Recordati S.p.A

"First Half 2023 Results Conference Call"

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OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome, and thank you for joining the Recordati's 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. Federica De Medici, Investor Relations & Corporate Communications. Please go ahead, madam.

FEDERICA DE MEDICI: Hello everyone and thank you for attending the Recordati conference call today. I am pleased to be here with our CEO, Rob Koremans and our CFO, Luigi La Corte, who will present the 2023 first half results. Then we'll be running you through the presentation.

As usual, the set side is available on our website in the investors section. We are also joined today by our 2 heads of business unit, Alberto Martinez for Specialty and Primary Care and Scott Pescatore for rare diseases. Both gentlemen will be on hand to answer your questions together with Rob and Luigi during the Q&A session.

I will now give the floor to Rob. Please go ahead.

ROBERT KOREMANS: Thank you, Federica, and good afternoon, ladies and gentlemen. Thank you for having joined us today on the Recordati 2023 first half year results. We've really delivered a strong financial performance with continued growth across our business and with ongoing delivery of sector-leading margins. With revenue at €1,044.3 million, up 17% versus previous year or 15.4% on a like-for-like and constant exchange rate, we confirm the strong momentum of the group across our entire business.

SPC grew double-digit, 10.2% versus last year or 15% at constant exchange rate. And this business performance has been ahead of relevant markets and across all key therapeutic areas. Thanks to the continuous improvement of our competitiveness in every single market.

Also rare disease has delivered very strong results with double-digit growth at 32.2% versus last year and 15.5% on a like-for-like and constant exchange rate basis with a very strong growth of both the Endo and the Onco fully in line with plan and very resilient sales of metabolic franchise.

The group has been able to achieve these strong results despite strong FX headwinds, especially over the most recent months, the adverse FX impact has been approximately €30 million or 3.3%, mostly concentrated in Quarter 2 and mainly affecting our specialty and primary care business unit.

What I would like to highlight is the strength of our profitability with EBITDA at the margin at 38.9% in the first half year. This has been enabled by operational leverage and by a very strong continued cost discipline across the business. This brings a adjusted net income of €287.4 million, up 27.9% versus last year, driven by the strong positive operating performance and also lower net financial charges.

We are very confident in our ability to convert revenue in positive operating income and even stronger free cash flow. Free cash flow was up €43 million versus last year and reached €261.7 million. This brings to secure a leverage of 1.8 times EBITDA.

Our key R&D pipeline projects such as Signifor in post-bariatric hypoglycemia, Qarziba in the U.S., our REC 0559 program and our Carbaglu launch in China are all in plan, and we are very happy with the progress we're making there.

And finally, last, definitely not least, I'm very proud of the recent agreement with GSK. We'll give you a little bit more color in the slides to come. But this allows us really to strengthen our specialty and primary care urology franchise, where we now have a completely leading portfolio in PBH [ph] .

Thanks to this excellent performance and the strong momentum of the businesses, I'm very pleased to say that despite the very strong FX headwinds over the recent months and the expected headwind to come, we can confirm that we are on track to deliver the full year guidance for 2023 as to the updated guidance that we gave in May.

So on the next slide, happy to share a little bit more background and color on the agreement for the distribution of 2 leading brands from GSK's urology franchise in Europe. Avodart and Combo DAT are indicated for the treatment of moderate to severe symptoms of benign prostatic hyperplasia and for the reduction in the risk of acute urinary retention and surgery in patients with moderate to severe symptoms of BPH.

Recordati will commercialize both products across 21 countries upon completion of the relevant more administrative transition activities, which we expect to be finished with the majority by the end of this year of 2023.

GSK has received an upfront payment of €245 million, and we will start recognizing revenue and margin on country-by-country transition, and GSK will continue to receive income on an ongoing basis for the supply of product.

The agreement is fully greeted from '24 onwards and contributing to top and bottom line already in '23, but minimally so it is a very small

contribution in net revenues of €10 million to €20 million and a slightly positive EBITDA contribution as well.

Our ambition for Avodart and Combo needs to stabilize and then even generate a modest growth in our key markets. So, we're very excited to get this opportunity and be able to bring these 2 products into our urology portfolio. And we see a number of clear advantages. One, this was clearly in line with our strategy as we said out. We bring in well-established or originated brands in our core therapeutic area, high synergistic with Urorec and being able to really use the existing sales force that have shown to be able to drive also Urorec sales post loss of exclusivity. Both products are both loss of exclusivity that are extremely well established brands that we feel confident that we can bring into our portfolio, combining with Urorec and be able to cater to the different needs.

There are different patient segments for all 3 products, different indications for all 3 products, and we see a very good opportunity for portfolio management without additional costs, be able to really bring this in a very nice accretive way. So very happy with this agreement, this long-term agreement with GSK. And we believe this will help us to grow the sales clearly adds to the sales of SPC in urology, and that's an important aspect as well. So this deal, you will start to see the real impact in 2024.

And for the results of 2024 so far, I'd like to hand over to Luigi to take us through the financial performance in the first half.

LUIGI LA CORTE: Thank you, Rob. And good morning, good afternoon, everyone. As I started doing already last quarter, I will take you through the...first of all, the revenue of the 2 business units. And then as Federica has said, Alberta and Scott are here with us and can add more color to the results in the Q&A.

As anticipated by Rob, both business units really delivered a strong performance in the first 6 months of the year. As you will see from Slide 5, 6 months into 2023, SPC showing still a growth above 10% absorbing what was a very strong FX wind in Q2. It also post the normalization of some of the growth that we saw in Q1, which had benefited from a couple of one-offs, most of which have been now reabsorbed.

All of the therapeutic areas are contributing to this result, as you will see from the slide, our biggest TA [ph] cardiovascular growing by 8%, led by Lercanidipine, which still is benefiting from some of those early shipments in Q1 and which will unwind in the second half of the year.

We have continued to be successful in stabilizing sales of metoprolol and pitavastatin, which in fact, showed a small positive evolution, and also saw good uptake of our atorvastatin ezetimibe combination in France, Reselip.

Urology, which thanks to the deal with GSK will become in the future, our biggest therapeutic area, also showed a very strong growth of just over 12%, clearly driven by Eligard, which continues to gain share across markets. But also thanks to a solid growth of silodosin across several markets, in fact. And of course, we're now starting to deploy the new device of Eligard with the first markets going live with that in Q3.

GI revenue was up 10%, behind good performance of both our OTC portfolio and Rx. On the OTC side, obviously, I'll call our Procto-Glyveno and some of our probiotics offering, whilst on the Rx side, we saw continued good growth of our [indiscernible] and other products in the portfolio.

Cough and cold, which as you recall, was a very strong driver of growth in Q1, it's still showing a very, very strong numbers, 73.5

million of revenue, up 41% versus previous year. Q2, as you say, as you all have seen, has come down closer to 2022 levels but still ahead despite some of those benefits that we had in Q1 being reabsorbed. This is really driven by good continued growth across all markets, Italy, France and Russia. Of course, we still see Q3, Q4 comparables from 2022 for cough and cold has been more demanding as we already started seeing a recovery of that segment in the second half of last year. And obviously, as we will see significant headwind on the ruble.

And finally, other therapeutic areas are broadly stable with growth of products like [indiscernible] in Italy, offset by some of the erosion on our tender business in Germany.

With regards to rare disease on Slide 6, we are absolutely extremely pleased with the progress of all our key growth drivers on the rare disease side, both delivering sales in the first half in line with the targets that we set at the start of the year for 2023, and on track to deliver on the future ambitions that we have for both endocrinology and oncology. Endo obviously, stands out with 65% growth of Isturisa with both U.S., EU and rest of world markets contributing to that, but also just over 15% growth of Signifor, which again is a fantastic achievement.

Oncology, you recall we said in Q1, it benefited from some small phasing benefits which are unwound but still growing by over 13% in the first half of the year and once again on-track with both Qarziba and Sylvant contributing to that across regions. So both EMEA and rest of world and in the case of Sylvant U.S. also.

We continue to be very happy with the resilience of our metabolic portfolio, and in fact, extremely happy with the growth of Panhematin, which grew double-digits in the U.S. and also with growth outside U.S. We are starting to see a little bit of erosion on Carbaglu from recent generic entries, but well below expectations at the start of the year.

Carbaglu is growing in international markets. And as you will have seen from our notes, we do celebrate now having received the approval in China for the launch of Carbaglu, and we're now engaging in pricing negotiations to make that available to Chinese patients.

And finally, we're continuing to progress the life cycle management initiatives that we talked about earlier this year with more updates to come on those in the second half of '23. So both units are showing really solid growth and the same is really true of all geographies.

As you will see from Slide 7, clearly, with one exception Germany, which we called out at the start of the year, expecting a reduction in our tender business there. I won't go line-by-line in the interest of time and maybe just comment the...those markets, which, in absolute terms, contribute the most. Clearly, the U.S. on the back of the Endo and the growth of the endocrinology portfolio and the addition of...and growth of the oncology portfolio.

Also the international sales, thanks to strong growth of the rare disease business and contribution of oncology there. But also, as already commented, the early shipments to international distributors of lercanidipine. And then finally, you will see Turkey and Russia are still contributing strongly to our growth. Although with growth rates in local currencies, which have come down quite a bit since Q1, once again, with some of those phasing benefits normalizing in Q2.

Still in the case of Turkey, obviously, very strong growth both in terms of volume and price, with most of the pricing benefits offset by the very sharp devaluation of the Turkish lira. And in the case of Russia, growth really driven by the strong cough and cold performance, particularly in Q1 and also benefit of price decisions taken in 2022. It looks like both of those markets are expected to face a significant FX headwind in the second half of the year because of the even when just

comparing current FX rates to the average of 2020…to the second half of 2022.

But once again, very, very strong growth across the business. And once again, very pleased, as you will have seen from Slide 8, that aside from delivering strong revenue growth of 17% with revenue in the first half of well over €1 billion, continuing to, as Robert said, deliver margins which are absolutely at the top end of the sector.

You'll recall, we said at the beginning of the year, we were expecting synergies in SG&A to offset pressures at the level of gross margin, adjusted gross profit margin, and you clearly see those synergies are there with particularly selling expenses at 22.4% of sales from 24.2% of sales in the first half of 2022. But we are managing to hold those margin better than we had anticipated, and you see that it's broadly in line with last year. Clearly, that benefits from the higher volumes, but also from great work done by the procurement teams and of course, also the easing of some of the pressures on gas and energy prices.

R&D expenses, as expected, are gradually stepping up. You'll see slight increase in the percent of sales, in part also due to increased amortization mainly coming from the integration of EUSA. And we do expect this to continue to step up a little further in the second half of the year as we step up the activities behind this life cycle management initiatives.

And many of you, I'm sure, will be pleased to see that when we said what we called out non-recurring expenses of €26 million in '22, these really were non-recurring. You will see that line coming down significantly in the first half of 2023 to only $4.2 million, really being the sort of wind down of the SPC rightsizing with the first half of last year, also reflecting the initial integration costs and one-off costs linked to the EUSA transaction.

All of this results in very strong operating income and EBITDA with EBITDA of $406.2 million, a growth of 21.3% versus the first half of 2022 and staying at 38.9% margin, clearly strong results and we will remind everyone historically, our second half has been somewhat lower than the first half. But clearly, very pleased with how margins are holding up year-to-date. And below the operating line, you will see also financial expenses below last year. Now this really was driven by effect of gains and losses, while FX provides a headwind on revenue. It did provide $4.7 million of gains which compared to €18.8 million of losses in the first half of 2022.

This, combined with the lower non-recurring cost translates into very strong results at the level of adjusted net income and net income with adjusted net income close to 28% up versus 2022 and net income up 50% versus the first half of last year.

Very pleasing results, and once again, a very strong job done by their teams to convert those results into cash, which you will see on Slide 9. Free cash flow, $261.7 million; it's €43 million, up versus last year, absorbing obviously the increase in working capital coming from the increase in business and higher financial expenses and clearly more than funding the increase in the dividend payment in the first 6 months and the residual milestone payments made to Novartis for Isturisa, which account for the majority of €26.3 million increase in intangible assets.

Thanks to this operating performance and the cash generation. I'm happy to say our net financial position remains very solid, again, despite the final dividend payment in the first half of the year. Net debt to EBITDA is at 1.8 times trailing 12 months. And as you will see, we have…as you will see from the slightly higher cash balance, obviously anticipating the closing of the agreement with GSK. We funded that by taking down a new €300 million new club loan facility in June, which will be our first with ESG KPIs linked to it. They were

finalizing those details, and we'll announce those shortly. But I hope you appreciate we will be putting some money at stake behind our end commitment to sustainability. We expect leverage following the transaction with GSK to be at around 2 times EBITDA and pro forma below 2 times for the remainder of the year.

And finally, as Rob has already anticipated and as you'll see from Slide 11, we're very happy to say that on the back of the very strong performance despite the very strong FX headwinds that we had already in Q2 and that anticipate now for the remainder of the year to the tune of minus 5% in the second half versus 3.3% in the first half of the year. We do confirm the upgraded guidance that we provided in May.

The growth...underlying growth of our portfolio is absolutely on-track. Our underlying margins are also absolutely on track. Yes, we will have a small contribution in '23 already from the agreement with GSK, more so at the level of revenue. But clearly, FX impact is significant, prior guidance was around minus 2%, it is now around minus 4% for the full year at the level of revenue. But very happy that the momentum of the business allows us to confirm that upgraded guidance that we already provided.

And with that, I will pause and turn the call back to you, operator, for Q&A.

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 James Gordon of JP Morgan. Please go ahead. Mr. Gordon, your line is open. Is your telephone on mute? The next question is from Niccolo Storer of Kepler. Please go ahead.

NICCOLO STORER: Good afternoon. Can you hear me? Hello?

ROBERT KOREMANS: Yes, perfect.

NICCOLO STORER: Okay. Perfect. Thank you. A couple of questions. The first one on the Avodart/Combodart acquisition. You talk about, are you targeting stabilizing revenues. While in the press release, I think you talked about the acquisition being margin accretive since 2024. So which kind of profitability should we think being attached to the over €100 million revenues you bought. Is it right assuming something in the 35% area flat over time? Or should we expect a sort of ramp up? How should we think about it?

The second one is on your guidance. Your guidance basically is implying flattish, if not declining margins in the second part of the year against the growth that we've seen in the first part of the year and against further revenues growth. So which are the elements that would bring marginality...profitability do depress, keep profitability so depress at around 35%, plus or minus?

And very last and quick question is a clarification on the revenues associated to early shipments in Q1, if I understand...if I understood well, basically the unwinding has not started yet, and so you haven't recovered anything in Q2, right? Thank you.

ROBERT KOREMANS: Well, I'll ask Luigi to answer in essence, all 3 questions he can answer. I think it's the financial questions here. Maybe Alberto can skip in on the GSK agreement.

LUIGI LA CORTE: Yes. Hi Niccolo. Maybe I may take them in reverse order, if that's okay. Sorry if I wasn't clear on the winding. I would say most of what we would have expected to unwind has done so with one exception, really, which is the $6 million, $7 million benefit that we had in Q1 on lercanidipine, you know, that I think, will probably will be reabsorbed in the second half of the year. So I think most of that is actually done. What was going to unwind because some of the benefits also translates into the higher guidance that we provided for the full year.

On the implied lower margin for the second half, first of all, I know many of my peers would dive to have a 35% EBITDA margin. So I wouldn't call it low, but it is lower. I agree. And if you recall, I mean, it's historic one, has historically been the case, right? We've always had a somewhat softer second part of the year. First of all, I think FX is going to play a little bit overall as well. The R&D activities, as you probably know, when you start a study, you do take a number of costs upfront, and we are looking to start the PBH study in the second part of the year. And as we always said, we would expect the sort of R&D cost to ramp up gradually and some of them are lumpy, just in nature.

And again, the GSK, you know, the GSK provides a benefit on the top line and as usual, though in the transition period, less so at the bottom line level. In terms of...so I hope really that addresses your question in terms of the phasing of the EBITDA margin second half versus first half. On the other the Combodart deal, and I will maybe on the revenue, also ask Alberto to comment.

On your point around accretive, what we mean by that is it will...the deal will be accretive to the SPC margin and particularly thanks to the fact that it's absolutely synergistic, it's plug-and-play with minimum incremental investment required. I mean I won't go into the details of the margin structure of the product. We never do it for any of our products, certainly not on the partnered one. But that's effectively

what we mean. And also as of 2024, will deliver positive obviously, contribution all the way down to the level of net income.

And maybe on the revenue expectation, I'll turn to Alberto.

ALBERTO MARTINEZ: Very happy to chip in. This is Alberto Martinez speaking. With Avodart and Combodart, what we expect is to, first of all, stabilize the sales. These 2 products lost exclusivity in recent years. We have seen the sales declining, and we have full confidence that the sales will be already stabilized this year, and the expectation is to be able to maintain them over the coming years, potentially with some limited modest low single-digit growth, as Rob described, in the key markets. We do have very strong confidence in our ability to do that because we have a perfect analog with Urorec in our own portfolio with silodosin when we have experienced a similar loss of exclusivity. We've seen the sales declining in also the key markets like Italy and Spain, and now the sales have also been stabilized. So our confidence is very, very strong in our ability to deliver on what we have commented. Thank you.

NICCOLO STORER: Maybe just a clarification on this one. When you mean stabilizing revenues, you mean at €115 [ph] million, so in 2022? Or should we expect a further drop in 2023 and then stabilizing from this lower level?

ALBERTO MARTINEZ: We should be able to stay at the level of €115 million also in 2023 and beyond.

LUIGI LA CORTE: But of course, we will only record sales progressively a transition. So what you will see in our P&L is somewhere between €10 million and €20 million for this year.

FEDERICA DE MEDICI: Okay, next question.

OPERATOR: The next question is from Harry Sephton of Credit Suisse. Please go ahead.

HARRY SEPHTON: Really and thank you very much for taking my questions. I have an additional one on the Avodart deal. So on the margin contribution typically through some of these transfer service agreements, we can see a pure gross margin being recognized. It sounds like from your commentary that it will have a modest EBITDA contribution this year that has probably not the structure of this particular deal. Can you maybe confirm that?

And then I also had a question on Eligard regarding the phasing of the rollout of the new device. Can you maybe confirm how rapidly you expect the new device to be rolled out across markets and your expected uplift to sales from that?

And then maybe just another one on the cough and cold portfolio. To what extent has the benefit in cough and cold being more driven by competitor stock-outs versus what we've seen as a more of a recovery in underlying demand and what you might view as sustainable market share. Thank you.

ROBERT KOREMANS: Maybe I'll take the structure and cough and cold one quickly, and again, hand over to Alberto for the new device. You're absolutely right in terms of the structure of the deal. It is different from previous ones whenever we have an initial peer that's great drop through to gross margin was when we would have economic benefit from the point of closing, and we would book the margin before the sales order to cash transition. In this case, the agreement were slightly different, which is we start getting the benefit once the full transition has been finalized. So that is absolutely why you don't see that effect.

I think on cough and cold, we're not going to be able to sort of split, I think it's been a combination of certainly a pickup in demand, and

we've seen that across markets really. And I think we elaborated on the call last time at what maybe some of the drivers of that in terms of lower immunity levels post pandemic. But also our great...I think we were...we were more responsive to the increased demand than others. And we've always said that we were expecting the revenue rates to come back in line with levels closer to the second half of 2022 in the second part of this year.

In terms of the new device rollout on Eligard Alberto.

ALBERTO MARTINEZ: The new device rollout of Eligard is fully on track. Actually, it's being launched as we speak. And Denmark, the first country will be followed by Ireland and other countries within this year, larger countries will...are expected to happen at the beginning in the first quarter of next year. Everything is on track for that to happen, the regulatory pathway is fully cleared and all plans are in place in order to maximize the launch opportunity upon a very solid trajectory that we are seeing in each and every market where we have seen a real turnaround of the sales. We've seen how we have been able, over the last 2 years to increase the monthly sales of Eligard by more than 20%, which is quite significant. And this has not only happened in 1 or 2 countries, but effectively across the region. So a very successful relaunch. We expect the new device to be able to help and to support this continued momentum of Eligard in the market.

HARRY SEPHTON: That's very helpful. Could I just ask a follow-up on the Avodart deal. So GSK did report some quite strong growth in this product in the first half of the year, which obviously given it's more of a legacy product. We just wanted to gauge your confidence on the levels of inventory that you have available to yourselves for the product. And yes, if you're confident in the supply of that product through, I guess, on the near term. Thank you.

ALBERTO MARTINEZ: The short answer is yes, we are. We are following that closely in partnership with GSK. We're seeing in-market demand in alignment with the stock. There were some stock issues at the end of last year that were addressed, and that's partly why some of the factory sales were higher, but the sales ex-factory and in markets are correlated, and we are fully confident that the level of stock in the channel will be the appropriate one at the time of transition in each and every market.

HARRY SEPHTON: That's great. Thank you very much.

OPERATOR: The next question is from Brian Balchin of Jefferies. Please go ahead.

BRIAN BALCHIN: Hi, thanks. I think I missed your answer with regard to the step down in EBITDA and also in second half, which I think implied a 34.5%. Did you say that was [multiple speakers].

ROBERT KOREMANS: [Technical difficulty].

BRIAN BALCHIN: Yes. So I think I missed your answer with regards to the step down in EBITDA margin in the second half, I think it's implied at 34.5%. Did you say that was mainly driven by an uptick in R&D or was there something else that I'm missing?

And then the second one is, does the guide, [indiscernible] does the guide include the contribution from the GSK deal.

LUIGI LA CORTE: HI, Brian. I'll go through that again R&D step up is part of it. But you know, as I said earlier, so first of all, again, putting in perspective, 35% is a strong margin, even in sort of an absolute term. If you look at our history, the second half of the year and Q4 in particular, has always been somewhat a lower quarter. We R&D costs are lumpy in nature. We've always said these will gradually step up. And often, they're most lumpy when you start a study, because there's a number of payments which are made up front. And we will be starting...we do

plan to start the PBH Phase II study in the second part of the year, in fact, in Q3. We expect there's going to be a little bit of...on the operating side, there's going to be a little bit of headwind from FX.

And again, I think, yes, there will be a small contribution from the agreement with GSK, but more so at the level of revenue as typical at the bottom line level, it's a little bit less so in the first month. Again, because of the structure of this deal, which is different from the Eligard deal, the [indiscernible] deal and those structures, we have economic benefit from signing, from closing effectively, which meant for the initial period before up-taking over direct selling, we would get a straight through gross margin benefit. In this case, the agreement is structured slightly differently. We will only take benefit as and when we start taking over the sales activity, and that always takes a little bit of time. So that will be slightly dilutive in the next few months. So really, it's a combination of those factors, including the fact that you know, it's always been a little bit lower in the second part of the year while still being fairly strong…fairly strong results. So hopefully, that addresses both of your questions, Brian.

BRIAN BALCHIN: Yes. Thank you very much.

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

MARTINO DE AMBROGGI: Thank you. Good afternoon, everybody. Just to finalize on the GSK deal. Probably you are not willing to share with us. But what's more or less the cost of the financing for the funding of the deal? And how long is the license?

And the second question is on the 2025 guidance, because as it typically happens, your guidance…long-term guidance includes acquisitions. And now after this deal, you are already achieving this

range in 2025. I don't know if you can elaborate on this, because seems clear that it must be updated sooner or later, I don't know.

LUIGI LA CORTE: Hi Martino, so maybe start with the last one. Yes, it will be updated sooner or later, and usually, as you know, our schedule is every other year. So we're not updating the 2025 guidance today. Clearly, we're very happy with the really strong performance of the business. Clearly, so far, in terms of underlying business, we're tracking ahead of plan and hence the revised guidance for 2023.

The agreement with GSK gives visibility to some of that BD overlay component of the guidance as well. But we're 1.5 years away still with a very volatile FX environment, and we simply are not going to...we haven't updated 2025, and we're not going to be doing that near term. The agreement with GSK is up to 15 years, subject to customary performance conditions and the cost of financing.

Recordati, thanks to our performance, our cash flow, our balance sheet is seen as an investment grade company by our bank partners, investment grade loans are anywhere between Euribor plus 170 basis point and 200 basis points depending on the leverage and the tenor, and that's consistent with what we've…with what we will be paying for this new facility. Hopefully, that gives you some sense.

MARTINO DE AMBROGGI: Thank you. And 2 very quick follow-ups. The first is on R&D. What is the projected amount for this year? And what is included roughly in 2025 guidance? And just an update on the visibility on your Russian business, if you see any difficulty or any problem?

LUIGI LA CORTE: So on Russia business, operations are continuing. And you've seen in terms of the results, obviously, not keeping to that sort of growth rate that we had in Q1, but still solid and continue having an issue both getting our products to patients and getting our invoices for the products that we sell and pay into Russia. Of course, we will say

significant FX headwind on the...from the ruble in the second part of the year. The average was 62% in the second half of 2022. It's now at around 100. So clearly, that will provide a headwind.

And Martino…in terms of R&D, I'll go back to what we said in the plan, which is we expect the sort of cash R&D, so excluding amortization to go up by 1 percentage point of sales over the plan period. We didn't quite give a phasing of that, then I won't do it now. Of course, they will go up this year. I won't sort of break out now the P&L, but that was the magnitude of the increase that we were expecting.

MARTINO DE AMBROGGI: Okay. Thank you.

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

ISACCO BRAMBILLA: Hi, good afternoon to everybody. A couple of questions on my side. The first one is on U.S. performance. Could you give us a detail of the performance at constant perimeter. So excluding the perimeter factor into the oncology franchise in the first half of the year?

Second question is a follow-up on your medium-term guidance. I appreciate you cannot update Business Plan every 6 months, but considering the strong delivery on M&A and the current robust momentum, is it fair to say it that you are clearly adding at least towards the mid to high end of the guidance range you are going to provide it for 2025

ROBERT KOREMANS: Hi, Isacco. Thanks for trying again. We were absolutely happy with current momentum and very, very confident on business performance underlying both in our rare disease business and in the SPC, specialty primary care, we are doing better than we planned, and we continue to see the good momentum. But 1.5 years is a long time, and we haven't

really like Luigi said, updated anything...and you know, so I don't want to speculate. Recordati has never speculated, and we will not start that now.

In terms of performance in the U.S., I will let Scott because that's all rare disease comment on the extreme strong performance that we did see in the U.S. where our business in the last 3 years has actually more than tripled. So we are very happy with that, and that is all in terms of rare disease, but I don't want to speak for Scott here. So over to you, Scott.

SCOTT PESCATORE: Well, thank you, Rob, and this is Scott Pescatore, and thanks for the question. As Rob and Luigi had mentioned, the business in the U.S. continues to be very, very strong. It's our fastest-growing market. And all 3 franchises are growing very, very nicely versus last year. The endocrinology business continues to have significant growth on Isturisa and very, very strong growth also on Signifor. Our metabolic franchise is resisting the generic impact on Carbaglu and Cystadane, and we have a very, very nice growth on Panhematin in the metabolic franchise. So very good performance there, contributing to our overall growth for the metabolic franchise.

And with regards to oncology, as we've mentioned before, we fully integrated the team in...not only in the U.S. but globally. The team that's working on Sylvant in the U.S. is doing a fantastic job growing that product by double-digits this year, and we anticipate continued strong growth as we prepare for the entry and the launch of Qarziba, which we're working on as part of our development programs as well.

ISACCO BRAMBILLA: Okay. Thanks.

OPERATOR: The next question is from Neil Alexander of Deutsche Bank.

NEIL ALEXANDER: Hi, it is Neil Alex here from Deutsche Bank. And just one on Qarziba. And the Type C FDA meeting, it was previously communicated that would, the outcome would be Q3 '23, thus now move to the second half of this year. So it'd be just good to get your thoughts on any regulatory hurdles and any reason for the change? Thanks.

ROBERT KOREMANS: Thanks for the question. There really isn't any change in that sense. It's a slip of 2 weeks from the end of September to the beginning of October, and that happens with FDA, because there's no other thing than this. So we're very strongly committed to this and confident that we're on the right track. And that's the only reason for making this site adjustment.

NEIL ALEXANDER: Thank you.

OPERATOR: The next question is from Jainesh Mehta of Permira Credit. Please go ahead.

JAINESH MEHTA: Okay. Thanks very much for the presentation. Just a couple of quick follow-ups. The first one was just on Russia. I know you group the exposure among several other countries. Can you just call out what proportion of your total revenues is coming from Russia?

And then the second question was around the existing debt maturities. Can you just remind us when those mature and the new facility that you've just taken out when does that mature as well? Thank you.

LUIGI LA CORTE: Russia, $58 million of revenue in the first half of the year. Debt maturities, to be honest, are noted in our sort of detailed financial accounts there over the next 7 years in various chunks really not going to be able to go into that sort of full detail now.

And the last question was around. So hopefully, that helps. But again, we publish full details of our you know, funding facilities in our

detailed financial statements, which will be coming out Monday, I believe.

JAINESH MEHTA: Thank you..

OPERATOR: The next question is from Alex Simon of Tikehau. Please go ahead.

ALEX SIMON: Thanks for taking my call and congrats on the results. Could you please bring more color on the lower growth CAPEX in H1 versus last year? Is it phasing? And do you have guidance for full year CAPEX? Thanks.

ROBERT KOREMANS: Thanks, Alex, for the compliments. We are also really happy with performance. I'll pass to Luigi on the lower CAPEX, we do not have a policy of saving on CAPEX. We do the maintenance that we need to do and investments that we need to do. So off the top of my head,

LUIGI LA CORTE: And CapEx was actually higher than last year by a couple of million, let's say relatively, it's never been a big line of our cash flow statement, slightly higher than last year. So I'm not sure if I fully understood your question.

ALEX SIMON: Financial statements in terms of investments in PPE intangible assets.

LUIGI LA CORTE: Okay. Sorry, intangible assets...okay, sorry, CAPEX. If you look at Slide 9, CAPEX, is I guess a fixed asset. That's just...we just happen to have had lower amount of milestones that we...on a number of our licenses, we have sort of milestones payment attached most of what you see going through there in the last couple of years have been linked to the agreement with Tolmar on Eligard and some residual milestones due to Novartis on Isturisa. We had some first part of last year. We had some payments to Tolmar for the progression of the new device, the regulatory milestones around that. We have another one which we'll be paying in Q3, the last one $70 million milestone for the

regulatory recognition of the new device across all the key markets in Europe. And the milestone are only 3 that the markets are pretty much finished. But it's really just phasing of payments of milestones linked to some of the licenses that we took out over the years. Hopefully, that addresses your question.

ALEX SIMON: Much clear. Thank you. That's it from me.

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

CHARLES PITMAN: Thank you for taking my questions. If you can hear me okay. I just got a first question on cost. So I was just wondering if you could kind [indiscernible] shown very good kind of cost control and cost initiatives. If you could just, I don't know, if [technical difficulty].

ROBERT KOREMANS: Sorry, Charles, we can't hear a word of what you're saying. Could you [technical difficulty].

CHARLES PITMAN: My first question is cost initiatives you used, and whether or not a cost to take out and whether or not, would you think energy costs have played a role in your tight cost control so far? And then just secondly around what potential of Carbaglu in China could be. Thank you very much.

LUIGI LA CORTE: I'll interpret your first question.

ROBERT KOREMANS: Lost initiatives...it comes in a bit staccato very bumpy. So it sounds like the line is not very good. But yes, we've had a number of cost initiatives across our company, not only in terms of procurement where we look at energy and securing the right contracts for the right price, but also in terms of rightsizing our commercial footprint, which we have done quite successfully and a number of other things in terms of operations. I think this record at has always been very good at

managing the cost anything specific. If so, let me know, for launching in China, I'll pass to Scott for...we expect that launch to happen early next year in China. It is an interesting product. What I'm very excited about is not only the opportunity for Carbaglu in China, but the fact that this brings us with an organization in China that is already getting underground and active and training and being a good basis for future launches such as Isturisa, which probably have more potential than the Carbaglu in China per se. But I'll pass to Scott to answer.

SCOTT PESCATORE: Thank you, Rob. Absolutely, I have to first say that we're very excited about the positive news on the approval of Carbaglu because as Rob mentioned, we committed to invest in starting a business in China. We are going at it alone. And as you know, it's not an easy task to get products on the market from the ground up in China. So we're very pleased first with the approval of Carbaglu. And as you also know, Carbaglu is lost exclusivity in other markets. So the opportunity to grow that product in China is very good news for us. As Rob mentioned, there's modest growth in the peak year in China $15 million and $20 million with Carbaglu. But really, the full potential, as Rob mentioned, that we see in China, the opportunity for us to bring the endocrinology portfolio to fruition there, which is what the team is currently working on now.

So as I said, I think this is the first step in the right direction for us to realize the investment that we're putting in China and we anticipate more good news when we bring the product formally to market by the end of this year or early next year and then onwards with our endocrinology portfolio.

ROBERT KOREMANS: Maybe just to add, Charles. So to your first question on costs. First of all, just to remind you and everyone, the focus of what we did on Specialty Primary Care was really work on improving the commercial effectiveness of the organization. also reallocating resources from primary care to specialty care. And we're really seeing that bear fruit,

not just on the cost base, but also an acceleration of the growth rate in SPC, which continues to grow above the relevant markets. Another driver of benefit has been you know, synergies from the integration of EUSA, and I think you heard me also speak of synergies, which we expect now from the agreement with GSK being 2 products that we bring on the very limited or close to nil additional investment required. So those opportunities will continue to present themselves. So at the angle of the question was, are you done? They always continue to look for opportunities to improve. So hopefully, that addressed your question which we didn't quite hear so well

CHARLES PITMAN: Thank you very much.

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. Gentlemen, there are no more questions registered at this time.

ROBERT KOREMANS: Thank you, operator. I think we can end the session here. I'm very pleased to have shared with you and discussed the excellent performance, strong momentum across both our businesses fully in line or even ahead of plan. The fact that we just did a good agreement with GSK strengthens our urology SPC business franchise, and that significantly improves also the position we have in that and makes them very confident for the future. So our current performance makes us very, very happy. And the thing that is on all of our minds is, can be really...and that's unpredictable for us is the FX headwinds. I think we've highlighted to you that we want to really be prudent on that, and that this is part of our continued commitment to the full year guidance based on that strong momentum, but with the FX in our face. We still feel very, very confident that we can make close the year as we have increased our guidance, and I'm very optimistic about our future. So thank you for joining us today and hope to see you in person soon. Thank you.