributions to global sales by ex-US markets, with Vyepti now available in some 29 markets and delivering 206% growth over prior year. These markets are both exhibiting strong anti-CGRP market growth, and Vyepti continues to gain meaningful market share across these markets.

I do want to focus just a moment on the US. Over the past year, we've worked very hard to refine our speciality commercial model to support Vyepti by focusing on HCP engagement, patient activation, patient experience, and market access. These four levers have made material contributions to helping accelerate demand by driving depth and breadth of prescribing, and also increasing momentum in new patient starts and driving patient adherence. Next slide, please.

Rexulti continues to perform well, propelled by the continued strong progress in the AADAD launch in the US. US TRx growth during the second quarter of 2024 was 17% versus prior year. As Charl indicated earlier, global reported net revenue increased 13% for the first half of 2024 versus prior year. What I think is important to mention is that the revenue growth during Q2 2024 accelerated to 18% versus the same time period a year ago, and that's compared to the 6% growth we reported in 1Q 2024. We are pleased with the strong demand growth observed across all of our priority markets. The majority of the volume growth is driven by the US, particularly the AADAD launch, with 265% monthly volume growth when we compare May 2024 claims data to the pre-launch baseline. The long-term care channel continues to disproportionately contribute to Rexulti AADAD growth, with nearly 656% monthly volume growth since baseline prior to launch, and our market share in LTC has increased more than sixfold. Next slide, please.

Rexulti AADAD volume is becoming increasingly important to the

overall Rexulti growth, and we expect this momentum to continue through 2024 and beyond. AADAD contribution has grown to 14% of the entire brand, based upon our most recently available data, and represents 22% of new to business prescriptions. We expect AADAD overall contribution to the brand to exceed 20% by year end. The AADAD launch has also had a positive halo effect on the overall brand, with non-AADAD volume growing monthly claims volume by 16% from our pre-launch baseline in April 2023 to May 2024.

Now, in looking at the most recent TRx data, non-AADAD TRx growth has accelerated to 10% since February, due to the continuation of our MDD direct-to-consumer campaign, which was off the air from November through the end of February. And we've also seen improved execution across the broader marketing mix, including our sales team. Importantly, the latest MDD indication level data appear to confirm our decision to elevate our Rexulti strategic investments in to 2Q 2024. And this was particularly in DTC, and have yielded positive results with Rexulti MDD and TRx growing at 20.4% over the time period, outpacing our branded competitors.

I'll now turn the presentation over to Michala to discuss performance of our other strategic products.

Michala Fischer-Hansen

Thank you for that, Tom, and good afternoon, everyone. If we look at the Brintellix/Trintellix, we also here continue to see a very strong performance, where we've delivered 11% growth versus the same period last year. And as you can see now, at 2.35 billion DKK globally at the reported rates. If we look to the US specifically, we also see a nice growth and solid performance at 5% up compared to last year at 727 million, where we see some indications of stabilisation in the market.

If we look to the rest of world, you can see here that we have 15% growth compared to last year, now delivering 1.6 to 4 billion DKK. Specifically, we see Europe having grown 16% versus the same period last year, which has been driven by Spain and Italy. And in international markets, we've seen 13% growth, which has been driven by Japan and China. If you look at the right side of the slide, you can see the MAT volume growth in the market versus the growth of our brand. You can see, again, that we outgrow the market considerably in our key markets, which again underlines the very strong performance of the brand, despite several years in the market. And as a result of this, we continue to see all-time high market shares in these markets. Next slide, please.

If we move to the Abilify LAI franchise, you can also see here very strong performance, with 9% growth globally, now delivering 1.725 billion DKK compared to last year. If we look at

the atypical long-acting injectables market, the business here accounts for 38% of the total atypical market in value. And as such, continues to outgrow the oral atypicals. If you look to the US, you see very strong growth at 11% versus the same period last year. And in the rest of the world, you see 8% growth. We generally see continued strong performance across most of the markets, including US, Spain, Canada, Australia, and France. If you look at the right graph here, again, you can see the MAT volume growth and how that has developed between the market and our product, the Abilify LAI franchise. And again, you can see that we continue to outperform the market growth.

A reminder that we last year in June launched Abilify Asimtufii in the US, the two monthly. We now see that the brand is performing, delivering 11.5% TRx and 16.3% of new patient starts for the Abilify LAI franchise. And similarly, the brand was approved in Europe in March of this year. Please bear in mind that here it's called Abilify Maintena 960 mg, and we have at this point launched Abilify Maintena 960 mg in five markets outside the US.

With that, I'd like to hand over to Johan for a R&D update.

Johan Luthman

Tom, great progress and momentum on our key brands. Let me turn the page and go a little bit more into R&D. As you may recall, already Q1 we had a very strong start with approvals and progression in the pipeline. Now coming further into the year, we have achieved FDA validation of the submission dossier and have our formal filing acceptance of the S&A for post-traumatic stress disorder, PTSD, for brexpiprazole. A programme that is run within the Lundbeck/Otsuka alliance. The PDUFA action date is set on February 8th 25.

Also, a comprehensive data set from the PTSD programme was presented for the first time at the American Society of Clinical Psychopharmacology meeting in May. It was a clear interest in the programme, which is not surprising, given that this condition is substantially underserved without any new pharmaceutical therapies introduced in over two decades.

In the early development pipeline, we are right now progressing to programmes into proof of concept trials, the critical watershed moment in clinical development. As Charl already mentioned, our anti-ACTH monoclonal antibody programme 909 has entered into Cushing's disease, a rare new hormonal indication in a trial called BALANCED. By this, we have two different patient studies ongoing for this antibody. I will come back to this programme in the coming slide.

The other proof of concept trial that is starting up is with the CD40 ligand binder 515. The programme is just gearing up in thyroid eye disease, TED for short. TED is a condition closely

related to Graves' disease, an autoimmune disease that affects the thyroid gland. In TED, which is a subset of Graves', the tissue behind the eyes become inflamed and swollen. One of the key symptoms of TED is proptosis, bulging eyes. This is one of the main goals of this trial, which is run in patients with moderate to severe TED. Proptosis is determined using objective measurements, allowing for an open label approach, and early detection of possible efficacy signals. Next slide, please.

In the coming two slides, I'd like to highlight continue R&D contributions to support our key brands, Rexulti and Vyepti, in approved indications. Let me start with Rexulti in the indication agitation associated with dementia due to Alzheimer's disease. At the end of July at the AAIC meeting, the world's largest Alzheimer's disease conference, we presented three important aspects of the effects of Rexulti based on further post-hoc assessments from the latest of the three registration trials in the programme. the trial we call 213, and also adding data from its extension part called 1A2. First, we evaluated CMI data, the primary end point beyond the 12 weeks' double-blind period.

In the graph on the upper right side, response rate is presented as defined by a clinically meaningful change of 20 points on this CMI scale. Here you can see a response to the treatment at about 55% of the patients at 12 weeks, increasing to about 75% of the patients at 24 weeks. Moreover, the switch of the placebo group to Rexulti brexpiprazole at 12 weeks confirms the efficacy, leading to an increasing response rate up to 68% at 24 weeks. This dataset not only verifies the efficacy further by the placebo switch, but also importantly, demonstrates longer term sustainability of the treatment effect with continuing increased benefit over time.

Another important insight comes from the integration of real-world data on caregivers' identified most bothersome symptoms with data from trial 213. The caregivers reported ten behaviours as for them most troublesome, as listed in the table to the right. Those behaviours spanned across all agitation factors of the CMI scale. On aggression, this included items such as verbal aggression and spitting. On physical nonaggression behaviours, these include items such as pacing and verbal agitation. And on verbal agitated behaviours, these included items such as unwarranted requests for help. Those of you that have experienced as caregivers of dementia patients probably well recognise those challenging agitation behaviours.

We see an effect of Rexulti on all those ten items identified by caregivers as most troublesome, with a clear separation from placebo of at least confidence into the low 90%. Through activities as exemplified here, we are building up a very strong presence and critical increased awareness of the availability of

the only approved treatment in the US for agitation in Alzheimer's. It is important to communicate the uniqueness of the medical profile of the drug in terms of effect versus tolerability. This is particularly essential, given that we're aiming to also change the treatment approach for agitation, in particular, by neurologists. Next slide please.

And then a few words about Vyepti. Also for Vyepti we obtained additional data and done further analyses that have generated additional insights. Some of these data were presented at the American Headache Society meeting in June, where Lundbeck overall had a very strong presence with our migraine programmes. I'd like to highlight a couple of datasets. To start with, the PREVAIL study, a 300 mg Vyepti single-dose arm, open-label trial on patients with chronic migraine. PREVAIL stretches out 104 weeks of treatment, with 96 patients reaching that stage. Proper [?] results have previously been reported, but today I focussed on the patient reported outcomes. It is clear, as illustrated in the graph on the left side, that Vyepti showed substantial and sustained reductions in headache frequency and severity for up to two years.

The other example I like to mention is the real-world evidence that they called REVIEW, that looked as something very critical for chronic migraine patients, brain fog. Together with headache frequency, brain fog is one of the most bothersome symptoms of migraine perceived by patients. Brain fog is a feeling of being confused, having cognitive difficulties in learning and memory, as well as impairment in speaking and reading. Brain fog was reported in up to 80% of the patients, but since starting Vyepti, 86% of the patients are reporting some improvement in their brain fog symptoms. Very interesting to note is that one third of the patients reported brain fog symptoms are very much improved, and some see complete disappearance of brain fog. We continue to generate strong scientific support for our brands in the key indications. Next slide, please.

I promised to talk a little bit more about our anti-ACTH programme, 909. 909 is our IgG1 monoclonal antibody that binds to ACTH with high affinity, and thereby it reduces ACTH levels. This is an essential hormone in the so-called hypothalamic pituitary adrenal or HPA axis. In December 22, we started a proof of concept trial on congenital adrenal hyperplasia with 909, where we already have established now proof of mechanism on key androgens, and we are therefore building a more comprehensive PKPD model. Before I go into the design of the now initiated proof of concept trial called BALANCED, I'd like to mention a few characteristics of Cushing's.

The disease is the very characteristic set of bodily changes, with weight gain being one of the most apparent, combined with

muscle weakness, the blood pressure increases, development of diabetes and bone weakness. Also, the disease comes with several cognitive and psychiatric changes. The disease is substantially underserved, with surgery commonly only partially effective or insufficient. And also, glucocorticoid synthesis inhibitors have only effect on some of the critical symptoms and lacking effect on many other CNS symptoms. The BALANCED trial will evaluate PK safety and efficacy. Here, efficacy is measured through biomarkers, including the well-known steroid hormone, cortisol, which is the key readout. The trial starts with a very adaptive, individualised titration scheme, with increasing doses of 909 given IV every second week. We will then, after finding an appropriate level of biomarker effect, turn dosing over to sub-Q for six weeks. Through this innovative, flexible design, we will be able to achieve critical peak PKPD data, which is fundamental to understand the potential of this mechanism also in Cushing's disease. Next slide.

We continue to see very good progress in the R&D pipeline throughout the first half of 24. Several milestones have been achieved, for example, we did get the important approval of aripiprazole two month, long-acting, ready-to-use formulation in Europe during early Q2. We also had our first in class PACAP antibody, 222, for migraine prevention, enrolling subjects in the PROCEED trial. It's too early to tell how the timelines will look, we're still at the early phase of enrolment. On the other hand, this programme has continued to gain significant recognition by leading academic clinicians, and we expect some major publications occurring soon on the drug target and the data we obtained so far in the program.

Already during Q1, we talked quite a bit about the breakthrough potential of the anti-alpha synuclein antibody and multiple system atrophy, with very encouraging data from the AMULET proof of concept trial. We are now progressing well with our preparations to initiate the development programme for registration. We have had very fruitful and good interactions with FDA, and we are about to wrap up the interactions with other regulatory agencies.

Our oral active D1-D2 dual agonist996 as an add-on treatment in Parkinson's disease started a tailored, small patient population study earlier this year. However, the programme may require some rethinking, so it's very likely that the start of the proof of concept trial may be a bit delayed. Additionally, important events that we are awaiting include the Vyepti SUNRISE trial, a trial that is aimed to pave the way for further expansion of the product in Asia, mainly Japan and China. The enrolment has gone very well during Q2, so we are maybe able to speed up the readout.

Finally, in the very early development area, we hope to conclude one of the MAGLi platform molecules that has been through a let the molecules speak evaluation in human experimental pain models. With that, I'd like to hand over to our CFO, Joerg.

Joerg Hornstein

Thank you very much, Johan. Great to see the progress in our pipeline. We're very pleased with our financial results for the first half since several of our conscious choices, reallocating spending to the most long-term attractive growth opportunities yields the desired results. This also gave us the confidence to have significantly raised our financial guidance for the year slightly. Our revenue for the first half of 24 grew by 10%, driven by the strong performance of our strategic brands, which are up 19%. The significant contribution of Vintellix in Europe, and Vyepti and Rexulti in the US, representing nearly 70% of the overall strategic brand growth.

The adjusted gross margin was 88.6%, decreasing 1.3 percentage points, primarily driven by a higher raw material and manufacturing costs, and increasing share of Vyepti on cost of sales. This is an impact we anticipated, and it's in line with our guidance around 88 to 89% of an adjusted gross margin for the year. Sales and distribution costs increased 10% to 3.8 billion, and reflect again the continuous investments in the key strategic assets of Rexulti and Vyepti in the US, as well as investments tied to the global and continued rollout of Vyepti. Administrative expenses increased by 31% to 738 million, primarily driven by investments in Lundbeck's focussed innovator strategy, ongoing transformation, as well as higher legal and personnel costs. R&D costs increased by 12%, reaching 1.9 billion, mainly driven by investments in anti-pay cap and the anti-alpha synuclein antibody.

Adjusted EBITDA increases 5%, as a result of a strong revenue growth driven by the performance of our strategic brands. The adjusted EBITDA margin was 33.3%, representing a decrease of 2.1 percentage points, primarily related due to higher raw material and manufacturing costs, increasing share of Vyepti on cost of sales, as well as unfavourable currency and hedging effects. Next slide, please.

Our EBIT grew 17%, reaching 2.3 billion, growing in line with the underlying operating performance, benefited by lower amortisation of product rights. Net financials reached an income of 25 million, equivalent to an increase of 118%. The positive development is mainly driven by development in interest income, due to the underlying change in net debt cash position, and favourable currency impacts due to the underlying development of the US dollar exchange rates. The effective tax rate of 23% is in line with full-year expectations. Net profit increased by 20% to 1.8 billion, and adjusted net profit increased by 7% to 2.6 billion,

reflecting the adjusted EBITA performance and the positive net financial results. Next slide, please.

The cash flows from operating activities in H1 24 represents an inflow of plus 2.2 billion, compared to an inflow of 1.6 billion in the first half of 23. The operating cash flow reflects the continued solid EBIT performance, further impacted by slightly lower adjustment for non-cash items, predominantly related to the amortisation of product rights and the lower change in working capital comparison to the last year. The cash flow from investing activities was an outflow of 245 million, driven by CapEx investments in the first half of 24, compared to an outflow of 265 million in the first half of 23. The cash flow from financing activities was an outflow of 784 million in the first half of 24, compared to an outflow of 1.25 billion in the first half of 23, primarily driven basically by two factors. Lower debt due to the repayment of the revolving credit facility in 23, offset by higher dividend payments in 24, partially. The first half of 24 ended with a net cash position of 1.9 billion, compared to a net debt of 1.4 billion in the first half of 23, effectively deleveraging the company, bringing us into a very strong financial position for the future. Next slide, please.

As you saw yesterday, we have communicated a significant increase of our full-year guidance. We've raised our revenue guidance to 11 to 14% and our adjusted EBITDA growth is raised to 15 to 20%. The revised sales outlook for 24 is primarily reflecting high expectations for Rexulti and Vyepti volume sold in the US, as well as higher Brintellix/Trintellix demand in Europe and Asia. The updated adjusted EBITDA reflects revised sales growth expectations, partially offset by higher investments in R&D and sales promotion costs for Vyepti and Rexulti. And please also note that the guidance reflects a significant pre-commercial investment for PTSD.

Other relevant financial information for the guidance remains unchanged. And with that, I hand over to Carl.

Charl van Zyl

Thank you, Joerg. And thank you to the team for sharing the first half results. I would like to make some concluding remarks before we open for questions and answers. If we can go to the final slide, please. Again, I think what you heard from us today is that we are well on our way with our strategy to becoming this focussed innovator. You've seen acceleration of the advances in the pipeline, and also the very disciplined investment to fuel growth. Both of these are important proof points to our focussed innovator strategy. And again, I want to express my confidence on the path that we have set to continue to deliver on our mid-term targets that we have set out for you in terms of guidance.

I want to draw your attention also to a capital markets event that

you could pencil into your calendars for 23rd October, with a goal that we will go deeper with you into our mid-term target summit and guidance, and also give you more insight into how we look at capital reallocation to fund the long-term sustainable growth of Lundbeck. Thank you again for joining today, and we look forward to having questions and answers now.

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. Questionnaires 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. Our first question comes from James Corden with JP Morgan. Please go ahead.

James Corden

Hello, James Corden, JP Morgan. A few questions, please. Thanks for taking them. Firstly, on Maintena, latest thoughts on when we're likely to actually get generic competition in the US and EU? I think there were some lawsuits that got withdrawn in the US and EU, the generics only filed earlier this year, so it's worst case mid or even late 25 in both regions now? And when generics pop up, is there much else that could slow down how quickly they launch, like whether it's vial versus ready-to-use form, so an update there is the first question.

Second question, Brintellix in the US and the Takeda renegotiation, just so we can model this, what royalties should we assume you're now going to get on in-market sales? Could it be something like 20%? And how much were you spending on promotion that you're going to save? Were you spending 30% of the sales that you were booking or something like that? What's the sales and marketing saving, and how will you reallocate that spend?

And then third and finally, PTSD, good to see they’re finally accepted. Do you have any indication yet as to whether you're likely to have an outcome? Is it likely to get an outcome in Q4? And fair to say, you seem quite optimistic or quite confident that you will get the drug approved or the indication approved?

Charl van Zyl

Thank you, James. Good to hear you again. And I'll refer to your first two questions related to Abilify Maintena, and also to Trintellix. Maybe, Tom, you would like to address those.

Tom Gibbs

We continue to see the Abilify LAI franchise as a key growth driver for the US. We're continuing to promote Abilify Maintena, as well as accelerating conversion to Abilify Asimtufii. As we talked about, we've had good success, and I would say we're ahead of schedule, as it relates to our conversion of Abilify Asimtufii with 11.5% of total business being attributed to Abilify

Maintena and 16.3% in new prescriptions. And I'd say we're ahead of schedule based upon what we've seen other analogues in the marketplace. As it relates to the patent, we do not see something as an impact over the course of our mid-term planning.

Charl van Zyl — Thank you. Tom, do you want to comment further Trintellix, as well?

Tom Gibbs — With Trintellix, this was an important representation of our focused innovator strategy. We're looking across our portfolio and ensuring that we're disproportionately allocating resources to the brands that we see the greatest growth. And when we looked at Trintellix in the US, it was just not a significant growth driver for us. We're actually very pleased to be able to ultimately reallocate those resources to support Rexulti, because we see a higher promotional return on investment response with detail in Rexulti versus Trintellix. We do not see any material impact in terms of financials as it relates to our mid-term planning with Trintellix.

Charl van Zyl — Thank you, Tom. Johan, would you like to address the question of PTSD?

Johan Luthman — Thanks for the question, James. At the time of the acceptance of the file, they did not at the FDA announce any outcome. They can always announce that in the review process, if they see that needed. But it's an indication how they see this. And remember, this is the third and the eighth for these molecules, and they know it quite well, they're familiar with it, so we'll see what how they look at it. Safety is well documented across many studies, which may often trigger an outcome if they have safety concerns. We'll see what's going to happen, but it doesn't really look like it right now.

In terms of our optimism, I'd just like to remind you that the package in PTSD are three trials. One was an exploratory phase II called 061, which showed that the combination with Sertraline was working against placebo. Here we have now the two registration trials, 070 and 072, 72 being a fixed dose and 71 flexible. In the flexible trial, we had a significant effect, but unfortunately, we missed it in the fixed dose. Obviously, they like to see replication across big trials, but we have overall a very comprehensive dataset, the biggest they ever looked at for this indication. It's a little hard to judge, it's in the hands of the regulators, how they will view it.

Charl van Zyl — Could we have the next question?

Operator — The next question comes from Marc Goodman with Leerink. Please go ahead.

Marc Goodman — Thank you. Johan, can you remind us of how 909 looks relative

to the Crinetics product and what you think about the Crinetics data and CAH from the ENDO meeting? And then if you could just give us a little more colour on 996, your comments about needing to rethink, what did you mean by that? Thanks.

Johan Luthman

Thank you for those questions. First of all, 909 has a pretty unique mechanism of action. It's differentiated entirely in its mechanism of action, that's the main difference. And if that pans out to clinical differentiation remains to be seen, but we're working at the key factor in the pathway, so we believe that could add substantially more benefits.

Crinetics, they have good data, no doubt about it. But we are looking forward to do our own data generation and see how it pans out. We have some clear ideas what we need to achieve with that programme.

The 996, it's an add-on in Parkinson's disease, an area that is pretty well established with different drugs, but lacking an oral option. And this is really where we like to position it. Are we going to reach all the different aspects of what you like to see in an add-on? Meaning effects on off time or better on time, meaning that you have less dyskinesias when you're on. Those are the two things we like to nail in that programme, and that's really what we need to figure out, how we bring that forward. It's still early stage, but it's a very promising mechanism. As you know, it's an oral active, D1-D2 agonist.

Charl van Zyl

Thank you, Marc. You have additional questions?

Marc Goodman

No, thanks.

Operator

The next question comes from Charles Pitman in Barclays. Please go ahead.

Charles Pitman

Hi. Charles Pitman from Barclays. Thanks very much for taking my questions. Just to start, maybe if you could just speak about how comfortable you are with the implied progress on margin going forward. You've raised your margin target, but consensus seems to be a bit ahead of you still on this, given the amount of ongoing investment you're going to need behind Rexulti and the preparation for PTSD. How should we think about FY 25 compared to mid-term targets? Should we expect that you're going to remain below that corridor going into next year? Just some directional help on that modelling would be great.

Second question is just on the admin expense adjustment. Can you give any more details about what that driver was around the 150 million adjustment? I assume this relates to the legal fees you mentioned, but should we consider this a one-off or something to consider going forward as well?

And maybe just a final point on Vyepti. I would just love to get a

little bit more information around how you see the pricing versus volume dynamics developing in the US market. And if you could also speak about Europe and the increased contribution you see to sales from that region, that would be great. Thank you.

Charl van Zyl — Thank you, Charles. On both margin and admin, I think Joerg, would you?

Joerg Hornstein — Happy to take the question. I think, first of all, our medium-term targets are fully in place. And we see, I would say, exactly the kind of progress towards the trajectory of the medium-term targets that we tend to have. We don't provide guidance yet on 25, but I think what is fair to say is when we revise the guidance, this includes a certain amount of pre-commercialisation spend on PTSD. That is, you can say, significant. And at the same time, we always look at opportunities to also free up and invest specific capital into the long-term growth in our most strategic brands and in our most strategic geographies. And I think to a certain extent, that is reflected in the H2 assumptions. I think if you would eliminate that, you would also see a nice progression towards our ambition level. Every other factor of the guidance remains from the underlying phasing of dynamics, I would say intact.

The second question on the admin of 150, as I said, the increase in admin is not only due to higher legal costs and legal provisions, but also higher personnel expenses and costs we have due to the implementation of the focussed innovator strategy. I think in general, we don't budget for adjustments, but we also don't provide any further details in terms of legal costs. This is a steady revisiting of our legal exposure on a quarterly level, and therefore, we will not go further in detail.

Charl van Zyl — Thank you, Joerg. And Vyepti, if you don't mind, Tom.

Tom Gibbs — Thanks for the question, Charles. I think if you look at Vyepti in the US, this is predominantly a demand story. If you look at demand over the course of the first half of the year, it's increased 54%. And I think what's important to understand about the demand is we continue to see steady flow of new patients. If we look at our volume from a breadth and a depth perspective, one third of our growth is coming from new prescribers, and that's really healthy, as you think about the fundamentals of the brand when you're fifth year on the market. And then two thirds of the business is coming from increased depth of our current prescribers.

Charl van Zyl — Thank you. And, Michala, would you like to comment on Vyepti Europe?

Michala Fischer-Hansen — Thank you for the question. Generally, on Vyepti in Europe, as I think I also mentioned or Tom mentioned, we see a very strong uptake and we see a nice market share progression across the

market and the rollout continues. We also see an increase in demand. And as you can see from the statement, the revenue has also grown considerably compared to the same period last year, I believe around 275%. We're very positive of the development of Vyepti in Europe.

Charl van Zyl — Thank you, Michala. Could we have the next question? Thanks, Charles.

Operator — The next question comes from Lucy Codrington at Jefferies. Please go ahead.

Lucy Codrington — Hi there, thank you for taking my questions. Just a few left. Just given the strength of the Vyepti performance so far, are you starting to rethink your peak sales expectation for this asset, or is this still all within what your previous expectations were?

And then secondly, just to go back on the Abilify Maintena question, and specifically the IP. Just remind us how we should be thinking about the IP expectations between the US and Europe, just following up on James's point about the potential formulations available at patent expiry.

And then finally, again another follow-up, just on the Parkinson's programme. What is it that's causing the recruitment challenges, given the promising profile of the drug? Thank you.

Charl van Zyl — Thank you, Lucy. We'll first of all maybe address Maintena, if we want, straight away, Michala.

Michala Fischer-Hansen — Thank you for that. As for the EU, we've seen some generic or some filing activity going on lately, and our expectation is to see something next year, but we don't want to speculate on timing, since we don't know. I think what's worth noting is that the submissions we've seen at least have been bioformulation, so we're not seeing prefilled syringes. And where we have 70%, roughly, of our sales being in prefilled, so that's at least something to be aware of.

Charl van Zyl — Thank you, Michala. Lucy, on the question of Vyepti peak sales, I think we have obviously communicated in the past peak sales potential, which I think when we get to our capital markets event, we would be happy to go deeper into that discussion on how we see the evolution and what that might mean for peak sales. But today, we stand with what we have communicated previously. And, Johan, you want to talk quickly on the Parkinson's programme?

Johan Luthman — Thanks for the continuing interest in 996. It's, as you know, a very early-stage programme and it's in that area when we like to have very early patient trials to really figure out how a molecule behaves. I'd like to remind you that this is a very advanced technique behind it. Avery simple thing, we like to stimulate D1

and D2 receptors with a [48:12 unclear ?] structure. It's a prodrug with a very advanced way of converting the prodrug into an active ingredient. And we actually have shown that we deliver on the PKPD very nicely. It's a drug that has shown that it's in business. The challenge is really the population. And when you run small trials, you basically do two things. You test out the feasibility for a population, and then of course you like to see effect.

The feasibility here is a little challenging, because we like to look at two things that are not married. One thing is the good time being on, have less off time, which quite early in the disease gradually gets more problem with the on time, with dyskinesias basically being overactive. And those are two very different stages of disease. And we actually tried out something we might not should have done, but we tried to combine the population in a small proof of principle study. Now we have to rethink how we approach it, basically. But I still have big hopes in this molecule, but it's one of the very early-stage assets we had to play with.

Charl van Zyl — Thank you, Johan.

Operator — The next question comes from Michael Novod with Nordea. Please go ahead.

Michael Novod — Thank you very much. A couple of questions. First of all, maybe for Tom, are there any kind of one-off true-ups wholesaler swings in the strategic brand performance in the US, particularly Rexulti or Vyepti?

And then secondly, to Joerg, you said it is significant, the pre-launch course for PTSD. Is it possible to quantify a bit better on how much you're actually absorbing in the guidance for 2024? Did you take in pre-launch costs?

And then lastly, one thing is obviously that you want to do bolt-on acquisitions, but you've also previously been talking about if you want to go broader with anti-mAb [?], perhaps in Parkinson's, so the CD40 ligand beyond CED. Any kind of traction on moving towards potential partnering considerations if you want to go broader with those two molecules? Thanks.

Charl van Zyl — Thank you, Michael. Tom, do you want to comment on wholesaler?

Tom Gibbs — Hi, Michael, and thanks for the question. As we look at performance across all strategic brands in the US, specifically Vyepti and Rexulti, there were no extraordinary items during the quarter. In fact, we saw a bit of a destocking on both Vyepti and Rexulti during the quarter, and there was no material gross to net adjustments.

Charl van Zyl — Thank you, Tom.

Joerg Hornstein — And, Michael, maybe I take your question on the PTSD investment. We don't reveal, in principle, the exact amount, but I think it's fair to say whenever we talk about something being significant in terms of spend, we would talk about an amount being greater than 100 million.

Charl van Zyl — Thank you, Joerg. And, Michael, just to comment quickly on partnerships and business development. Clearly, our business development focus remains on bolt-on acquisitions that, in a sense, can fit into the scale of our organisation, and we can leverage the speciality focus of these potential acquisitions. That remains the core. We have and continue to look at partnerships in the rest of the pipeline. And you're absolutely right, these indications, like Parkinson's or MS, in both the assets you referenced, are larger populations where we see more competition and also more risk and costs for us to do it ourselves. We will continue to look at partners there, or alternative financing models, if we want to advance them.

Michael Novod — Thank you very much.

Charl van Zyl — Thanks, Michael.

Operator — As a reminder, if you wish to register for a question, you may press star and one. The next question comes from Mattias Häggblom with Handelsbanken. Please go ahead.

Mattias Häggblom — Thanks much. I have two questions, please. A follow-up on a previous question on Trintellix in the US and the new structure with Takeda. You said it wouldn't be something that would impact your mid-term planning that ends 26, but I'm trying to make sure we understand the EBIT contribution of 25 correctly. Contribution being neutral for 25 as well, is that how we should understand it?

And then sales and distribution costs grew 35% year-to-date in constant exchange rate. In light of the efforts to make Rexulti and Vyepti prepped for PTSD, help me think about the pace of investment for the remainder of the year. Is the current pace correct to think about? Thanks so much.

Charl van Zyl — Why don't we start with your last question, Mattias. Rexulti, the question here, Tom, is around our investment, how we see DTC, how we see that for Rexulti and comments may maybe on activities in PTSD as well.

Tom Gibbs — Sure. As we look at Rexulti, we did increase our second quarter 2024 DTC spend, and it was an intentional strategic choice to make sure that we could jumpstart, if you will, Rexulti MDD direct-to-consumer share of voice to recover some of the lost ground we made, based upon the DTC being off air from November through February. I think proof of this jumpstart strategy was evidenced by Rexulti reaching number one TV ad

spend in April and May. Importantly, I think the latest MDD indication, as I talked about earlier, appears to affirm the high second quarter of 2024 strategic investment paid off with Rexulti MDD and BRXs growing at 20.4%, outpacing the competition.

I think it's also important to note that we intend to revert back to our normalised levels related to Rexulti moving forward for the back half of the year, and we'll continue to dynamically allocate these resources based upon our quarterly margin return on investment analyses.

Charl van Zyl — Any specific comments on PTSD, activity wise?

Tom Gibbs — From a PTSD standpoint, we will be appropriately investing based upon good ethics and compliance from a medical standpoint, from a disease execution and product shaping perspective. As we think forward, within the context of if we do get a PTSD approval, we have the ability to really create a very efficient model. Because if we look at the overlap of targets, about 80% of the PTSD targets fall within MDD targets as well, so we'll be able to fully deploy and leverage what we call our Sierra sales force within psychiatry. And we can do that based upon the strategic choice that we made by freeing up capacity from the Trintellix deal.

Charl van Zyl — Thank you, Tom. Joerg, you want to comment on Trintellix? I think the question here is for the team around the impact on EBITDA.

Joerg Hornstein — I think very well received. I don't think we see in principle any significant impact in 25 or in 26 on an EBITDA level. And I think we also communicated that, in principle, we're talking about a flawed agreement from a royalty perspective.

Charl van Zyl — Thank you so much.

Operator — Ladies and gentlemen, this was our last question. I'll hand it back to management for any closing remarks.

Charl van Zyl — Again, thank you very much for joining the call today. And again, want to re-emphasise the confidence on these great results in the first half of the year. And we look forward to hopefully seeing all of you at our capital markets event on 23rd October. Thanks for joining us today.