Recordati S.p.A

"First Nine Months of 2024 Conference Call"

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OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati First Nine Months of 2024 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, Vice President 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 the first 9 months of 2024. 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, good morning. Thank you for joining us all today. I'm pleased to share once again our outstanding results for the first 9 months of 2024. We are proud of our performance and our excellent track record of consistently delivering at or above our financial objectives over the last decade.

For these 9 months, starting with net revenue of €1.743 billion, up 12% versus the previous year or 9.3% like-for-like at constant exchange rates. This performance reflects continued excellent growth across Specialty & Primary Care, which was up 6.5% like-for-like at constant exchange rates and Rare Diseases, which was up 14.5% like-for-like at constant exchange rates.

The strong top line growth and operating leverage translated into our usual sector-leading profitability with an EBITDA margin of 38.2%. The adjusted net income was €445.4 million, up 9.5% versus the previous year, successfully absorbing the increase in financial expenses and tax rate. And with a very robust free cash flow of €434.3 million, we ended the first 9 months with a leverage of just below 1.6 times EBITDA.

Now in September and a bit earlier than anticipated, Isturisa was approved in China for the treatment of adults with Cushing's syndrome. We remain very optimistic about the overall market potential. Given the strong results year-to-date and a positive outlook for the remainder of the year, I'm pleased to confirm our full year 2024 financial targets, which were upgraded in July. These targets reflect the strong momentum across the business and our confidence to successfully execute on our plans.

I would also like to clarify that these targets exclude any potential contribution from Enjaymo. Our agreement with Sanofi to acquire the global rights to Enjaymo reaffirms our continued commitment to address serious unmet needs in rare diseases and is a perfect strategic fit with an attractive product and financial profile. On the following slide, I would like to highlight the key points of the transaction in a little bit more detail.

Enjaymo provides patients with cold agglutinin disease, a novel treatment option as the only approved targeted product. It was launched in 2022 in the US, Europe and Japan. Last 12-month sales, as of August '24, were approximately €100 million. Enjaymo is a great complement to our rare disease portfolio in an area of high unmet medical need and is synergistic with Sylvant with hematologists as the key target physicians.

On the financial side, we expect 2025 revenue of greater than €150 million and peak sales in the range of €250 million to €300 million. We anticipate

positive EBITDA contribution immediately after closing with margins becoming accretive to our current rare disease business from 2025 onwards.

And lastly, I would like to highlight the derisked deal structure with an upfront payment and potential commercial milestones, which are subject to the achievement of net sales at or above the top end of our peak sales year sales expectations.

I'd like to remind you that the closing is expected by the end of 2024 pending, of course, regulatory clearances. And as such, we expect minimal financial contribution this year, which has not been factored in in our '24 outlook.

We are thrilled to welcome many wonderful new colleagues who played an essential role in making Enjaymo as successful as it is today and who, we are convinced, will continue to play a crucial role in the success of Enjaymo going forward.

It's now my pleasure to turn the call over to Luigi.

LUIGI LA CORTE: Thank you, Rob, and good afternoon. Good morning, everyone. Very happy to have yet another opportunity to comment what is a strong set of results.

I'll start as usual with revenue on Slide 5 with Specialty & Primary Care which very clearly delivered once again a strong quarter on the revenue side and continued to show solid like-for-like growth at constant exchange rates which you see for the 9 months is 6.5%, continuing to outperform the relevant markets on key promoted products.

And I would highlight that, as I know many focus on individual quarters, sales continue to be somewhat distorted by dynamics in Turkey, which had a strong adverse effect in Q3, and was benefiting from a positive year-on-year comparable in Q2. And you note that excluding Turkey, what we show as like-for-like growth at constant exchange rate at the end of the 9 months is slightly ahead of where it was in Q2.

So underlying performance of the business from our perspective continues to be very strong driven by, as was the case earlier in the year, urology, which clearly reflects the strong contribution of Avodart, Combodart, very much in line with plan. But also continued double-digit growth of Eligard, and also nice to see a mature product like silodosin continuing to grow, and we had a very good contribution in the quarter on mix to normal in Turkey.

The Cardiovascular and GI franchises continue to be very resilient. They're showing marginal growth and it's very nice to see mature products like metoprolol, pitavastatin and even lercanidipine in direct markets continuing grow volumes and revenue, complemented by the continued uptake of Reselip in France.

Cough and cold, which as you know, started the year on the back of a slightly milder flu season and by still strong and certainly strong in terms of in-market performance was behind in the first half of 2023. You have seen that in Q3, it was very much on par despite still being affected by adverse effects.

And finally, I just called out for SPC, the very strong growth and performance in the other bucket. Magnesio Supremo, the OTC food supplement in Italy, drove most of the growth in that segment. So a number of growth drivers across SPC, which again, continues to

outperform the markets and continues to grow very much in line with our expectation of a mid-single-digit like-for-like growth at constant exchange rates with a solid contribution in line with plan of Avodart and Combodart.

With regards to rare diseases, similarly, dynamics are very much unchanged for this business as well. We continue to deliver strong double-digit growth and the business has a basis for continued growth in the future, with the acquisition that we announced of Enjaymo but also with the approval of Isturisa in China in the month of September.

Growth clearly continues to be driven by our 2 key franchises. And it's nice to report that all of the key 4 products within that are really contributing. As we've commented before, Isturisa with €152 million of revenue in the first 9 months, is set to become a €200 million revenue product this year. Signifor at €87.4 million year-to-date is continuing to grow double-digits and set to surpass the €100 million mark this year. And continued strong growth of both Qarziba and Sylvant is offsetting the mild erosion of the metabolic franchise due to the generic entries affecting Carbaglu in the US and EMEA. Carbaglu, is however growing in international markets. And within metabolic, we do have other growth drivers as well, such as Cystadrops.

Of course, the key next catalyst in this franchise for the rare disease business is the potential approval of the label extension for Isturisa in the US which, as we said, we expect by mid-2025. And whilst there is no major news to report, we are continuing to progress the work to address the request from the FDA on dinutuximab for a potential BLA in the US and continuing the enrollment of patients in the Phase II trial for pasireotide for PBH. So once again, for rare diseases a very strong growth

with a number of drivers and a number of reasons to feel bullish around the continued growth opportunity of the segments in the periods to come.

Moving to Slide 7, very briefly in terms of revenue by geography. Everything is still very much consistent with the first 6 months with good growth across all of the regions and several showing double-digit growth. Certainly, that is the case of our 2 lead markets, the US and Italy, which continue to grow strongly, as is Spain. In the case of the US, this is driven by the growth of the endo franchise combined with Sylvant and in case of Italy and Spain, the addition of Avodart, Combodart, but also growth of both Rx and OTC portfolios in those markets.

And the only one material change I will call out, and just to reinforce the message I gave earlier versus the picture that we shared in the first 6 months, is Turkey, which in the first 6 months was growing by 55% on a reported basis, is growing by 23.5%. Volume growth in the market is still strong, but Turkey, as I said, was benefiting from year-on-year comparison on FX in the second quarter, and penalized in the third due to the recent devaluation and also a difference in the timing of price increases, which we know are significant in that market. Price increases in '23 in Q3 in Turkey were awarded to the industry in July. And so, we lapped the full year at the end of Q2. And we've just recently had the confirmation that price increases in Turkey have now been awarded effective November, which then sets Turkey to achieve a higher growth rate in the last quarter of the year. And I think that's all on the revenue side.

Moving on to Slide 8. Very pleased to be able to comment the P&L, which shows pretty much double-digit growth on all the key lines. Revenue, 12%; EBITDA, 11.8% growth; adjusted net income, 9.5% and net income, 11% growth as well. Clearly, this reflects the strong

performance in terms of revenue, but also the usual cost discipline, which helps sustain margins just above the 38% mark.

As commented in the prior quarters, adjusted gross profit margin decline is mainly due to the consolidation of Avodart, Combodart and product mix. But again, those that look at the individual quarters will have noticed a slight improvement in Q3 relative to the first 6 months.

We continue to see benefit, in terms of operating leverage on SG&A which is down to 20.7% of revenue. And you see a modest increase in R&D expenses, a good part of which is amortization on a cash basis. Excluding amortization, R&D expenses are only around 6.2 of revenue, very much in line with last year, so being outpaced by the revenue growth. There's more growth in other expenses, reflecting mostly roughly €2.5 million of costs related to the Enjaymo acquisition, pending regulatory clearance.

So very strong financial results and very pleased to say on Slide 9 that this looks set to be yet another year also of strong cash generation supported not just by strong growth in EBITDA, but also somewhat lower absorption in net working capital despite the growth in volume of business with these 2 clearly more than offsetting somewhat higher interest expenses and income taxes, leading to a free cash flow of €434.3 million for the 9 months which is close to 11% growth versus the previous year. And in the first 9 months, the free cash flow has been used to fund the dividend and pay down of debt, which as you will see from Slide 10, clearly reduced versus end of December last year and with leverage now just below 1.6 times on a reported basis. And once again, positioning us now very well, with the financing lined up for the acquisition of Enjaymo.

And finally, to conclude from my side and as there are no changes for the full year guidance on Slide 11. You will have seen we have reiterated with confidence the upgraded targets that we published in July. For 2024, we increased across all lines relative to the targets that we set at the beginning of the year, and we are still expecting solid growth in line with plan for both business units as well as EBITDA margin around 37%.

All this despite still expecting FX headwind of around 2%. And again, as Rob highlighted, with minimal contribution, if any, expected in this year from Enjaymo subject to timing of regulatory approvals and marketing authorization transfers. Of course, as we do every year, we will confirm targets for 2025 in February along with the preliminary results. However, it's safe to say we are still very much in line and the business is performing absolutely in line with the previously provided steer that we've given to the market.

And with that, we will open the call for 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. We will pause for a moment as participants are joining the queue.

First question is from Niccolo Storer, Kepler. Please go ahead.

NICCOLO STORER: Hi, good afternoon. Thanks for taking my question. I was looking at EBITDA margin evolution this year compared to previous year by quarter. We have had Q1 slightly up, Q2 down, Q3 up, Q4 implied in the midpoint of your guidance down. So what is your comment about this erratic trend in profitability. Is there a specific reason why this has been happening and how should we look at it going forward? Thank you.

LUIGI LA CORTE: Hi, Niccolo. It's Luigi. I'll take that question, which we do get pretty much every year at this time of the year. We do have some phasing to our quarterly EBITDA margins, which tend to be very strong at the beginning of the year in Q1, and that's a combination of both the cough and cold business, which does have a healthy margin. Also, as we said, over the years, we've seen many of our international distributors, the ones where we ship, let's say, you know, in very lumpy amounts tend to get their orders in early in the year.

And the opposite is true, particularly on the international distributor side towards the end. So it's a little bit less heavy on those. Both of those businesses have higher than average margins. There's also a little bit of a skew to Q4 activities. Now in this case, and again this year will again be a year where Q4 margin is going to be somewhat lower than other quarters. And again, that's just historical phasing. And we are also starting to put a little bit of investment in to prepare for the expected approval of the broader label for Isturisa in the US. There's nothing more than that really.

And again, there as well, unfortunately, the Turkish lira and the rules around accounting and hyperinflation economies do create a little bit of volatility as well, because any change to the Turkish lira needs to be reflected retrospectively for the full year, which does create a little bit of volatility in the P&L, unfortunately. I hope that addresses the question.

NICCOLO STORER: Thanks, and maybe, another one sorry if you already answered this question or already deal with this. I connected later at the call about Isturisa approval in China, which are your expectations about that, about the phasing, the ramp up in potential revenues?

ROBERT KOREMANS: We got the approval in September, which was a bit earlier than we expected, and that's positive news. Isturisa China, is a beautiful opportunity, and we expect peak sales there in the range of €50 million. And with Isturisa there's a fantastic development and we are very upbeat and optimistic. Luigi already alluded to us now investing into the Isturisa label extension for the United States, and we hope to be able to get the approval to extend the label to Cushing's syndrome as well in the US, and that will give an additional potential of 20% to 25% and we see with all the dynamics in the US market that we're very well positioned to capture there a really good opportunity.

Of course, we invest now and that opportunity is there. So Isturisa not just in China but also in US and a very good and continued growth story and the momentum isn't stopping at all.

NICCOLO STORER: This €50 million more you might expect from China are on top of the big-sales guidance you provided?

ROBERT KOREMANS: The China and also the label extension for Isturisa in US, both of them have been in the guidance we gave earlier.

NICCOLO STORER: For €400 plus million, right? Isturisa?

ROBERT KOREMANS: Exactly.

NICCOLO STORER: Okay. Thank you.

OPERATOR: The next question is from Charles Pitman with Barclays. Please go ahead.

CHARLES PITMAN: Hi, thank you very much for taking my questions. Just 2, if I may, both kind of more product focused. Firstly, just on the metabolic portfolio and the Carbaglu erosion in US may be offset by growth in international markets. Can you just give us a little bit more detail on how we should think about that portfolio going forward? Should we assume, kind of, low single-digit erosion in the rare disease portfolio is more likely now or is that likely to kind of trough in the near term the offset by international growth?

And then just a second one on the apparent slowdown in growth of Eligard and the EUSA portfolio. Just again, also how do think about that going forward? Is it just the impact of strong comps from 3Q last year, and if you could just explicitly detail any potential impact of phasing or one off impacts from shipments that we need to keep in mind? Thank you.

LUIGI LA CORTE: Charles, maybe I'll have a start and then maybe we can ask Scott Pescatore, who is here with us to provide us a little bit more color. I think to be honest, on your suggested slowdown on Onco, you know we've always said individual quarters can be lumpy so do not make a lot of that. I think we take oncology and annualize the revenue of the first 9 months, and you see that is already getting as some have commented close to what we indicated being big sales for that franchise. So you know, we feel very strong about the health and the growth prospect of that for portfolio. Metabolic, you recall when we gave the plan we said would be flat to a slight decline over the period as a result of those growth drivers being offset by short-term erosion in US and EMEA but again, I will pass maybe to Scott to give a bit more color.

SCOTT PESCATORE: Thanks, Luigi. Hi, this is Scott Pesatore here Charles. Yes, as Luigi mentioned, we see the portfolio relatively flat in the coming months, but remember that there are a number of products within that portfolio. So we do have a decline of Carbaglu. We are a maintaining a lot of the volume there in the US and also in Europe, obviously subject to price adjustments based on tenders or individual patients in the US from a commercial perspective, but also, we anticipate to continue to grow panhematin and cystadrops within that portfolio. So as Luigi mentioned, we tend to see that to be flat growth moving forward.

CHARLES PITMAN: That's great. Thank you very much.

OPERATOR: The next question is from Alistair Campbell, RBC. Please go ahead.

ALISTAIR CAMPBELL: Hi, thanks so much for taking the question. Just a quick question actually on Enjaymo. Just looking at Sanofi's Q2 results. I mean, it's delivered another very strong quarter, growing 80%. So maybe perhaps unlike some acquisitions in the past that maybe have been products that are more mature, this is still very much in aggressive growth phase. So I guess the question is, you know as you go through the transfer from Sanofi to yourselves, presumably it's creating quite a bit of disruption and uncertainty at Sanofi. So how do you minimize the risk of that disruption sort of disturbing the launch phase of this product and ensuring that you could maintain the momentum through Q4, and obviously, when it comes to board path for Recordati. Thank you.

SCOTT PESCATORE: Hi, Alistair. This is Scott Pescatore. I'll take that one. No, it's actually a very good question. And I can tell you that we've had some early interactions with our Sanofi colleagues over the last few weeks, both in the US and Japan and in Europe. And they've been incredibly helpful in the transition so far. As you know, we obviously haven't closed the deal

officially yet. But the early integration that we've been able to do and the communication we have with Sanofi has been very, very positive. And so, we anticipate minimal disruption as we go through the integration, mostly because we've had discussions with the people that are impacted by the acquisition. They're very excited to join our company. We're excited to have them, and we're doing all that we can do in the immediate term to welcome them. And then, of course, after the closing anticipated towards the end of this month, we'll bring them on board and make them fully onboarded with our organization. And then, of course, all the document transfers and everything else that we have to do in order to make the integration flawless. But the early indications that we had so far are incredibly positive, and we're very, very, very excited to welcome all the Enjaymo employees.

LUIGI LA CORTE: And maybe if I can just add to that, you know this is not new for us, right? I think when we did the Novartis deal in 2019, we picked up you know Signifor, which was already on market, but also Isturisa, which was due to be launched and due to be launched in the midst of the pandemic. And despite that, the team did a fantastic job to get to the product where it is. So I think we've got quite some experience in the group in terms of how to address that. And maybe, I wanted to go back and realize we missed giving a response to a question on Eligard and maybe I can ask also Alberto to comment that. There's no change to the end market performance of the product, very much in line with our expectations. Alberto, do you want to...

ALBERTO MARTINEZ: Yes, it was the previous question from Charles. He was referring to a potential slowdown of Eligard. And what I can tell you is that in market performance continues to be equally strong. We see 14% from IQVIA on a September year-to-date basis, which is consistent with our reported growth of ex-factory 12%. And Eligard continues to be the only product

in this class that gains market share. So we remain certainly happy with the exceptional performance of Eligard as we have launched the new device throughout the year very successfully.

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

ISACCO BRAMBILLA: Hi, good afternoon, everybody. 2 questions from my side. The first one is on revenue guidance. Can you give us an idea of what may drive you between the lower and the upper part of this guidance? Is this like for a growth or FOREX?

Second question is on…is probably for Luigi, if you can recall as a sort of overview of financing of Recordati after Enjaymo sort of the split variable versus fixed financing, average cost and how we should think about 2025 financial charges versus this year?

ROBERT KOREMANS: Hi Isacco. I'm sure Luigi is happy to give a little bit of an overview on the financing. Our momentum on the 2 businesses continue to really grow and is fully in line with our own expectations, fully in line with our own plan and clearly not trending to the lower end of the guidance, but I'd like to be cautious and not over promise on things that you cannot completely influence impact of hyperinflation in Turkey can have an impact. So I don't want to overpromise, but business is doing well, and we're very happy with the momentum. And hence, our confirmation of the guidance that we increased in July, we're fully on track to deliver on that.

Luigi, do you want to comment on the financing?

LUIGI CORTE:" Yes, sure. And of course, as you said, Isacco FX, particularly as a reference to the Turkish lira in the way needs to be accounted for, does

provide a little bit of volatility and can make that different. But as Robert said, we're very confident and very happy with the momentum.

In terms of the financing, you know we have fully secured the financing for the transaction. As you know, its US $825 million upfront, all of which we will finance through a new syndicated loan facility. I'm very much on track to finalize that. Probably the cost will be very much in line with our existing facilities. I'm not going to comment on the fixed versus variable because we need to still decide of that amount, how much we will swap the fix, but we are aiming to keep around the sort of 50:50, 40:60 split. The one thing I will say, very happy that we bought the majority of the US dollars, which are required for the acquisition before the results of the US elections. And so, we're able to, I guess, do most of those purchases forward, obviously before the US dollar appreciated in the last few days. I hope that addresses your question, Isacco.

ISACCO BRAMBILLA: Yes. Maybe just a qualitative follow-up, how should be higher debt versus lower interest rates play out in financial charges next year versus this year?

LUIGI CORTE: No, I think you should still expect an increase in financing expenses. Obviously, I mean, it's a big…it's not a small acquisition that we've done. Although having said that, they clearly very happy that on the…hopefully even most of closing that, leverage is back down to below 1.6 times. And you will have noticed we don't even have to say pro forma in the sense that it is just below 1.6 even just on a reported basis. We do expect to end the year somewhere between 2.4 and 2.5 times but then, of course, we'll continue to deleverage. I think you still expect the financing costs for next year to still be higher than 2024. But as always, you know we will provide targets for '25 in February when we report the full year preliminary full year results for this year.

ISACCO BRAMBILLA: Very clear. Many thanks.

OPERATOR: Ladies and gentlemen, there are no more questions registered at this time.

ROBERT KOREMANS: So thank you all for having joined us this afternoon or morning, whatever part of the world you are at. Thank you, and looking forward to meeting with you soon again, and have a great weekend.