

# **Recordati S.p.A**

**"Full Year 2024 Preliminary Results and 2025 Targets Conference Call"**

**Thursday, February 13, 2025, 16:00 CET**

**MODERATORS:**      **ROBERT KOREMANS, CHIEF EXECUTIVE OFFICER**  
**LUIGI LA CORTE, CHIEF FINANCIAL OFFICER**  
**ALBERTO MARTINEZ, EXECUTIVE VICE PRESIDENT OF**  
**SPECIALTY AND PRIMARY CARE**  
**SCOTT PESCATORE, EXECUTIVE VICE PRESIDENT OF RARE**  
**DISEASES**  
**MILAN ZDRAVKOVIC, EXECUTIVE VICE PRESIDENT OF R&D**  
**EUGENIA LITZ, VICE PRESIDENT AND HEAD OF INVESTOR**  
**RELATIONS**

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati Full Year 2024 Preliminary Results and 2025 Targets 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, Head of Investor Relations of Recordati. 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. Together they will present results for full year 2024. Also joining for the Q&A session will be Alberto Martinez, Executive Vice President of Specialty and Primary Care, Scott Pescatore, Executive Vice President of Rare Diseases; 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.

ROBERT KOREMANS: Thank you, Eugenia, and good afternoon. Thank you for joining us on our call today. I'm very pleased to share our outstanding results for full year 2024, where once again, we delivered at the top end of our upgraded targets.

Beginning with net revenue of €2.341 billion and an increase of 12.4% compared to the previous year or 9.2% like-for-like at constant exchange rates. This performance demonstrates continued momentum across Specialty and Primary Care, which increased by 5.7% like-for-like at constant exchange rates and our Rare Disease business, which grew by 15.7% like-for-like at constant exchange rates.

Robust top line growth and operating leverage, partly offset by our accelerated investments to support the Rare Disease growth drivers resulted in an EBITDA margin of 37%. Adjusted net income was €568.9 million, up 8.4% versus previous year, effectively absorbing the increase in financial expenses and tax rate. And with a strong free cash flow of €535.1 million, we concluded the year with a leverage just below 2.4 times EBITDA. This includes the impact of the Enjaymo acquisition, which closed at the end of November.

Turning to ESG. I'm proud to highlight that our initiatives have been recognized by inclusion in indices and with positive ratings. This is an ongoing effort and something we feel strongly about continuing to advance.

As we began preparing for our 3 year plan update, which will be presented on April 29, it is evident that our key Rare Disease products are outperforming expectations. We are, therefore, pleased to announce an increase in peak year sales targets for these key growth drivers with the potential to more than double current sales.

Looking ahead, we expect our strong performance to continue in 2025, and I will provide more details about our financial targets a little later. As we work towards building our future, it's also important to reflect on our past, which serves as our foundation. Hence, let me remind you of our achievements so far.

Delivering 2024 results at the top end of our targets is confirmation once again of the successful execution of our strategy. This has resulted in high-single-digit growth, CAGR at 9% over the last 10 years, consistently achieving or exceeding our financial objectives.

Recordati continues to be a story of strong and consistent financial performance over the last decade. This growth, combined with high margins and cash generation has yielded and continues to yield a

significant return on capital and fantastic value creation for all our stakeholders. This really is second to none and something we are extremely proud of.

It's my pleasure to now turn the call over to Luigi to review our 2024 performance in more detail, which serves as a solid foundation for the year ahead. Luigi.

LUIGI LA CORTE: Thank you, Rob, and good afternoon, good morning, everyone. I will try and get through results as quickly as I can, having updated guidance and targets, I'm sure everyone is keen to discuss those.

Starting on Page 5, really great to see our mature Specialty and Primary Care business finished the year with reported growth of just over 10%, which absorbs FX headwind of around 2% for that segment, mostly due to the Turkish lira and the ruble. Now clearly, that double-digit growth reflects the contribution and full year consolidation of revenue from sales of Avodart and Combodart.

But also on a like-for-like basis, you see that Specialty and Primary Care is delivering mid-single-digit constant exchange rate growth that we've consistently said that this business can sustain. This is driven by a very robust underlying growth of the relevant markets and our ability through our targeted promotions to drive growth of key assets over and above that with evolution index for our promoted products of 105.

This growth in Specialty & Primary Care is clearly driven by our Urology franchise, which has now become the #1 franchise for the Specialty Primary Care segment, clearly reflecting the addition of Avodart and Combodart, but also a very strong double-digit growth of Eligard on the back of the new device rollout, with good growth also of silodosin across a number of markets, particularly Italy, Turkey and Russia.

The Cardiovascular franchise, our most mature legacy franchise also had a good year with growth of 5.5%. And really what is fantastic for this one is how broad-based that growth is with each of Lercanidipine, pitavastatin, metoprolol all showing growth. And in the case of metoprolol, with some help from out of stock of some competitors. And we also had good growth of Reselip in the first part of 2024.

You'll recall that at the start of the year, cough and cold had started a little bit behind what had been an exceptional start of 2023. But thanks to a strong rebound in Q4 of 2024, you'll see that it ended the year pretty much in line with what was a very strong comparable the year before.

Finally and noteworthy, whilst most of the biggest growth drivers this year in 2024 has been our Rx portfolio, there were a number of standout performances within OTC as well, namely Procto-Glyvenol across many of our Central Eastern European markets and Magnesio Supremo and others in Italy.

So very strong performance and momentum for what remains, our biggest segment. Moving to Slide 6, Rare Disease clearly also had a fantastic year. Rob has already mentioned, growth on a like-for-like basis of close to 16%, most of it being volume driven. Rare Disease now represents just over 35% of the revenue for our company.

But most importantly, we achieved a number of really exciting milestones in 2024. Isturisa, just over €200 million of revenue and continuing to grow significantly across all markets. Signifor continuing to grow double-digits, particularly driven by the LAR formulation and growth in acromegaly, achieving close to €120 million of revenue. The assets we acquired with EUSA growing a combined 20% driven by both Qarziba and Sylvant achieving revenue of around €230 million, clearly ahead of the original targets.

And finally, and you'll see we have rebaptized the franchise, hem-oncology, very pleased that we were able in 2024 to conclude yet another fantastic business development transaction with the acquisition of the rights for Enjaymo, which contributed nicely in the month of December with close to €11 million of revenue, in line with expectations. And as you know, we're expecting Enjaymo to deliver €150 million of revenue in 2025.

And finally, but also nicely, you have seen the metabolic franchise starting to stabilize and in fact, showing a little bit of growth in Q4 with growth of Cystadrops and increasing penetration in international markets, offsetting what is a reducing level of erosion on Carbaglu in EMEA and the US.

But as Rob alluded to in his opening, Rare Disease is clearly going into 2025 with very strong momentum, which is clearly a reflection of our own execution, but also increasing awareness, diagnosis and treatment of these patients, which also signals an increasing opportunity for our products. And we have reflected that on Slide 7, where you see that for each of our key growth assets, we have increased our peak year sales objectives, particularly for Isturisa, but also Signifor, Qarziba and Sylvant. Enjaymo we are obviously only a few months in. And combined, these products have the potential to double the revenue that has been achieved into 2024.

And importantly, there's been no fundamental change to the key assumptions underpinning these. These still assume, as was the case before, approval of a broader label in the US for Isturisa. It assumes we will ultimately be successful in bringing Dinutuximab beta to US patients. And again, there is no change versus previous assumptions and really just reflects the strong momentum and what we see in terms of market growth.

But there are also opportunities to go beyond these numbers. And again, consistent with prior assumptions, these numbers do not include potential new indications that we're working on and that we continue to be excited about, PBH for pasireotide, Ewing sarcoma for dinutuximab. And we will look at opportunities beyond CAD for Enjaymo.

So, very exciting for both franchises. On Slide 8, revenue by regions, as was in previous quarters, very strong really across the page with all regions showing really good growth. We've called out before France comparing against an exceptional 2023. But the standout, obviously, is the US growing by close to 24%, accelerating in Q4, thanks also to the addition of Enjaymo.

In Q4, we lapped a full year consolidation of Avodart and Combodart. Hence, you've seen some of the growth rates in places like Italy, Spain, other Western European countries come down a little bit versus the first 9 months of '24. In the case of Italy with the decision to destock a little bit in the market where going into Q4, we felt stock in some wholesalers were a little bit higher than we liked.

But again, strong performance throughout. And I'll call out Türkiye as well, which clearly this year made a very strong contribution to growth, certainly on Specialty & Primary Care, thanks to very robust volume growth and also price increases being awarded ahead of the valuation. You see all of that contributing to a 36% growth in Euro terms. But also our Rare Disease business in Türkiye tripled over the course of 2024.

So, again, very broad-based growth in terms of both franchises and regions. And very nice, as always, on Slide 9 to see how the revenue growth is fully reflected at the level of EBITDA, also growing by 12.5%, sustaining a strong EBITDA margin of 37%, absorbing incremental investments particularly in the later part of the year to really support those growth drivers that I just walked through.

In terms of the different lines of the P&L, of course, we said as we went into 2024, we were expecting adjusted gross profit margin to go slightly down, reflecting mostly the consolidation of Avodart and Combodart, but that is offset at the level of SG&A expenses, which really benefit from operating leverage and some of the efficiency initiatives that we've been driving, particularly on the Specialty & Primary Care side, where we did a little bit more rightsizing in places like Spain and Greece over the course of '24.

R&D pretty much unchanged as a percent of revenue, with almost half of the increase in absolute terms actually being incremental amortization. And finally, other expenses of €21 million includes €8 million of non-recurring costs, mostly related to those rightsizing that I referenced and €13 million of impairments of intangible assets.

So, very strong operating results below the operating line. Clearly, in '24, results reflect somewhat higher financial expenses and tax rate as far as financial expenses is concerned, a significant part of the increase is actually due to one-off events, FX, in particular, and the impact of net monetary losses due to application of hyperinflation accounting in Türkiye, both of which were headwinds in 2024 versus 2023. And that leads to still both net income and adjusted net income showing high-single-digit growth for the year.

And on Slide 10, again, very happy to see that translate into a very strong free cash flow, €535 million delivered in '24, a €79 million increase or 17% increase over the previous year, and clocking at over 90% of adjusted net income in line with sort of target that we'd set in the plan.

Working capital CAPEX really just growing in line with the business, and the operating cash flow clearly offsetting higher interest and tax payments. And clearly on the bottom part of the cash flow you see stand out the payments made for the acquisition of Enjaymo rights.



But this strong cash flow performance together with the strong EBITDA as expected result in a strong balance sheet still at the end of the year with leverage just below 2.4 times pro forma EBITDA, of course, assuming a full year benefit from Enjaymo, which is exactly in line with where we expected to land when we announced the deal, and going into '25 with strong business momentum, a strong balance sheet and appetite to continue doing what we've always done.

And with that, I'll turn back to Rob.

ROBERT KOREMANS: Thanks, Luigi. So concluding with our full year 2025 guidance, we are pleased to provide our targets of double-digit growth across all metrics driven by, as Luigi already pointed out, very strong continued performance of the business and a robust momentum going forward.

On the top line, we expect revenue between €2.6 billion and €2.67 billion reflecting mid-single-digit growth of SPC and double-digit growth of Rare Diseases, including approximately €150 million contribution from Enjaymo.

We expect EBITDA margins of around 37.5% slightly higher than in 2024 and reflecting also the increased investments behind Rare Diseases which Luigi already alluded to, which will be more heavily weighted earlier in the year.

Adjusted net income margin is expected to be around 25%, slightly higher as compared to '24, resulting in a strong operating performance, only partially offset by higher financial costs.

We're extremely pleased with our performance in 2024. We're extremely well-positioned for another fantastic year ahead and we're looking forward to presenting our updated 3 year plan and mid-term targets at the end of April.

And now, together with the team here, I'm very happy to take your questions.

## Q&A

OPERATOR: Thank you. 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 their 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 Isacco Brambilla, Mediobanca. Please go ahead.

ISACCO BRAMBILLA: Hi, good afternoon, everybody. 3 questions from my side. And the first one is on full year 2025 guidance. 2023 and 2024 were 2 extremely strong years for both Specialty and Primary Care and Rare Disease with guidance foreseeing another strong year on both organic growth and margin expansion. Could you elaborate a bit more on the pillars back in your confident outlook? Also if you can remind us the main appointment in terms of business development activities in the coming months?

Second question is on EUSA Pharma. The portfolio had a great acceleration in the final quarter of 2024. Could you please elaborate more on the drivers behind that? Also, is it fair to take the fourth quarter run rate as fully sustainable also for the coming quarters?

Finally, again on 2025, how should we think about top line growth and margin expansion trajectory throughout the year? If I recall correctly, first quarter will face a quite demanding comparison base.

ROBERT KOREMANS: Thank you, Isacco. Let me first address the full year 2025 outlook. What really drives this is the momentum and the performance in both our businesses, right? Really good growth, strong momentum, and combined with our traditional cost discipline, this brings the fantastic increase in all of the metrics really as I explained. Of course, we continue with BD, but BD is not factored in into our guidance. It has always been important for us and will continue to be important. And we continue to drive in both our businesses, the organic growth and very encouraged by the current momentum.

Maybe pass to Luigi on the other question.

LUIGI LA CORTE: Yes, sure. In terms EUSA, no you cannot take Q4. I mean, we've always said individual quarters are a little bit lumpy and we're not going to give guidance for the year for the individual components of the Rare Disease business, but certainly, you know, we expect continued robust growth across, those 2 franchises. I think the underlying drivers are still those that I referenced and in terms of growing penetration, growing patient acquisition.

In terms of the quarterly phasing, you're right. Well, first of all, Isacco, thank you for recognizing that we had very strong '23s and '24s and that '25 targets, herald another year in line with those. There will be some phasing, phasing may be a little bit different in the sense that Q1 last year was a strong comparable cough and cold. Also, some of the things that we're expecting to play out this year, like the approval of the broader label for Isturisa in US will really benefit the second part of the year. We want to be ready for that and, therefore, where we are investing, adding resources to our organization on the medical side in particular, but also in the field, we started doing ahead of that. So, you should expect, potentially Q1 margins not to be quite as perky as they've historically been recalled the previous years they've been around 40%. I'm not going to give sort of more specific guidance on that. But again, yes, Q1 will be a tough comparable for some franchises and will reflect

some of those investments. But again, very confident that we will see margin expansion in 2025 with a target set for the year of 37.5% versus the 37% that we achieved in '23 and '24. Hopefully, that answers your question Isacco?

ISACCO BRAMBILLA: Yes, sure. Many thanks.

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

MARTINO DE AMBROGGI: Thank you. Good afternoon, everybody. The first question is on Isturisa new peak sales, because this includes the Cushing syndrome in the US. If I remember correctly, but please update if I'm not correct, 25% of the patients should come from Cushing syndrome in the US?

ROBERT KOREMANS: Sorry, Martino, I'll pass it to Scott, but it does include and it always did include the Cushing syndrome label in the US. And Scott, maybe you can give a little bit more color to that.

SCOTT PESCATORE: Yes, hi, good afternoon everyone. This is Scott Pescatore. Yes, you're correct, we do see about a quarter, slightly more than that in terms of the overall population of Cushing syndrome patients. But again, you know, we're looking forward to that. We don't yet have the indication, but that's something that we're looking forward to later on this year. So the sales do rely on that, but you're absolutely right. There is only a subset of the overall sales that are related to the Cushing syndrome.

MARTINO DE AMBROGGI: Okay, thank you. And the second question is on the guidance this year, because if I take the Specialty Care mid-single-digit growth, and I add €140 million additional sales from Enjaymo, what is remaining is not double-digits for Rare Diseases? So just to clarify, Rare Diseases ex- Enjaymo would be double-digit up.

ROBERT KOREMANS: It should be.

MARTINO DE AMBROGGI: Okay, because, well, maybe I need to do twice the math but seems to be very low the guidance in terms of at least the bottom of the guidance for sales. So just my elaboration.

SCOTT PESCATORE: Maybe I don't know what assumptions exactly you're making, we're saying mid-single-digit on SPC, double-digit without being precise in terms of what the contribution of those 2 is going to be. We said already some time ago that we were expecting from the portfolio, ex-Enjaymo over €2.4 billion of revenue. We said we're expecting 150 for 2025. We're expecting 150 from Enjaymo. So again, depending on which point in the guidance range you take and how you're splitting that up, you may get a different result, Martino. But we do expect the Rare Disease franchise ex-Enjaymo to grow double-digit in 2025.

ROBERT KOREMANS: And the momentum continues, right? So that's...there's no slowing down in that at all.

MARTINO DE AMBROGGI: Okay, thank you. And very last, I don't know if it's too early to talk about it, but the potential upside for the new indication that you mentioned in the price release which are not factoring the guidance. Is it possible to ask you some additional comment?

ROBERT KOREMANS: Well for BPH, we already indicated that this is about €150 million opportunity, which is an exciting opportunity and for the rest we have not given any figures. And you're right, we wouldn't do that now we are clearly, and is evaluating also including potential new indications for Enjaymo. As soon as we have better insight and feel comfortable to share that we will. And the work on it is absolutely ongoing.

MARTINO DE AMBROGGI: Okay, thank you.

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

NICCOLO STORER: Okay. First question on margins. You talked about investment to support rare disease business, and in fact, probably profitability on this part of the business is a little bit lighter compared to previous years? Can you shed some more light on this investment to support this business? What to expect next? And is it fair to assume that 2025 guidance, 37.5% margin reflects basically just the consolidation of the Enjaymo the 50% improvement?

My second question is on SPC guidance for 2025, mid-single-digit growth. If I take 2024 excluding Türkiye, it was 2.5%. So which kind of assumptions on Turkey are embedded in 2025 guidance? And basically, I was trying to understand whether you are assuming some sort of acceleration or if maybe Turkey is explaining the delta to 2024?

And very last, if you can elaborate a bit on what drove up net financial charges in Q4? Thank you.

ROBERT KOREMANS: Maybe I'll start, Niccolo, on the Rare Disease margin. I will ask Scott to maybe comment on the activities that we're doing. I mean, in terms of unpicking the margin guidance for 2025, we're not going to give a lot more detail. We are expecting an expansion versus 2024. And of course, there's pluses and minuses, the pluses, you know, increasing share of Rare Disease, contribution from Enjaymo, but at the same time, and we've always said this, we feel it is as important to continue to invest behind these growth drivers, particularly with such significant opportunities ahead.

Scott, do you want to say what we are doing.

SCOTT PESCATORE: Absolutely, and I think it is important as Luigi alluded to earlier what we've done even in the end of last year was as we continue to expand our field presence in the US in anticipation of the CS indication. We've added additional sales personnel and also medical people in the field. Those people have all been hired. They are on-board, they are training

and they are at the door and they are active as we speak now in anticipation of the label expansion. So obviously, that comes with a bit of cost but that's already been, you know, absorbed again and we've taken that into consideration for the full year.

ROBERT KOREMANS: And going through your other questions, I think SPC look yes, Türkiye has contributed very well in 2024, and we've always reported rightly. So I think both the result with and without Türkiye and we do that for the simple reason that you know, Türkiye can create distortions because of hyper-inflation accounting. But you know, we are confident in this business continuing to achieve at constant exchange rate overall a mid-single-digit growth, and like always there will be countries that one year grow more, one year grow less but I think we look at it as a portfolio and we are confident on the sustainability of the growth of that portfolio.

And on financial expenses, yes...I mean, of course in Q4, we had the financial expenses that come from Enjaymo acquisition. It's not a small amount that we drew down for that, but also we've had at the later part of the year in particular a bit of a FX losses which compared to small gains in 2024. Hopefully, that addresses your questions Niccolo.

NICCOLO STORER: Yes, thank you.

OPERATOR: The next question is from Giorgio Tavolini, Intermonte. Please go ahead.

GIORGIO TAVOLINI: Hi, good evening and thanks for taking my questions. The first one is on the Enjaymo acquisition, in particular on the outlook slide. You talk about €35 million on amortization. So I was wondering if it's PPA, if it will be recurring for how many years?

The second question is on the recent proposed cuts by the Trump administration to the National Institute of Health. So I was wondering if you see an implication for your Rare Disease business in the US.

Another question on the financial expenses, I mean a follow-up for 2025. Is it fair to assume €96 million, €97 million financial expenses or something below?

And very last one on the peak sales, I was wondering what could be the ramp towards the updated peak sales. If it would be more backend loaded or we should expect a more, let's say, a more gradual progression towards these levels. In how many years if it is possible, I don't know if it's fair to assume some the reaching of these peak sales in 5 years' time horizon or 3 years, I don't know. Thank you.

ROBERT KOREMANS: Thank you Giorgio. So maybe to start off with question on the US, Giorgio. Our business in the US is substantial for us but relatively small I think for the US per se and we serve huge unmet medical need in a small group of patients where there isn't any alternative most of the times. So quite frankly we don't expect anything from...it's early to speculate, we don't know what is new administration, but I will think of it from everything we've seen and heard so far. We don't expect any impact on us and that's really driven by the fact that we address a huge unmet medical need, and that also ties into what we see as a ramp up for our products. Much of the growth comes from very hard work in field to really identify patient-by-patient. This is often times also why big pharma like the structure and patients and dedication to go after every single patients, getting them diagnosed, get them on therapy, get them reimbursed and then keep them benefitting from the product as long as they can. And the product term remains usual for them, and that is reflected in the double-digit growth that we are achieving in Rare Disease and you see that all of our products. So it's really a patient, by patient, by patient gaining. And I don't want to spend too much...we are not going to step away that...we don't see a change in that momentum in the foreseeable future. But I am not going to share, simply, I think it's not wise to share how long it will take to get to peak sales. And look we've just increased almost 30% of peak sales



expectations just also because the market dynamics and our own performance are so much better. So I think we should also leave some room there. So double-digit growth on Rare Disease is something that we are very confident about. And yes, we do believe that the US is going to continue to be a very exciting place for us to do business.

LUIGI LA CORTE: Thanks for the questions, Giorgio. So I think this may help from modeling purposes on the reported figures, not adjusted of course. But the €35 million is an annual amortization charge. So you would expect that for a while, 20 years or thereabouts. And with regards to the €60 million which is noted on the targets slide. That is mostly 2025 and it's really 1 year. I mean, we took I think about €8 million of inventory unwind noncash charge in 2024 in December and there is another roughly €60 million to go. And we think in this case...in the case of Enjaymo, we should go through that in 1 year. If you remember, we had something similar, more significant amount with EUSA acquisition, and it took a few years and there was a lot of inventory, a lot of also semi-finished product. Whereas in this case, it's finished products and it's about a year's worth so we should be through this over the course of 2025.

I think financial expense is a good guess, but I am not going to say how close you were, but I will just say that financial expenses are likely to be slightly higher than what we reported for 2024, because of the additional debt that we took over. But as I said there was also quite a bit of FX in the 2024 numbers. So let's see it depends also on how FX goes.

Okay. So I think we've answered all your questions, Giorgio.

GIORGIO TAVOLINI: Thank you very much. Good evening.

OPERATOR: The next question is Bruno Permutti, Intesa Sanpaolo. Please go ahead.

BRUNO PERMUTTI: Thank you. Good afternoon, everyone. A question related to the US BLA filing. So, I wanted to know if you can update a little bit on what is going on, and what could be the timing for a possible filing and approval. So, I understand what is the timing from possible timing of this business opportunity.

ROBERT KOREMANS: Bruno, are you referring to Cushing's syndrome or Qarziba?

BRUNO PERMUTTI: No, it was related to Qarziba for neuroblastoma.

ROBERT KOREMANS: Milan you want to comment on the...shall we take that immediately and then get your second question after that, Bruno.

BRUNO PERMUTTI: Yes, sure.

MILAN ZDRAVKOVIC: So this is Milan Zdravkovic, Head of R&D. Thanks for your question. So, as we already mentioned, we had a meeting with the FDA. And on the strength of that meeting, we are now collecting the data to engage with a further dialogue with the FDA in mid this year. And that work is ongoing well. And on the strength of that second meeting now with the FDA, so to say, then we can better triage exactly what a BLA filing would look like and the amount of data that would require. So, I think it's a little bit too early to talk about the timing of the BLA filing. But we are quite encouraged with the original dialogue with the FDA, and we are now collecting the evidence to go to the FDA and discuss with them.

BRUNO PERMUTTI: Okay. Is there something new compared to some months ago or you are doing the job that was expected to do by mid-2025 to talk again with the FDA?

MILAN ZDRAVKOVIC: There's nothing new from that perspective, this is exactly as communicated last time.

BRUNO PERMUTTI: Okay. Thank you so much. And yes, I was wondering if I may, a second question concerning Cushing's syndrome. So, for this opportunity, you are waiting for the approval. So, you file to the FDA for approval, and now you are waiting by mid-2025. So, is this correct or you were requested to do some more on top of that.

ROBERT KOREMANS: No, that is correct. You can say when you file a supplementary NDA, you have an ongoing dialogue with the agency, and we are encouraged by that dialogue. And as we have communicated, we expect, you can say, the approval towards mid of 2025 for the decision.

BRUNO PERMUTTI: Thank you.

OPERATOR: As a reminder, if you wish to register for a question, please press "\*" and "1" on your telephone. The next question is a follow-up from Bruno Permutti, Intesa Sanpaolo. Please go ahead.

BRUNO PERMUTTI: Yes. If I may, another question related to the R&D. I would like to understand if the 5.3% is going to remain stable or to change in 2025? And lastly, if you can help me to understand the increase in the SG&A and write-down that you had in 2024 for modelling purpose?

LUIGI LA CORTE: Yes. So the write-downs were around €13 million. I think we took earlier in the year, a couple of million on the REC 0559 program and then as reviewed trajectory of some of their products, you know, one in particular, Ledaga on the Rare Disease side, somewhat behind expectations, and then we thought it was appropriate to write the value down. So, that's included within that other expenses.

In terms of the breakdown of SG&A, there's about the 27.9% of revenue that we reported for '24 around just above 6.5%, say...close to 6.7% is G&A. The balance are selling expenses. We don't typically give guidance quite so precisely in terms of the component parts of the P&L. I would expect though in terms of just giving everyone some direction,

to see somewhat improving adjusted gross profit margin over the course of 2025 with OPEX overall compensating some of that. But still, as we said, with a net improvement, where we're targeting a 37.5% plus or minus EBITDA margin for 2025, which again is an improvement over '24 in R&D.

R&D...don't forget, R&D is a sum of a number of things, right? There's not...I mean, people when we talk R&D think clinical. In our case, actually a big chunk of that is things like amortization, which will increase obviously because we had 1 month of amortization for Enjaymo. We will have 12 months. Some of the investments that Scott referenced is medical and field medical. There's some regulatory expenses. So, there may well be a slight increase on the R&D line, but OPEX overall, I expect to be broadly in line. But again, I would focus on the overall EBITDA margin target that we set for the year. Hopefully, that addresses your questions, Bruno.

BRUNO PERMUTTI: Yes. Thank you. Thank you very much.

OPERATOR: The next question is a follow-up from Isacco Brambilla, Mediobanca. Please go ahead.

ISACCO BRAMBILLA: Yes, hi again. Just one quick follow-up on my side. Any comment on the M&A strategy for this year, any particular area of focus for you, any priority there by therapeutic area or geography?

ROBERT KOREMANS: No nothing has changed on our side, right? So, we continue with our strategy, both businesses remaining very important. We believe there's a big benefit from having both strong solid SPC that is extremely well performing, continues to grow and drives its second to non-margins and an even faster growing Rare Disease that requires now at this point in time, a little bit more investment, but all just marginally so and in light of the beautiful opportunities out there, very affordable and we see fantastic momentum, and we don't change our strategy. So, I think one

of the things at Recordati is we continue to do what we do and drive really good results with that. And there's no plan to change any of that.

ISACCO BRAMBILLA: Okay, thank you.

OPERATOR: Gentlemen, there are no more questions registered at this time. I turn the conference back to you for any closing remarks.

ROBERT KOREMANS: Okay. Then I'd like to thank you all for joining. Also, thank you for the very positive remarks on our performance that we also are extremely proud of. We are in...started an exciting year and with a great outlook going forward. I have the privilege of working with incredible good team here. And to be continued, right? But we're very optimistic on the outlook for Recordati and happy to share that. And on 29th of April, we'll give a little bit more detail on the 3 year plan. And in between, if there's anything happening, we'll for sure be able to reach out to you. Thank you for joining, and have a wonderful rest of the day.