Recordati S.p.A

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MODERATORS: ROB KOREMANS, CHIEF EXECUTIVE OFFICER

LUIGI LA CORTE, CHIEF FINANCIAL OFFICER

SCOTT PESCATORE, EXECUTIVE VICE PRESIDENT, RARE DISEASES

ALBERTO MARTINEZ, EXECUTIVE VICE PRESIDENT OF SPECIALTY AND PRIMARY CARE

MILAN ZDRAVKOVIC, EXECUTIVE VICE PRESIDENT OF R&D.

EUGENIA LITZ, HEAD OF INVESTOR RELATION

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati Nine Month 2025 Results Conference call. As a reminder, all participants are in listen-only mode. After the presentation there will be an opportunity to ask questions. Should anyone need assistance during the conference call, they may signal an operator by pressing "*" and "0" on their telephone.

At this time, I would like to turn the conference over to Ms. Eugenia Litz, of Recordati, Investor Relator. Please go ahead, Madam.

EUGENIA LITZ: Thank you, and good afternoon, everyone. I'm pleased to be here today with Rob Koremans, our CEO; and Luigi La Corte, our CFO, who will present results for the first 9 months of 2025. Then Scott Pescatore, Executive Vice President of Rare Diseases, will provide further insight into the exciting Isturisa opportunity. Also joining for the Q&A session will be Alberto Martinez, Executive Vice President of Specialty and Primary Care; and Milan Zdravkovic, Executive Vice President of R&D.

As always, the presentation is available in the Investors section of our website.

It is now my pleasure to pass the call over to Rob. Please go ahead.

ROB KOREMANS: Thank you, Eugenia, and thank you for joining us today. The agenda is a little different from what you've seen in typically quarterly calls. You've all seen the exciting news that we brought out on the peak year sales opportunity with Isturisa. And we wanted to give you a little bit more color on that. So, Scott is going to do that in just a little while. And as this additional investment behind the opportunity of Isturisa will impact the margins in 2026 specifically. We'd like to also give you a little bit

more of an update on the outlook, which is also a separate part here in the presentation.

But let me just start with the first 9 months of this year. And we're delighted that once again, we've really got very good results for the first 9 months of 2025. Beginning with the net revenue of €1.960 billion, an increase of 12.2% compared to the previous year or 8.1% on a like-for-like and constant exchange rate basis with very good momentum across SPC and a step-up in growth of rare disease, and an adverse impact of the currency of 2% year-to-date, mostly coming from the U.S. dollar and the Turkish lira.

EBITDA was €743.9 million, up 11.8% versus prior year, with margin at 38% of net revenues. Adjusted net income was €493.1 million, up 10.7% from the previous year. And the net income was down by 3.6% from the previous year, reflecting also a one-off provision of €14.1 million, which Luigi will talk about a bit further down in the presentation.

As for R&D, I'm very pleased to highlight that in line with plan, enrollment was completed in the pasireotide Phase II trial for PBH, and we had a very productive meeting with the FDA to define the potential U.S. regulatory pathway for approval of Qarziba in U.S.

Looking ahead, I'm pleased to say that thanks to our strong business momentum, we will deliver results also this year within the guidance range set at the start of the year, albeit in the lower half of the range due to FX headwinds. They are projected at approximately 3% for the full year and are very likely to persist into 2026.

And finally, we are thrilled to update our peak year sales estimates for Isturisa for the fourth time since the acquisition. We're confident to

double our peak year sales estimate for Isturisa to greater than €1.2 billion, and as we invest actively to target the broader non-overt Cushing's syndrome patient population. We're very, very excited about this opportunity, and Scott will give you some more insights a bit further down in the presentation.

But now let me hand over to Luigi who will take you into more details of our 9 months results.

LUIGI FELICE CORTE: Thank you, Rob, and good morning, good afternoon, everyone. I'm delighted and somewhat proud to be able to say for the 24th time we have once again delivered a strong set of quarterly results. I'll give, as usual, some additional color to the numbers you've seen on the materials.

And starting with SPC. I know there's a lot of excitement around the prospects on the rare disease side, but very happy to see that especially primary care has also delivered in the first 9 months of the year, a strong performance and continuing to outperform relevant markets with our promoted portfolio, a 5% like-for-like growth at constant exchange rates and around half of that range, excluding Turkey. This was achieved in the context of relevant markets, which we've seen slightly step down in terms of the rate of growth for a few separate and different reasons. Cough & Cold had a soft Q1, recovered a bit in Q2, but was again soft in Q3. And it seems that we are in for a bit of a soft season into 2026.

Turkey, we have not seen a price increase yet this year. And despite over 30% devaluation in the country, it seems authorities are reverting back to potentially only one round of price increases per year versus 2, and a cumulative excess of 100% in previous year.

And in Italy, there's been a general softening of market growth. You remember, we said coming into '25, we felt the stock levels were a little bit higher in the market, and that softening has allowed us to absorb that, and we'll start doing that a little bit more in Q4 and as we get into 2026.

But despite that, very pleased to see all of our core franchises growing nicely, driven by a number of products that you see highlighted on the page across both Rx and OTC and delighted also with the transition of Vazkepa, which is starting to contribute, but which will ramp-up as expected in 2026 and will offset the unfortunate loss of Cardicor, the license for which will not be renewed at its expiry in early 2026. It's a local product that we market in Italy with a run rate of around €35 million per year in terms of revenue.

These are some of the headwinds that I mentioned on SPC, together with Cardicor will mean SPC realistically will grow at low single-digit in 2026, but we do expect it to return to a mid-single-digit growth in '27.

With regards to rare disease on Slide 5, a very, very strong performance and accelerating in Q3. Constant exchange rate growth on a like-for-like basis of 14%, slightly up versus year-to-date at the half of year. Scott will talk about Isturisa. So, I'll just touch on the other ones, on the other key franchises and very simply say, we continue to be very happy with Signifor, Qarziba and Sylvant all growing at double digits and across geographies.

And Enjaymo, despite the summer months being usually slightly softer, posting close to 25% increase on a pro forma basis versus 2024. So very, very strong momentum across all of the key growth franchises, combined with metabolic that continues to be resilient and in fact, continuing to

show growth, which is net obviously of increasing headwinds on FX on the U.S. dollar.

We do feel really great about the long-term growth opportunity in rare disease, for what is one of the broadest portfolios in rare disease across the industry.

Very briefly on Slide 6, on revenue by geography. Once again, very pleased, all regions really are contributing to that momentum. The U.S. is now close to 20% of total revenue and growing in local currency by over 30% and accelerating on the back, obviously, of the momentum, particularly behind the endo franchise and of course, the contribution of Enjaymo, which is also contributing to the strong growth in both Germany and the international markets you'll see are very much in line with expectations. The more established markets in Europe, growing at single-digit rates and on the other hand, Russia and other Central and Eastern European markets growing strongly at double-digits on the back of both volume growth and selective price increases.

I'd like to also call out Turkey, which, yes, is being challenged by the high devaluation and the lack of price increases this year, but is continuing to grow double-digits and really outperforming the local market. So very happy with the revenue performance, both looked at from a product lens and geographic one.

When it comes to the P&L on Slide 7, very pleased with this double-digit growth at the level of both revenue, EBITDA and adjusted net income. And also, very pleased with adjusted gross profit continuing to creep upwards on the back of the changing mix and very solidly above the 70% mark. Operating expenses are very much in terms of percent of revenue in line with Q2 with a step-up versus '24, reflecting the investments we

started to make behind Isturisa, in particular Enjaymo, and which we do expect now to step up, as Rob has mentioned.

We did have an unfortunate and unexpected setback in an ongoing litigation that we had with Italian Pharma Agency, which took the view that we should have continued to play a claw back on Urorec even following the minus 40% price reduction, which we incurred in 2020 when the product lost exclusivity. The company considered that request to be absolutely ungrounded, and we still consider it as such. But unfortunately, in the context of budget pressures, the administrative courts ruled against us as they did also against other pharma companies in the countries engaged in similar litigation, and we've taken a provision to cover the cost of that, it's unfortunate, but really a one-off.

But notwithstanding that, very strong results, very pleased with the outcome. And you recall, we said from the start of the year that we expected our Q4 margins to be as usual, lower than the first part of the year, but to be above 2024 levels. And so, with these results and with that in mind, we're well on track to deliver on the margin objective that we set for 2025.

And finally, on my side, as you'll see from Slide 8, we've always on this call also talked about our strong underlying cash flow performance, and that remains true. In the first 9 months, we took the deliberate decision to increase our stock levels and particularly in the U.S., €95 million roughly of the €138 million increase in working capital is due to that, with that increase now covering almost 1 year worth of shipments into the U.S. So, we're very pleased with that. But of course, with that and also the higher spend on net share buybacks, we now expect leverage at the end of 2025 to be around the current level, so just above 2 times leverage.

So once again, very happy with the results. But with that, I will now turn it over to Scott to talk about the exciting opportunity that we see on Isturisa going forward.

SCOTT PESCATORE: Thank you, Rob. Thank you, Luigi. This is Scott Pescatore, and it's a real pleasure to be here today to provide a bit more color on this exciting opportunity that we have with Isturisa. But before I go there, I'd just like to start off with just a brief update on the current performance of Isturisa on Slide 9.

We're seeing quite a robust patient uptake in the U.S. since the FDA expanded our label for Cushing's syndrome back in April of this year. And as you know, the label has expanded our patient pool quite significantly. And the impact is clear from the graph, you can see there. And active patients in the U.S. have more than doubled versus previous year to over 1,200 in quarter 3, which is quite a nice increase versus quarter 2. And importantly, this growth isn't just about new patient starts. The patients continue to titrate up to optimal doses, which is also accelerating our revenue.

But equally as important, the expanded indication is broadening our ability to reach more patients, and we're just at the beginning of tapping into this full market potential. There's quite a bit of potential that remains in the Cushing's syndrome market, and I'll describe that in a bit more detail on Slide 10.

So, if we focus on the right-hand part of the slide, the U.S. Cushing's market offers a substantial room for growth, especially among what's called non-overt or mild Cushing's syndrome patients. Non-overt mild patients are typically those patients who present with cardio-metabolic comorbidities such as persistent and difficult-to-treat hypertension and/or

diabetes, and their cortisol levels tend to be in the range of about 1 to 2 times upper limit of normal. These patients are most commonly treated by community endocrinologists, select cardiologists and primary care physicians.

And with regards to the dose, we can expect the dose in these patients to be slightly lower than that of overt patients, but that's based primarily on the severity of the disease. And if we look at the addressable patient population, there's significant upside opportunity here within this group of patients potentially exceeding more than 30,000 at peak. But by expanding screening, diagnosis and education, particularly in the community settings, we're well positioned to capture this broader patient base and continue to drive long-term growth of the brand.

If we move to Slide 11. Clearly, you can see that we're raising our ambitions. Our peak year sales target for Isturisa is now more than double to greater than €1.2 billion, reflecting our confidence in reaching more non-overt Cushing's patients.

So, how are we going to achieve this? We're investing approximately €40 million to €50 million annually on things like expanding our U.S. sales, our U.S. field force in the U.S., our medical science liaisons, generating real-world evidence and conducting a Phase IV randomized controlled trial. Now just to remember that the study population in this trial is already within our approved indication, but the objective of the trial is to give physicians additional data on the use of Isturisa in milder patients.

Now these investments are designed to double our peak year sales by continuing to treat not only the mild patients, but the severe Cushing's disease and severe Cushing's syndrome patients, while putting special

focus on the non-overt segment that's been underdiagnosed and undertreated. And ultimately, this will allow us to capture approximately 35% of the addressable population at peak.

So, the outlook is strong, and we're building the infrastructure to capture and sustain this momentum. We're very excited about the road ahead. And with that, I'd like to turn it back over to Rob.

ROB KOREMANS: Thank you, Scott. Looking to the outlook and as mentioned, we anticipate that the robust performance across SPC and Rare Disease will enable us to achieve our full year targets for '25, in line with the original guidance. This comes despite a challenging macroeconomic environment and approximately 3% of currency headwinds expected for the full year, and they're likely to persist into 2026.

If you look ahead for 2026, we expect sustained high double-digit growth of Rare Disease at constant exchange rates with revenues nearing 50% of our total revenues. Isturisa will be a key driver and to fully capture this opportunity, there will be additional investments to target the patients that do not present themselves with all the typical clinical symptoms that you see with Cushing's, but are detected often primarily through persistent hypertension or difficult to treat diabetes. These so-called non-overt Cushing's syndrome patients are a very significant opportunity and the opportunity to tackle them going forward and help them and support them is what we're really excited about. And this underpins our double peak year sales estimates. As a result, 2026 should be an investment year aligned with our updated sales forecast for Isturisa.

For SPC, we expect low single-digit growth at constant exchange rate, which reflects also the loss of the Cardicor license that Luigi mentioned, but the fundamentals of the business remain very strong and intact, and we

are confident to return to the mid-single-digit growth in 2027. For 2027, our targets remain unchanged with strong organic growth expected to be complemented by ongoing BD and M&A. And finally, we are confident in our long-term growth prospects, supported by the doubling of our peak year estimate sales for Isturisa.

And now together with my colleagues here in the room, I'm very happy to turn over to you and take your questions.

Q&A

OPERATOR: Excuse me, this is the Chorus Call conference operator. We will now begin the question-and-answer session. Anyone who wishes to ask a question, may press "*" and "1" on the touchtone telephone, to remove yourself from the question queue, please press "*" and "2." Please pick up the receiver when asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from Shan Hama of Jefferies. Please go ahead.

SHAN HAMA: Hi, there. Thank you for taking my questions. Just 2 from me, please. Happy to take them one at a time. So firstly, given that the midterm guide was reiterated, does that mean the sort of incremental peak sales potential from the non-overt population will likely be realized outside of the midterm period? That's my first question.

LUIGI FELICE CORTE: Hi, Shan, maybe I can take that. I think the line wasn't great. I think the question was, as we are confirming 2027 guidance, does that mean the increase in peak is outside of that planning period? Well, no, the short answer is no. Of course, we expect the ramp-up already to be steeper on Isturisa. Of course, as you know, FX have unfortunately moved against us

versus when the guidance was set out for 2027. So, very happy and don't forget also that the 2027 guidance does include a contribution of BD and M&A. So, we are confident that we can achieve that guidance up despite the higher FX also on the back of the increased pace of growth that we expect from the Endo franchise. Does that address your question?

SHAN HAMA: Yes, that's perfect. Thank you so much. And then just for my second one. Sort of looking to 2026, with the OPEX for Isturisa obviously ramping and Rare Diseases potentially doing better than current consensus expectations and SPC may be not as strong as where consensus is at the moment, how should we be thinking about the margin trends for next year?

LUIGI FELICE CORTE: Yes. No, I'm sure many will have the same question, so happy to address that. Look, we're not going to give sort of precise guidance at this point, right? And that's simply because we typically do that, as always, at the beginning of next year, we will be reviewing budget in the coming weeks. We have made the decision to invest behind what we feel is a fantastic opportunity. And obviously, that will weigh on the 2026 margin. I think we've given you some indication of what that kind of looks like. If you take the bottom part of that range of spend, around €40 million, that's 1.5 points roughly of margin.

Of course, the mix improves as we go into next year, but we've got FX going in the opposite direction. So again, we want to make sure we gave you a sense, particularly because of that investment decision that we've taken. But we're going to, as always, give more precise targets for next year once we have discussed the budget with the Board. Is that okay?

SHAN HAMA: Perfect. Thank so very much.

OPERATOR: The next question is from Sophia Graeff Buhl Nielsen of JPMorgan. Please go ahead.

SOPHIA GRAEFF BUHL NIELSEN: Good afternoon. Thanks for taking my questions. Firstly, just on Isturisa, could you give us any further context on the market research you've done, that's given you confidence in expanding the Isturisa opportunity into the non-overt Cushing's syndrome population. Just what are the competitive dynamics in this market? And how did you arrive at the assumption of capturing 35% share of the U.S. addressable patient population that underpins your new guide? And then also just in terms of some of the headwinds that you've seen this year, including some destocking in Italy, weaker start of the Cough & Cold season and pricing dynamics in Turkey, can you give us any more color on the magnitude of these impacts and what we should expect for these in Q4 and going into next year?

LUIGI FELICE CORTE: Maybe I'll start with the second part of the question, and apologies, I couldn't catch the name. Yes, Sorry, Sophia. So, we said that in terms of those headwinds, first of all, again, we're very pleased with the momentum to date across both SPC and Rare Disease. I would expect, as I said, those headwinds to translate into an SPC growth rate for next year in the low single digits, rebounding to mid-single digit in 2027.

When it comes to the more detailed questions around the dynamics on the endo side, I'll pass over to Scott. We'll obviously be conscious that it is a competitive field and hence, there's a limit to what we will give away in terms of the research that we may have done.

SCOTT PESCATORE: Thanks, Luigi. Hi, Sophia, this is Scott. Thank you for the question. So yes, I mean to answer your question in short, we did significant market research around this opportunity, both internal assessment and using

external advisers. I mean, we spoke to many different endocrinologists and different treaters in the field to verify this market space. There are also other players in this space that are also verifying the patient numbers and this market opportunity.

With regards to our market share at peak, I mean, this is a competitive market space. It's been competitive and it will continue to increase in its competition. So, we believe that we can be confident in securing at least a third of those patients and then we'll see how things progress as we move forward.

SOPHIA GRAEFF BUHL NIELSEN: Thanks a lot.

OPERATOR: The next question is from Isacco Brambilla of Mediobanca. Please go ahead.

ISACCO BRAMBILLA: Hi, good afternoon, everybody. Thanks for taking my question. I have 3 that should be quite fast ones. The first one is on Isturisa. Considering the new sales target and the commentary around different dosage, the investments behind the product, how should we think regarding the profitability and regime of Isturisa compared to the rest of the Rare Disease portfolio?

Second question is on FX. I know you usually do not give this data, but if you can help us understand the FX headwind on EBITDA this year, so in 9 months 2025, just to have a sort of order of magnitude.

Last one is a more strategic one. Considering next year, Specialty and Primary Care will be a year of softer growth, could you think to restart your M&A campaign in this space doing maybe something more relevant than Vazkepa that you already closed?

ROB KOREMANS: Thanks, Isacco. So, I would think Vazkepa is extremely relevant. We indicated for '27 that we could and will achieve €40 million, and that's definitely not the end of the growth for that product. It's an important product for us and for patients, and it fits perfectly into our cardiovascular portfolio. So, I'm really happy with that.

I don't think we typically give percentages of profitability and margins on products like Isturisa, but you see that the overall portfolio of Rare Disease has a slightly higher margin than what we have in SPC. And Isturisa is an important contributor of our growth. So, it's a product that we believe is really well worth investing into. And this additional investment, and I think we've stressed it, I believe is fairly, first of all, low risk. So, we do some clinical work, some medical work and clearly also commercial, but we don't need a new label for this, and we already start seeing patients now with this so-called non-overt, so we're super excited by it, and this is an opportunity that is a bit like launching a new product. It will take time. It will take investments, but that's something that at any time we can always correct and adjust for, right? So that's something that I feel very, very low investment in terms of the €1.2 billion at least that we can achieve with these revenues. Luigi, do you want to take the middle question?

LUIGI FELICE CORTE: Yes. On the FX, you are right, Isacco, we don't usually give that sort of level of detail. But I think it's fair to say it's obviously where we say that we have a 3% headwind on the revenue side, you should expect a lower percentage at the EBITDA level. So, let's say, around about 2% would probably be the number on the…at the level of EBITDA. And as I said, we expect a similar level of headwind when we go into next year, also because, as the U.S. dollar devalued after Q1. So, we had one, let's say, a very positive quarter, and then we started to see this devaluation. So, we

have...but most are expecting a further devaluation of the dollar next year, but also the full effect of this year. Does that address your question?

ISACCO BRAMBILLA: Yes, sure. And many thanks on the products and your answers.

OPERATOR: The next question is from Charles Pitman-King of Barclays. Please go ahead.

CHARLES PITMAN-KING: Hi, guys. Charles Pitman-King from Barclays. Thanks very much for taking my questions. Just staying on the theme here. First question, please, just on Isturisa. Just thinking back to kind of 1Q '25 and your discussions around them on previously raised peak sales, this was originally driven by an expanded market outlook. And I remember from our conversations that you did not predict further raises peak sales unless there was going to be a significant market development. So, I'm just wondering, over the past 5 months, what is it that you define as a significant market development? And is it just your experience of seeing these non-overt patients that you didn't expect to see previously? Or has something changed that makes you more confident that you can, in fact, create this step change in diagnosis?

And then maybe just if you could give us a little bit more of an idea of what that non-overt Cushing's syndrome patient journey looks like, just so that we can get a bit more of an understanding versus the kind of currently addressed overt Cushing's syndrome patient? And then just one quick clarification …could you give us a little bit more detail on what high double-digit and approaching 50% means? I mean is this kind of just entering the range of 17% to 20% as high teens? And is it approaching just anything above 45%? Thanks very much.

ROB KOREMANS: Thanks, Charles. So high digits…high double-digits in terms of rare disease would be high teens, double digits. And approaching the 50% is approaching the 50%. You will see we'll be a bit more specific in February, clearly, but we see very good dynamic. And that is also answering to your first.

The dynamics in the Cushing's market and maybe because there's so much more attention to endocrinology in general are quite astonishing. And we had frankly not expected to see the ramp-up in some of these so-called non-overt patients that do not present themselves with clear Cushing's and clinical symptoms that you pick up through cardiovascular comorbidity. That is going much better than we expected, which prompted us, and we had already, of course, started to do very, very detailed market research and like Scott outlined in the US, and we actually really see this opportunity.

What also helps is we have colleague companies like Corcept that work in the same direction. And then the feedback from doctors in the field has just changed over the last couple of months. From no, I would never consider to, yes, I would absolutely treat. So, with that, and there is a fairly vast group of patients well beyond the 30,000 that we indicate of people that have high cortisol and also a comorbidity. And we are never known to be very aggressive in our assumptions. We believe that is an achievable target, the target audience of something just over 30,000 and to get one-third of those patients in the coming years. It's like launching a product, we believe it's highly realistic. And we've validated this from various parts.

And now we stand very confidently in front of you in that sense, right? So, it's an exciting opportunity. And one, it's not what you get every day, an opportunity to almost launch like a new product and value at so low

cost and risks. So hence, our excitement to share this with you. Does that answer your question?

CHARLES PITMAN-KING: Yes, it does. Thank you. Maybe if you can give us any detail about the kind of difference in the patient journey ,albeit [indiscernible] is on the sliding scale.

ROB KOREMANS: I'll let Scott to answer that question.

CHARLES PITMAN-KING: Thank you.

SCOTT PESCATORE: Thanks, Rob. Hi, Charles, it's Scott. So, a very good question on the patient journey for these. So first, on your first question on the market development, we are seeing these patients now. I mean we do have uptake of these milder patients within the patients that you saw on the slides that we presented. But again, as Rob had mentioned, it really prompted us to do a further investigation into this segment and understand what the potential could be and what that looks like over the years and how that's evolving.

But the patient journey is slightly different for these patients. And it's because typically, as I mentioned in the presentation, they're sitting with really 3 subgroups of physicians. One is the endocrinologist, 2 is the cardiologist and then some of the primary care physicians. And that's based, as Rob had mentioned, on these comorbidities that they present with, which is persistent difficult to treat hypertension and/or diabetes. Patients who have these comorbidities, physicians are now starting to look for reasons why they're not able to treat or control these diseases, and they're looking at cortisol levels as a culprit, prompting more cortisol screening for these patients. And we're finding that more of these patients are actually showing up with this so-called milder form of Cushing's

syndrome with their cortisol levels, as I mentioned, which is about 1 to 2 times upper limit of normal, which is significantly lower than your overt or severe patients.

So, the point is, is that the journey of these patients, if they're not sitting within the endocrinologists and keen endocrinologists will identify them and begin treating them, which is what we're seeing now in our numbers. But there's a big referral pattern that needs to take place from the cardiologists and the PCPs where these patients could be sitting for them to sort of understand their underlying comorbidities, then test them and then refer them on. So, the patient journey is slightly longer, which is why we see this opportunity that extends far into the future because there's a market that still needs to develop and get traction. But we do see uptake now. And that uptake as we continue the investment, continue the education, continue to do all the things that we're investing in the clinical trial, raising awareness, we'll get the traction to get these patients referred on from those other treaters to the endocrinologists and then ultimately treated.

CHARLES PITMAN-KING: All right, thank you so much.

OPERATOR: The next question is from Niccolo Storer of Kepler. Please go ahead.

NICCOLO STORER: Good afternoon, guys. Thanks for taking my questions. The first one, again, on high double-digit and approaching 50%. Again, I was wondering how you can think of keeping together these 2 things because if for you, high double-digit is 18%, 19%, 17%, then specialty and primary care growth is low single-digits, you're not going to get to approach 50%. And the other way around, if you're approaching 50%, probably growth in rare disease is going to be higher? So again, if you can clarify a bit on that?

Second question on cost associated to Isturisa development? In the press release, you talked about €40 million, €50 million and a gradual ramp-up, up to these levels? But if I understand well, we should expect €40 million already for 2026? Is this right or not, at least this is what I got from the previous answer? And last question just a curiosity on Cardicor loss of license, if you can explain what's behind this, which is something quite uncommon? Thank you.

ROB KOREMANS: Thanks for your questions, Niccolò. Let me start with the last one. It's indeed very uncommon. It was the end of the license. It's…the product is returning to its originator. And of course, we checked whether we have the similar risk in the rest of our portfolio, and there is no such risk for the next 10 years. Part of our SPC nature of business is you take licenses, and this one, it's on a full year base, €35 million on a €1.5 billion business, of course, not the biggest, but it doesn't help in generating growth for next year. That's why we flag it. For us, more important is looking at the similar risk present and the answer is no. Luigi, do you want to take some of the questions

LUIGI FELICE CORTE: No, on the spend for next year, Niccolo, I don't know that we're going to give a lot more than what I said. We said that, yes, we started, but we have incremental investments, which will get to €40 million to €50 million. You should expect the number for next year to be closer to the bottom end of that. And as I said, the margin for next year will reflect both that, but on the other hand, on the positive, the shift in mix, but on the other hand, the adverse effects. And I am not going to give too much more than that at this stage. With regards to the growth rates, you know, you should sort of take the, as we said the high teens, for the rare disease and approaching is approaching, is not getting to. So, it is clearly trending in that direction. And hopefully that addresses your question, Niccolo.

NICCOLO STORER: Yeah, thank you.

OPERATOR: The next question is from Martino De Ambroggi of Equita. Please go ahead.

MARTINO DE AMBROGGI: Thank you. Good afternoon, everybody. The first question is on the Slide #9, would you present the uptake and acceleration for the patients. Could you just very roughly indicate what was the percentage of new active patients coming from the expansion of indication? First question.

The second is on the peak sales guidance. Could you split in your assumption what is the overt and non-overt of these peak sales very roughly? And when you mentioned 45% in terms of share of patient, is it the same for overt and non-overt? And could you just very roughly quantify the difference in terms of potential sales of every patient if it's overt or non-overt? And very last, I am sorry, on Isturisa, what is the percentage of sales generated in the US in '24, '25 as you prefer?

ROB KOREMANS: Martino, I understand some of your questions, but you might appreciate that some of this is really competitive and sensitive information, which we are not going to share. We didn't say 45, if that came across as a percentage, market share is 35, 3-5. The US is a very important part of our today's sales already and going forward would be, actually even more important because we see the biggest opportunity for this so-called non-overt patients actually in the US. And Isturisa US is going to be the major growth driver for Isturisa.

At the moment, we still have mostly Cushing's disease patients on therapy. With the extension of the label, we got some Cushing's syndromes, and

that was the first patients coming in from April this year, so it's still a fairly small percentage. And quite frankly, we were positively surprised by the fact that they did present without us actually really promoting so strongly for this type of patient. And it was one of the reasons also to, like Scott said, to really look even deeper into this. But at the moment, the vast, vast, vast majority of our patients and revenues with that comes from the more severe or Cushing's disease patients.

Some more of the detailed information on what is US, Europe, how do we split. I'm sorry, we're not going to disclose simply because that's something that might be too sensitive for the market out there.

MARTINO DE AMBROGGI: Okay, I understand. Thank you.

OPERATOR: The next question is from Niall Richard Alexander of Deutsche Bank. Please go ahead.

NIALL RICHARD ALEXANDER: Hi, it's Niall Alexander from Deutsche Bank. Thanks for taking my question. So, first one on Isturisa and the expansion. So, given the investment there, does that impact how you guys will be looking at M&A and business development activity going forwards? Obviously, it's going to be a great focus on Isturisa, so does the strategy there change? That's the first question.

And then the second one on Qarziba and additional data requests from the FDA. Just wondering how that news could potentially impact the peak guidance that you gave earlier this year. Does it mean it might just take a little bit longer to get to that peak sale estimate? It would be helpful just to get some color there. Thank you.

ROB KOREMANS: Thanks for your questions, Niall. No, if anything…no, our BD and M&A strategy doesn't change. If anything, going forward, Isturisa will help us to fund even better and more deals because it's a really exciting opportunity. But our strategy remains completely unchanged, and we will continue to focus both on the SPC side and on rare side, and have a couple of really interesting discussions ongoing.

On Qarziba, I think you captured it right, but I will ask Milan to give a bit more color on it. It will not change the peak that we guided on. It will take a bit longer to get there. We, just for reminder of everyone, we guided 30 million peak year sales for this very restricted and limited group of patients with neuroblastoma. And that potential should really still be there if we get the product registered. And I think Milan is actually more optimistic than before, but I will pass to him to give us some color there.

MILAN ZDRAVKOVIC: Thanks, Rob. And thanks for the question. Yes, so, as we hinted at also in our 2025 call, we were planning to meet with the FDA once we had the first set of data also to establish a potential pathway towards regulatory approval. And we have now had the meeting, and it was a very successful meeting. We shared the data from the first data set. FDA wants additional data from a second trial, and that trial is already ongoing, and this is what we are guiding towards. But as I said, we had a very encouraging meeting with the FDA, not to only discuss the data but also starting to elucidate what should a potential BLA package look like. And I find that very, very encouraging. I think it's clear that Qarziba addresses an unmet medical need in this relapsed/refractory segment of neuroblastoma patients. Also, I think because of the more benign safety profile, in particular the neurotoxicity in comparison to competition. And this unmet need is also recognized by the FDA. So, I think all-in-all, we are encouraged, and we will keep working on potentially getting it approved in the US. Thanks.

NIALL RICHARD ALEXANDER: Great, thank you.

OPERATOR: The next question is a follow-up of Shan Hama of Jefferies. Please go ahead.

SHAN HAMA: Hi there. Thanks for taking my follow-up. Just really quickly, how do you view the sort of current competitive landscape for Cushing's, especially given relacorilant PDUFA at the end of the year. How do you think that will change the market dynamic and what will the shape of the market look like?

ROB KOREMANS: I don't want to speculate what happens to an FDA approval or not, but frankly more companies in this field that help to educate patients, doctors, to transfer cardiologists to patients with this persistent, difficult-to-treat hypertension or diabetes or obesity or anything in that field, I think it helps. The education is good. In our estimates, we believe that we would capture one-third of this patient population. Clearly, and we are very well aware that Corcept have started to move into this direction long before we did, but we believe this can actually really help us.

And in this case, more companies are making sure that these patients are getting diagnosed and transferred and supporting that is a very good and positive thing. We know that our product has a very strong clinical profile, both in efficacy and safety, so we feel very confident, and this is just also based on today's experience and all the feedback we get from the market, that we can capture this market share. But we will need to help and develop this market, and with that, having more companies in the space is going to be a good thing.

SHAN HAMA: Thank you so much.

MILAN ZDRAVKOVIC: And just one other thing to add on top of that because I completely agree with Rob. We're talking a lot about these milder non-overt patients, but the investment and awareness in Cushing's disease and severe Cushing's syndrome is just as important because there are patients there. There's a market there to be supported and any awareness or investment in this market will help the broader population of patients as well. So, this is about building the non-overt and the mild population, but it's about supporting and continuing to grow the severe overt population as well.

So, as Rob said, I think it's important that there's other players in this space and all the investment is welcome to raise awareness and education.

SHAN HAMA: Makes sense. Thank you.

OPERATOR: The next question is the follow-up of Niccolò Storer from Kepler. Please go ahead.

NICCOLO STORER: Yes, 2 please. One on peak sales, should we still think about 2031 as the peak year for Isturisa or should move, let's say, this a little bit further in time? Second question, now you are with this move, focusing 100% on the U.S, any chance to see a similar move outside the U.S.? Thank you.

ROB KOREMANS: Thanks. So, the focus is on the U.S. because that's where really the big opportunity is. But be assured we focus on focus, but we push for the rest of the world, and Scott is very much a global player. And our teams are active in the field of endocrinology everywhere. So that's important. I think that's the reality for almost every single rare disease indication in the world is the real big opportunity will be in the U.S. But we are, for instance, also extremely excited about Japan or getting into Brazil, and we're doing a really half decent job in Europe as well. So, it's really a global product and a global effort.

ROB KOREMANS: Yes. Maybe this is one of these products that peak in a couple of years. It's very difficult. I think by '31, you will be relatively close to your peak, but there will still be growth. So, you cannot technically say peak, right? But it will take definitely some years because it's a bit like launching a product really getting a new concept in for patients, for doctors, and making sure that these referrals really work. That's something that always takes time. And I think we have to be realistic about that and that's how we project it as well.

LUIGI LA CORTE: Yes. And maybe, Niccolo, just to build on that because if the question behind the question, if you were mentioning 2031 as being the former planning assumption for loss of exclusivity on Isturisa. I'd just like to remind that already in the 3-year plan, we highlighted that we do see the opportunity and growing confident around that, that this could be extended to 2033 in the U.S. subject to patent term extension. We're also working on a pediatric indication. And there are sort of patents in the Orange Book going out to 2035. And you recall, in Europe, most major markets, the patent term has already been extended to 2035. So, I just wanted to make sure that that was clear given that you sort of mentioned 2031.

NICCOLO STORER: Yes, thank you. The only thing is that 2033 for the U.S. is still probably a question mark. Am I right?

ROB KOREMANS: Well, we're really growingly confident with patents. In front of courts, you can never be 100%, right? But this is really like Luigi said, yes, the pediatric indication, we're progressing really well on that, and that's good. And then the PTE is also looking very, very strong and clear. So, we're fairly confident on this '33 date.

NICCOLO STORER: Thank you.

OPERATOR: Next question is from Bruno Permutti of Intesa Sanpaolo. Please go ahead.

BRUNO PERMUTTI: Thank you. Good afternoon, everyone. A question again on Isturisa. The wider population that you are now considering now is also a matter of studies, new clinical studies relating to the balance between benefits and cost of treating milder populations, also milder population. So, I want to understand if there are some developments on the market that in this sense make you think that it was the right moment to reach also these kind of patients.

And the second question was relating to the reimbursement. If there will be difference in the reimbursement between milder population treatment and/or severe population treatment and if you have to change something on that side? And the last one was on tariffs. You said that you have a consistent stock in the U.S. in 2026, how do you see the tariffs impact, if you can update on this point also? Thank you.

ROB KOREMANS: And let me start with the, Bruno, with the last question. Now, we've been building quite significant stock that goes well into '26 depending on when really and if at all these tariffs come into place. So, it's a bit speculative at this point in time. But we feel that for '26, we've done a lot to be able to mitigate the impact.

I'll pass to Milan and Scott on this question, but I want to really make sure …we don't need to do the clinical trial to get a label. We have the label. The trial will help to just get more data and evidence for patients to be able to be to get treated and doctors to feel comfortable about it. But the current label actually really covers these patients. And we already, like we said, see patients that get treated with this today. It's also not something

that depends on the reimbursement. But maybe Scott, Milan, you want to extend a little bit on it?

SCOTT PESCATORE: Yes. Sure. Thanks, Rob. So just very quickly on the reimbursement side, we don't anticipate any additional hurdles in respect to what we do today. First because this is already within our label within Cushing's Syndrome. These patients are diagnosed with Cushing's Syndrome, and they're seen by the endocrinologists. So, all the 3 sort of areas that we're seeing in severe patients today, so the reimbursement process will remain largely the same for over just expanding the population.

With regards to coming back to your question on how we arrived at this opportunity. As Rob had mentioned, we're seeing these patients today. And it prompted us to do additional investigation on the market viability of looking at patients that have a slightly lower cortisol level with comorbidities, as I mentioned, hypertension and diabetes. There's also other players in the market now that have generated some robust Phase III data with patients suffering from comorbidities and having lower levels of cortisol. So, those are some of the data points that we use in addition to the research that we've done and discussions that we've had with a pretty large base of endocrinologists around the opportunity here.

BRUNO PERMUTTI: Yes. Thank you.

OPERATOR: Management, there are no more questions registered at this time.

ROB KOREMANS: So, then let me thank everyone for joining today for your questions. You can hear our excitement not only about the solid performance in the first 9 months, but also really in the…what lays ahead of us, really good opportunities, of course, with some challenges as always, and we will manage them as always. But the opportunity is wonderful, and we

continue to be a very nice profitable growth company with a very clear mission on helping patients everywhere in the world and real proud to lead this company. So, thank you for joining today, and I hope to see you all in person soon.