Recordati S.p.A.

"First Half 2025 Presentation Conference Call"

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OPERATOR: Good afternoon. This is the Chorus Call operator. Welcome and thank you for joining the Recordati First Half 2025 Presentation Conference Call. As a reminder, all participants are in listen-only mode. After the presentation, there will be an opportunity to ask questions by pressing "*", "1" at any time. Should anyone need assistance during the conference call, they may signal an operator by pressing "*" and "0" on the telephone.

At this time, I would like to turn the conference over to Eugenia Litz, 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. Together, they will present results for the first half of 2025. 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, and thank you for joining us today. We are very pleased to share our good results for the first half of 2025. Beginning with net revenue of €1.32 billion, an increase of 11.7% compared to the previous year, or 7.8% like-for-like at a constant exchange rate. This reflects an adverse FX impact of minus 2% in the first half, mostly from the Turkish lira and increasingly from the US dollar.

This performance demonstrates continued momentum across specialty and primary care, which increased by 5.1% like-for-like at a constant exchange rate, and rare diseases, which grew by 12.8% like-for-like at a constant exchange rate.

Robust top-line performance and operating leverage, partly offset by higher investments to support the expanded approval of Isturisa for Cushing syndrome in the US, integration of Enjaymo, and for continued geographic expansion, resulted in EBITDA margin of 37.5%. Net income was €327.8 million, up 8.9% from the previous year, reflects higher operating income partially offset by a higher tax rate. And with a strong free cash flow of €256.8 million, with higher EBITDA partly offset by working capital absorption and income tax paid, leverage at the end of the quarter was just below 2.3 times EBITDA pro forma.

During Q2, we announced the signing of the licensing and supply agreement with Amarin to commercialize Vazkepa in Europe, further strengthening our cardiovascular franchise, and I will provide more details on the next slide.

As for R&D, I'm very pleased to highlight that the clinical trial for dinutuximab beta for Ewing sarcoma has been initiated in the second quarter. And finally, I'm glad to confirm our full year 2025 financial targets, despite increased FX headwinds, as the positive momentum of the business is expected to continue.

Now, to provide some additional details on Vazkepa transaction. Vazkepa is an approved product indicated to reduce the risk of cardiovascular events in statin-treated adult patients with high cardiovascular risk. It has patent protection in Europe up to 2039. It has been approved in 2021 in the EU and in the UK in 2022 in Switzerland.

Based on the REDUCE-IT Phase 3 cardiovascular outcomes trial, this trial included over 8,000 patients and demonstrated statistically significant and clinically meaningful results. We believe Vazkepa is a great strategic fit

and compliments our existing SPC business and cardiovascular portfolio in our core markets, while also enhancing our presence in the UK.

In terms of financial contribution, Vazkepa is expected to be EBITDA positive from 2026 onwards and to generate over €40 million in revenues in 2027. As for the expected financial impact in this year and the remainder of 2025, the top line impact is expected to be below €10 million, and there will be a slightly negative EBITDA contribution level due to the integration and launch cost.

Finally, the terms of the agreement was an upfront payment to Amarin of US $25 million. And Amarin is also eligible to receive commercial milestones up to a total of US $150 million if annual revenues exceed certain sales thresholds starting from 100 million euros.

I will now turn the call to Luigi to give a bit more details to our results.

LUIGI FELICE CORTE: Thank you, Rob, and good morning, good afternoon, everyone. And once again, happy to comment on the results which wrap up the first 6 months of 2025. And once again, actually, very happy with how the business is performing really across both sectors.

As usual, I'll start with revenue and with SPC specifically on Slide 5, which you will see is not just growing solidly, but in fact, picked up slightly in Q2 the pace relative to Q1.

You see growth at constant exchange rate of just above 5% and continue to be underpinned by solid performance of our key promoted products, and also supported by growth of both our OTC and Rx drugs. So really broad-based growth there. The standout in terms of performance within the therapeutic areas, clearly cardiovascular, with very broad-based growth of

our legacy portfolio there across markets, and also solid growth of the GI franchise, both on the Rx and OTC portfolio.

Nice to see equally, as we'd anticipated, starting to see some recovery of the cough and cold business in Q2, particularly in Russia, you know still negative to was a strong first half of 2024, but not quite at the same level as was the case in Q1.

And finally, within neurology, a very positive growth of Silodosin and a number of our local products. Very happy also to see the in-market performance of Eligard, which however compares to the first half of last year, where obviously we had the selling of the new device, and therefore a strong ex-factory sale in the first half of last year.

And also positive, although still down, Avodart, Combodart very happy to start seeing signs of stabilization in Spain, and that stabilization is very much consolidated in Italy, these 2 being the key markets. So once again, a very resilient growth of SPC, and of course, we'll now start adding to that as of Q3 revenue from Vazkepa, it'll be a gradual ramp as we transfer sales and distribution activities over from Amarin, but look forward to that contributing to growth, particularly in 2026 and beyond.

And on there to rare disease on Slide 6, and here equally, nice to flag also in the case of rare disease, a small tick up in the growth rate in Q2 relative to Q1. You see at the constant exchange rate, just under 13% overall, with a nice step up in both the rate of sales of Isturisa and Qarziba, as we'd expected. And also, with Enjaymo posting very strong sales in the quarter, nicely stepping up as we expected, and Enjaymo contributing over €69 million of revenue in the first half, up 26% versus the same period of last year, on a pro forma basis.

In terms of the key franchises, clearly very happy and growingly so with the prospects for this franchise to drive continued growth both this year and in the future, particularly with respect to Isturisa, where we have now achieved over 1,000 patients in the US, which is an exciting milestone for us. Isturisa recently also getting approval in Canada and Russia, but equally happy that that's complemented by continued double-digit growth of Signifor across most geographies.

So, very excited about the prospects there. Very happy to see both Sylvant and Qarziba contribute to the strong growth of the hematology franchise, and obviously pleased by the resilient growth that metabolic is continuing to show this year, driven in particular by Panhematin.

With this performance, rare disease now represents close to 40% of our revenue, and given the really strong momentum across all franchises and the progress that we're making in our lifecycle management programs, clearly this percentage is destined to continue growing.

Looking at it by geography, the picture doesn't change on Slide 7 in terms of all key regions contributing to the growth. As I've done in previous calls, I'll only focus on some of the main trends. Clearly, the standout performance is the US, with over 32% growth in local currency. Of course, that includes a contribution of Enjaymo of just over €35 million. But, that also reflects strong growth of all of the franchises really in the US.

Spain growth a bit subdued due to the strong comparable of Eligard last year, and the stabilizing now pressure from generics on Avodart. Enjaymo clearly contributing to the growth in Germany. And also, internationals, we've also sort of caught up with phasing of shipments to international distributors on the SPC side.

You'll note Russia returning to a solid double-digit growth on the back of the recovery of the cough and cold, which I've mentioned. Strong performance in Portugal, where we've now launched Magnesio Supremo, our OTC food supplement, which has been very successful in Italy, and we've now introduced in Portugal as well.

And of course, I skipped over Turkey, where we continue to see solid growth, of course, in local currency, but also in terms of volumes. Very strong performance there unfortunately, fully offset by the strong devaluation, which was really sort of focused in Q2.

So, in terms of revenue, as I said already, very happy with the performance of the business across all of the portfolio. And also pleased on Slide 8 to see that we are still tracking very much in line with our expectations for the year. You will recall we said at the beginning of the year that we were expecting the phasing of margin to be slightly different from previous years as a result of the combination of early investments behind the broader label, which we were granted in the US for Isturisa, and also obviously the integration of Enjaymo in the first part of the year, with the expectation that both of those products would really step up and contribute to even stronger momentum in the second part of the year.

And that clearly is reflected in the numbers. But despite that and the FX, very happy to see in the first half of the year, both double-digit growth in revenue and EBITDA, with adjusted net income just slightly behind. Still very strong, 9% growth, reflecting the strong operating performance, but a slightly higher tax rate.

The integration of Enjaymo and the step up in investment in Isturisa, are clearly explaining the step-up in SG&A and particularly selling expenses in

R&D in the first part of the year, with obviously the progression of our lifecycle management programs contributing to that as well.

Decline in net income really being driven by, despite the strong operating performance, the non-cash charges which arise from the acquisition of Enjaymo and the somewhat higher non-recurring costs that we incurred in Q2 as part of our continued optimization of our sales organization, particularly in Italy and to a lesser extent in Spain. So, very happy with the P&L performance. Once again, very much in track with expectations.

Turning to cash flow and leverage on Slide 9 and 10, continue to deliver, very solid cash flow. We did elect in the first part of this year, for reasons I'm sure you all understand, to increase our stock levels a bit, particularly in the US, which is really the key driver of the higher working capital absorption in the first 6 months of this year, alongside obviously the growth of the business, the higher results that we achieve obviously result in somewhat higher income tax payments, all of which are leading to free cash flow in line with the first 6 months of last year, but driven by strong operating performance.

Following the payment of the dividend for 2024 in May, the higher share buyback and the upfront for Vazkepa leverage is pretty much unchanged relative to Q2 at just below 2.3 times EBITDA, but clearly set to deleverage further in Q3.

And with that, I will pass it over to Rob to comment on the outlook for the remainder of the year.

ROBERT KOREMANS: Thank you, Luigi. Concluding with our financial targets for the full year of 2025, we're very pleased to confirm our targets of double-digit growth across all metrics. On the top line, we expect revenue between €2.6 billion

and 2.67 billion, including increasing FX headwinds, now expected to be approximately minus 3% for the full year.

Top line is driven by the strong underlying performance of the business and reflecting a small contribution of less than €10 million for Vazkepa this year, a further step up of Enjaymo in the second half, and we're particularly encouraged by the strong positive market dynamics and performance of Isturisa, especially in the US following the label extension. On the back of this, we continue to increase our investments to maximize the opportunity of Isturisa.

We expect EBITDA margin around 37.5%, driven by operating leverage, positive mix, and efficiency initiatives, but partly offset by the FX impacts from the US dollar and the already mentioned Vazkepa transition and integration costs and the continued investments into the Isturisa maximization.

Adjusted net income margin is expected to be around 25%, with strong operating results and with a tax rate of approximately 24%. We're extremely pleased with the start of the year and the continued momentum going forward.

And now, together with the team, 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 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 from Jefferies. Please go ahead.

SHAN HAMA: Hi. Thank you for taking my questions. 2 from me, please. So, given the higher level of investments just based on Isturisa and Enjaymo and the expectation that it will ramp up in 2H in terms of their performance. How are you thinking about level of investments in 2H? Is this something we can expect to stay at steady levels, or will there be a slight step-up to also complement that increased ramp?

And then, secondly, in the presentation, you flagged the go/no go decision for Enjaymo and ITP 1Q '26. Can you provide additional color on the potential opportunity here at the moment? Is this more of a bolt-on or a step change in the total addressable market? Thank you.

ROBERT KOREMANS: Yes, well, I think especially for Isturisa, we see incredible good market dynamics, and with mild Cushing's becoming more and more of a reality, and where we're also tapping into. And the performance of Isturisa, where we've now exceeded 1,000 patients in the US only a couple of months after getting the extended label. We see this opportunity, and we're really very keen to continue to invest, to maximize the opportunity for Isturisa. So this was also something that very much is part of our plan, and we're executing on that plan.

SCOTT PESCATORE: As you guys all remember, we made a significant investment at the end of last year into this year for the approved label in April. And obviously, as you see from the results, those investments are certainly paying off, and we expect that trend to continue and even ramp up in the second part of the year.

And just to reiterate what Rob said, we're looking now more closely at the mild segment of patients with Cushing's, and looking to make additional investments to capitalize on that opportunity as it becomes more and more concrete.

ROBERT KOREMANS: And maybe, Milan, you care to comment on ITP?

MILAN ZDRAVKOVIC: Regarding the ITP program, we plan to meet with the FDA during this year and take a stop-go decision in Q1 around how we want to progress this as a potential into Phase 3 development. This is on the basis of the very strong, Phase 1 data, in particular, in very treatment-resistant patients with ITP. But we want to make sure that we have, you can say, the regulatory path cleared before we, I think, comment further on how this may progress.

SHAN HAMA: Thanks.

OPERATOR: The next question is from Sophia Graeff from JPM. Please, go ahead.

SOPHIA GRAEFF: Hi, thanks for taking my question. Another one on Isturisa. I just wanted to ask, could you expand a bit more on the progress on Isturisa uptake since the label expansion into Cushing's syndrome? I think we've seen a relatively limited step-up in quarterly revenue, just €3 million quarter-on-quarter. Could you explain some of the dynamics there in terms of why we haven't seen more of an inflection or a bigger acceleration here? What should we be expecting in terms of an H2 acceleration? And what gives you confidence in this acceleration in light of what we've seen in this quarter's performance? Thank you.

SCOTT PESCATORE: Thanks, Sophia. Hi, this is Scott Pescatore. No, it's a great question. And so, what we're seeing now, as Luigi alluded to, is we've broached now the

1,000 patient mark, which is a significant milestone for us, also for the treatment of the disease. And it's really showing that the expanded investment that we put behind the business in the US is starting to now pay off. We've seen now in the early parts of the year, you know with the embedding of the new reps, that the uptake was, let's say, a little bit slower than we had anticipated. But now that uptake is continuing much more rapidly.

In the second part of the year, we're seeing the ramp-up of even more patients that are being put on Isturisa and Cushing syndrome. And this is something that we see very strong momentum coming out of the second quarter, continuing to the third and the fourth quarter, and into next year as well. As Robert also mentioned, we do see some of these mild patients that were inside some of the numbers earlier in the year. And those patients will also continue to be put on therapy as needed.

So, we're really excited about the second part of the year, because this is where we see the true ramp-up and the momentum behind the performance that we've had in the first half of the year will certainly continue in the second part of the year.

ROBERT KOREMANS: Maybe if I can add, just from my side, don't forget that approval was during Q2, not quite from the very start. And also, of course, in Q2, we did have quite a bit of FX headwinds in the US, which impacted. In fact, the dollar was positive in the first quarter and then turned negative in the second. So, I think you'd have to factor in. But to echo what Scott has said, very happy with how we're seeing the product take off now. And we do expect continued uptake.

So, I think maybe just to round that also on the first question from Shan, yes, we do expect those investments to continue. And they're looking at

potentially adding to that. We do expect also the pace of revenue to step up. So, in terms of margins, expectations for the year are unchanged. Yes, FX is a factor. Yes, Vazkepa will be slightly diluted. But the momentum of the business is strong and it's picking up, particularly on those 2 franchises.

SOPHIA GRAEFF: Thank you.

OPERATOR: The next question is from Alistair Campbell from Royal Bank Canada. Please go ahead.

ALISTAIR CAMPBELL: Great. Thanks very much for taking the question. It's actually on Vazkepa, if that's okay. You've obviously given us expectations for sales around 2027. But I wonder if I could press you in what you think the longer-term sales ambition could be here, maybe to sort of in context, your next set of thresholds kick in if sales cross €100 million. Do you think that's a stretch target? I think that's something we could see sort of within the foreseeable forecast horizon? Thank you.

ALBERTO MARTINEZ: Thank you for the question. This is Alberto Martinez from SPC. Just confirming the expectation would be in the range of €100 million around the expiry date of the patent that we expect around 2039. Obviously, this is based upon the current markets where Vazkepa is being commercialized, although we are also looking at opportunities in other markets that could increase that expectation beyond that figure. But we are obviously now focused on the transition, which is going very well, smoothly, and we will be able to revisit and continuously explore opportunities for further growth.

ALISTAIR CAMPBELL: Thank you.

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

MARTINO DE AMBROGI: Thank you. Good afternoon, everybody. Again, on Isturisa, because you mentioned 1,000 patients in the US. Could you provide a figure for the worldwide in terms of patients and what is the updated potential market that you see for Isturisa in terms of patients?

And the second, I clearly understand there is a step up in the second half for both Isturisa and Enjaymo. Could you provide any rough indication in terms of expected sales for the full year?

And just a very quick double check, are we comfortable saying that rare diseases are excluded for any US price cut or duties going ahead? Maybe you have a better picture than mine.

ROBERT KOREMANS: Maybe I have to start with your last question. So, this Section 232 analysis is still going on. It is expected to be finalized in August. From what we hear on tariffs, the max cap seems to be 15% on pharmaceuticals. And yes, there is a very strong comments coming from regulators and people in the FDA and Republican Party that rare diseases get a special better treatment and are excluded for many. But we also only have the same crystal ball as you have, right? So, yes, we are on top of this. We take it extremely serious. But I don't want to pretend that anyone knows at the moment, really. And I think we have to take it as it comes. From what we hear initially, it seems to be manageable in that sense.

SCOTT PESCATORE: So, with regards to the global Isturisa uptake, I mean, certainly in the US is where the biggest opportunity lies. So, we're happy to sort of share more specifics around the patient uptake there. I mean, globally, we don't have the specific number to share for the global uptake. However, I can tell you

that, since launch, we've had significant success, as you can imagine, in markets across Europe and now in the Middle East and Latin America. So, we're really pleased with the opportunity that we have with this product globally. But certainly, you know, we're even more excited about the opportunities that we're going to have now with Cushing Syndrome in the US and onto sort of bigger and broader things that are going to happen there in the future.

With regards to our anticipated landing for Isturisa and Enjaymo, Luigi can probably share a bit more of the specifics there, but I can tell you that we're on track to achieve our expectations. And as you rightly said, we do have a step up in the second part of the year, but we have very strong momentum, both on Isturisa and Enjaymo. We haven't spoken about that yet, but Enjaymo had a really strong first half of the year, as you saw from the numbers Luigi shared. We had 26.4% growth. And I can tell you that in particular we are very pleased with the performance in Europe, particularly in Germany. Also, the uptake in Japan has been very successful year-to-date.

And one sort of piece of information that was important is that we've seen ourselves through the warmer periods in Japan at the moment, and where we anticipated some patients coming off of the product due to the nature of the disease, and that hasn't played out. So, we're really pleased about that patients are staying on product through the warmer months. So that's an important piece that as we learn the sales cycle of this product and we experience patients through 12 months of the year.

Just to sort of tie up the last piece around Enjaymo and expectations for the year, we anticipate landing at €150 million. And then Endo, you know, we're well within the range of €400 million to €440 million, but that also includes, of course, Signifor as well.

ROBERT KOREMANS: And those Martino where the targets you recall Enjaymo we set at the beginning of the year on Endo, I think this is what we sort of provided that when we did the 3 year plan, and we're still very much on, on track, of course again, we'll have to deal with the FX. But the business is doing well and performing in line with those.

MARTINO DE AMBROGI: Thank you.

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

ISACCO BRAMBILLA: Hi. Good afternoon, everybody. A couple of questions from my side. The first one is on the cash side, absorption from trade working capital was to the tune of €100 million, in the first half. You elaborated a bit on the drivers behind that. Could you help us figure out a sort of trajectory to embed in full year forecast for this line of the cashflow statement?

Second question is a follow up on operating margins, full year guidance implies and adjusted EBITDA margin in the second half in line with one of the first half, actually in the past years we were used to see second half margins slightly below the first semester? So, just if you can recap the moving parts that should lead to different seasonality margins this year. Thanks.

LUIGI FELICE CORTE: Sure. Isacco and thanks for the question because actually that was exactly what we were trying to sort of anticipate to everyone at the start of the year when we said that there would be different phasing, right? So, as you rightly pointed out historically Q1 was our strongest margin quarter, Q4 much weaker than the previous ones and we did say at the start of the year that because of that sort of phasing of investments relative to the ramp up of the

revenue that we were expecting in those products, we would expect to see a more balanced sort of evolution of margin over the course of the year. That's still very much the case. So that is why, you know we still expect, to be in line with guidance. Again, Vazkepa will have a slightly dilutive effect. And obviously that wasn't built into the original numbers, FX is a bit of a headwind. But again, we're, still confident on our ability to deliver, where exactly within that range will depend on sort of the trade-offs between how FX plays out over the next months and the speed of the further ramp up that we are expecting, on both, the Isturisa and Enjaymo in particular, of course, the performance of the broader portfolio. But those 2 really are where we expecting to see continued growth.

In terms of working capital. I don't think, I would expect a lot more than, this for the full year.

ISACCO BRAMBILLA: Okay. Thank you, Luigi.

OPERATOR: The next question is from Niccolò Storer from Kepler Cheuvreux. Please go ahead.

NICCOLÒ STORER: Good afternoon and thanks for taking my 2 questions. The first one is another one on Vazkepa and the growth trajectory. I mean, you said you're expecting around €100 million by 2039, but 2039 is quite far in the future. So how should we expect the trajectory from the €40 million to the €100 million in 2039 as a linear one or something different?

Second one is on let's say restructuring cost. I saw you booked around €17 million in H1. Should we expect anything more here…in the reminder of the year? Thank you.

COMPANY REPRESENTATIVE: Thanks, Niccolò. Let me maybe answer the second part of the question in. No, I think, we've done our right sizing and we as a company, we continuously look at where can we improve, but I think in terms of the mass of that, that should really be behind us after this restructuring. So, we will always try and adapt to the market and to opportunities and constantly try to have the right structure in place. But with this, I think the…say, the one-off in that sense is in terms of substantial figures significantly behind us.

ROBERT KOREMANS: On the first question we gave guidance around '27 and '27 revenue is expected of around €40 million, and we have given you the directional figure of a €100 million for the current countries where the product is commercialized by 2039, we expect the product to continue to grow and last year it was above €11 million. This year it is going to be well above €20 million, so it's in a good launch trajectory and obviously it is expected to continue to have a strong double-digit for a number of years then flattening in the outer years.

Luigi you may want to add.

LUIGI FELICE CORTE: Yes, no, I was just to make sure it's €20 million for this year. That's obviously on a sort of total year basis and sort of full revenue. We will get a fraction of that for the time period that we own it. We are being transferred a net margin until we pick-up sales and distribution and obviously with the costs of the promotion behind the product. That's fairly limited, which is why you will see it in the sort of outlook, we said it's going to be less than €10 million in terms of revenue. And actually, slightly negative in terms of EBITDA, but that's a really up just sort of, you know, only for this year. We did say it's going be contributing positively as of next year.

NICCOLÒ STORER: Thank you.

OPERATOR: As a reminder, if you wish to register for a question, please press "*" and "1" on your telephone. For any further questions, please press "*" and "1" on your telephone. Eugenia Litz, there are no more questions registered at this time.

ROBERT KOREMANS: Thank you. Thank you for having joined us today and we were very happy to share our first half year with continued really good momentum of our business and a nice stepping up of specifically Enjaymo and Isturisa, very confident that we see this momentum going on based on the in-market performance that we see. And, we're happy to answer your questions. Look forward to giving you further updates, further down the year. Thank you and have a wonderful day.