

# **Recordati S.p.A**

## **"First Half Results Conference Call"**

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MODERATORS:     **ROB KOREMANS, CHIEF EXECUTIVE OFFICER**  
                      **LUIGI LA CORTE, CHIEF FINANCIAL OFFICER**  
                      **FEDERICA DE MEDICI, INVESTOR RELATIONS AND CORPORATE**  
                      **COMMUNICATIONS**

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome, and thank you for joining the Recordati 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 and Corporate Communications. Please go ahead, madam.

FEDERICA DE MEDICI: Thank you Judith, and good afternoon or good morning, everyone, and thank you for attending the Recordati conference call today. I'm pleased to be here with our CEO, Rob Koremans and Luigi La Corte, our CFO, that will be presenting the 2022 first half results. They will be running you through the presentation. As usual, the set of slides is available on our site under the Investors section. After that, we will open up for Q&A.

I will now leave the floor to Robert. Please go head.

ROB KOREMANS: Thank you, Federica. I'm happy to announce very strong revenue and profit in the first half of this year for Recordati, with continued strong cash flow generation. We have a revenue growth of over 15% and at constant exchange rate and adjusted for both the EUSA Pharma acquisition including accounting of Eligard in 2021, prior to the switch to direct sales. Our growth is strong and just under 9% compared to previous year.

EBITDA at €34.9 million was up by 11.5%, compared to the first half at 37.5% of revenue, reflecting the strong revenue growth and continued cost discipline, more than offsetting impact of inflation. Also, very strong free

cash flow generation of €18.7 million, increasing by 7% versus the same period last year.

There is a really strong momentum across both our businesses and continued post-COVID recovery. SPC with high single-digit growth ahead of reference markets. Of course, this level of growth rate is also explained by slightly softer first half of 2021, still at that point impacted from COVID.

Overall, we are seeing a very strong rebound from the Cough & Cold segment and OTC, but we see also a very broad growth across the entire portfolio. And our Rare Disease business shows double-digit growth, driven by both metabolic and the Endo franchise with sales of Isturisa and Signifor on track with plan.

And then our new Rare Oncology franchise, the former EUSA Pharma results are really above plan, with strong revenue of €46.1 million in Quarter 2. In fact, with some favorable phasing of shipments to partners in the quarter and the business is now fully integrated and fully operational and fully in line with our schedule.

We've taken multiple actions to offset inflation. Price increases across multiple parts of the portfolio wherever possible and very effective SPC efficiency measures already announced earlier, like the rightsizing of our sales forces. These actions sustain our margins. Year-to-date results are affected by hyperinflation accounting in Turkey which determined a revaluation of local assets and minor P&L impacts, resulting in the revenue uplift of around €3 million and a negative effect on operating margins of around €5 million.

As expected, and broadly in line with our plan, non-recurring cost of €26.4 million. They're mostly related to the EUSA Pharma acquisition. That's about €15 million and to one-off charges of SPC's rightsizing and also to the assistance in the Ukraine conflict related to donations.

As Luigi will explain later, our reported net income and operating income are impacted by fair value IFRS 3 adjustments related to the EUSA Pharma acquisition and they are expected. And also, some FX volatility affecting our financial expenses. On an adjusted basis, our adjusted net income is €24.8 million, up 7.1% versus previous year. And with that absorbing the unplanned FX losses, particularly related to the Russian ruble. Then there is also some good news from the ESG side. Our efforts to continue to be recognized by FTSE4GOOD Index series, we are reconfirmed, and an increasing rate from Gold to Platinum by EcoVadis.

Before handing over to Luigi La Corte, I will give a little bit more detail on performance of EUSA Pharmaceuticals on the next slide, please. Here you see the EUSA Pharma results and some of the key highlights. Like I said, we are really well on track for the integrations. We've announced a new Rare Disease organization earlier this month, early July, and we are operating fully integrated with our Onco franchise in place.

Sales in the second quarter of this year were €46.1 million and pro forma, in the first half of 2022, are €84.5 million, a growth of about 15% versus the first half of 2021, mainly driven by sales and performance across all regions and an increased penetration of Qarziba in Europe, but also benefiting a little bit from shipments to partners, particularly to China in relation to the Sylvant launch.

For full-year 2022, we expect to close, close to €130 million revenue and EBITDA margins of approximately 25% to 30%. Qarziba, US discussions

with the FDA are ongoing. Target timing is still expected to be in 2024 and also like we mentioned in the first quarter results, we are looking at new indications for Sylvant in the process of evaluating this, and should be able to come back later this year with some concrete proposals around that.

Then there is very positive news related to the finance and the financing of the transaction. This has been finalized with the new 5-year variation...variable rate term loan at very competitive rates, which reflects the strong creditworthiness of our Group. And finally, as anticipated before, we have finalized the purchase price allocation related to the EUSA Pharma acquisition.

I will let Luigi explain and address the questions related to this. Luigi, please.

**LUIGI LA CORTE:** Thank you, Rob, and good afternoon and good morning, everyone. I will comment first, as usual, revenue, but we'll try and go through this quickly so as to get to the P&L, which I'm sure we'll...which I'm sure some people may have questions. As Robert said, our sales of both of our business units, were very strong in the first half of the year, yet, benefiting from the recovery of market but in a number of areas with growth ahead of the relative market as measured by IQVIA and with very strong momentum of our key growth drivers.

I would first of all, like to call out in this slide, the stability of our key mature products. The lercanidipine franchise sales in markets where we have direct presence are broadly stable with the decline overall really been driven, as we anticipated at the start of the year, from the loss of tenders in China and the high initial shipments we made to our Chinese distributor in 2021, and a little bit of phasing of shipments to our partners, particularly

in Eastern Europe, which we do expect to recover in the second part of the year.

You do see Seloken after an increase in 2020 declined in 2021, now again stable, broadly in the first half of the year as is silodosin. And nice to see actually Livazo posting a strong growth on the back of growth in Russia, Portugal and Switzerland. And I think this growth again, reinforces the ability of the Group to stabilize and drive...sustain the sales of these products post loss of exclusivity.

You will see also a strong contribution to growth of Eligard, which we licensed at the beginning of 2021, which added close to €15 million of revenue in the first half of this year. Of course, as we've explained multiple times, a part of that is due to the gradual switch to direct selling over the first part of 2021, roughly €1 million of that account for roughly €1 million of the growth.

But as you will see, Eligard franchise is starting to return to growth, particularly in Spain, in France, and now starting to see a good signs also in Italy and in other markets. Sales of other corporate products, of course, grew very strongly, close to 19% and these really reflect the recovery of the Cough & Cold portfolio where revenue is pretty much back in line with levels that was achieved before the pandemic.

I hope to see strong growth of the gastrointestinal portfolio, CitraFleet, [indiscernible] Reagila and several of our key OTC products, and then particularly probiotics, Magnesio Supremo and the Hexa line. All of this, I would like to underline, achieved, whilst at the same time continuing to innovate our go-to-market approach and rightsizing in a targeted way some of our sales organization in SPC.

The drugs for rare diseases, of course, posted a very high growth, close to 44%, €260.4 million. Clearly, that includes the contribution of EUSA, which Rob has already spoken to, of €46.1 million. But nice to see both of our, let's say, legacy rare disease franchises both the Endo and the Metabolic are both continuing to grow. In the case of Endo, it's nice to see Signifor continuing to grow above 10% and revenue of Isturisa at €26.5 million, 2 times the sales that were achieved in the first half of 2021. They on track to deliver on the expectations that we had set for this product.

Switching to Slide 5, drugs for rare diseases now account for close to just under 30% of the revenue and of course will grow as we sort of fully consolidate for the full year, the revenue from EUSA. I'll again emphasize OTC growing by double-digit, in fact above 15% in the first 6 months.

On Slide 6, revenue by geography. And again, here, I will not go market by market. I know it's a very busy day for many of you on the call. I'll just call out...comment some of the, let's say, outliers in terms of growth rates. But first of all, nice to see most of our key geographies growing. Now, of course, this reflects, also the contribution of EUSA. Revenue in Italy growing by 6%, slightly below the average, with strong growth of Cough & Cold at OTC. And strong growth also of rare disease, which does however contribute a little bit less than for other markets in Italy are pending reimbursement discussions on Isturisa in particular.

US is clearly a key growth driver and now our #2 market with growth of 48.4%. Now, of course that benefits from a bit of tailwind on the US dollar, which accounts for roughly €10 million of growth and the contribution of EUSA which you will have worked out from Rob's slide at roughly € million to revenue. But beyond that, as we already

commented, strong growth in US of both the Endo franchise and the Metabolic portfolio, particularly Panhematin and Cystadrops.

I'll skip over to Turkey where you will see revenues are in euro terms is essentially flat versus last year with...reflecting the impact of very significant devaluation of the Turkish lira over the last 12 months. Revenue growth in local currency is up 68.4%, reflecting robust volume growth of the portfolio but also significant price increases that were awarded by the authorities and reflecting also the hyper-inflation environment that the country is facing. Russia and other CIS and Ukraine revenue of €50.3 million is up by 51% versus last year. This reflects actually a very strong growth of Russia of close to 65% in local currency.

Russia sales for the first 6 months were at €41 million. And revenue in Ukraine, at €6 million were just 6% down versus last year. Most of that, obviously achieved over the course of Q1 before the conflict. We still continue to see some sales from Ukraine, but very, very limited and we don't expect a significant contribution in the remainder of the year. We do also expect the demand in Russia to soften in the second half versus the strong levels, which clearly also reflect the destocking in the market in the first half of 2021 and the return to more normal levels of stock in the channel in the first 6 months of 2022.

And finally, the sales in North Africa are flat with still limitations of imports into Algeria, offsetting the growth of our Tunisia business, which is up 9% and other international sales, reflecting strong growth...strong additional contribution from both Isturisa and the rare disease portfolio, which offset the decline in lercanidipine, which I have already commented.



And you will see from the next slide that...and of course, the Group continues to have a very well-diversified footprint. The US is not only our #2 market but soon possibly will start to compete with Italy to become our #1 market for the Group.

And now then to the P&L, which on Slide 8, you will see reflects what we see, a very strong operating performance but also a number of one-offs and unusual items, some expected, some obviously not expected, in particular the FX losses, which I'll comment in more detail. As a result of the significant impacts on the reported results of the fair value adjustment arising from the consolidation under IFRS 3 as a business combination of EUSA, we did decide to add 2 additional disclosures to facilitate the read of year-on-year underlying performance of the business. And you'll see that clearly flagged there.

And let me start commenting the figures. Gross profit...we already commented on revenue. Obviously, growth of close to 16%. Gross profit of 70% of revenue is impacted by €16.9 million of unwind of the fair value adjustment to the inventory, which was acquired from EUSA obviously for the portion which was sold in the quarter. Adjusted gross profit which adjusts for this non-cash item at €641.5 million is a 13.6% increase versus last year. And the margin of 71.9%, you will see, is still a very strong level with the decline versus last year, really due to 2 effects.

#1, again, as you recall in the first half of last year, we were not yet selling in most of our markets as we are directly and that enhances gross margin by about just over 50 basis points. And margin in the first half of 2022 is impacted by roughly €5 million adjustment arising from the application of IAS 29 to our Turkish business which in April, met the criteria to be considered a hyperinflationary market. Barring these 2 effects, gross

profit margin...adjusted gross profit margin would be broadly in line with the levels achieved last year.

SG&A expenses, as you will see, exactly in line that with the first half of 2021 in terms of incidence on sales growth, obviously at 15.6% reflecting the addition of EUSA and additional investments behind our growth drivers, in part offset by again some of the initiatives that we've taken to innovate our business model and the SPC rightsizing. Selling expenses are 24.2% of revenue, and G&A at 5.7% of revenue in the first half of 2022.

R&D expenses at 11.1% of revenue, also growing versus last year clearly also reflect the consolidation of EUSA and continued progression of some of our pipeline programs. Half of the increase is driven by incremental amortization to the tune of €10 million, €6.2 million of which are driven by amortization related to EUSA.

Other income expenses reflect the non-recurring cost incurred for the acquisition of EUSA and the ones related to rightsizing of SPC. You'll recall that we had announced at the start of the year as part of our guidance that we're expecting €35 million for the full year, mostly coming from EUSA. Now clearly, a large share of that is incurred in quarter 2, just after the acquisition is closed. €15 million of the €26.2 million are driven by EUSA and €10 million from SPC.

Operating income which clearly is impacted by both the €16.9 million fair value adjustment to gross profit and the non-recurring cost, I've just commented, is at 26% of revenue. Adjusted operating income, which adjusted for these 2 effects, is at 30.9% of revenue and EBITDA, which is also adjusted for these items, is at 37.5% of revenue and growing by 11.5% versus last year, both of these remaining at strong levels. I would

highlight both operating income and EBITDA are impacted by about € million low operating impact of hyperinflation accounting in Turkey, which we do not adjust in these figures.

Clearly, the somewhat less expected impact in the P&L for the first half of the year was the one which is impacting on financial expenses, €38.1 million, an increase of around €33 million versus last year. Now, if we pick that, our actual increase in debt financing cost is only around €4 million in the first 6 months, really driven by the extra debt taken on for the EUSA acquisition. And that's very much in line with our expectation. Unfortunately, impacting on this number is €4 million of FX...and €4 million higher FX losses, driven by the ruble in the beginning of the year from the escalation of the conflict, we did take...we created a short...more short position on the ruble to create an economic hedge against the risks to the assets that we have in the market.

Now, of course as you know, the ruble went from just over €0 to the euro at the end of Q1 to around €6 at the end of Q2. And that's generated a significant part of those FX losses, and also triggered some consolidation adjustments for margin held in stock. The same is true to some extent of the US dollar, but the majority of these are really driven by the ruble. In addition to that, we've had a net €4.7 million monetary loss arising from the application of IAS 29 in Turkey, driven by mainly the revaluation of shareholder equities and the local affiliate.

So all in, on a net income basis, reported net income, you will see at €51.4 million, it's down 27% versus 2021, reflecting both of these one-off impacts in '22, but also the high non-recurring tax benefits that we had in the first half of 2021 of €6 million. And you see to help understand the bridge between net income and adjusted net income, we've added on Slide 9, a reconciliation, which you may be familiar with, that we've typically

shared this in our more detailed financial results. We thought it appropriate to already share that on this call given the stock, the magnitude of the FX.

And you see that net income of €151.4 million adjusted for the increasing amortization, the non-cash charges from the purchase price allocation to inventory, non-recurring cost and the net monetary gains and losses providing from application of the IAS 29, net of the FX effects lead to adjusted net income of close to €225 million, which is 7.1% increase versus last year. And you will notice, by the way, we're not adjusting for the FX losses which impact financial expenses as we've never adjusted for these. And as we also said, we do expect it to recover some of these in the remainder of the year. Hopefully that was clear, but obviously happy to take further questions.

On Slide 10, you will see EBITDA contribution of Rare Diseases is now roughly third of the total. And margins of both our franchises remaining stronger, clearly Rare Disease EBITDA 42.3% is below the levels achieved last year. As we said in this first year we expect EUSA EBITDA levels to be below the level of our legacy portfolio, but we do see EUSA achieving the levels of our...balance of our Rare Disease business over time.

On Slide 11, a summary of our cash flow statement. As Rob has highlighted, our free cash flow remains very strong, despite the non-recurring cost at €18.7 million, an increase of 14...just over 14% versus last year. And you'll recall last year was a strong year in terms of cash flow performance. You will see that free cash flow is almost at the level of adjusted net income, so a higher rate than it has been historically. Clearly, the bottom part of the cash flow statement reflects the acquisition of...the consideration paid for the acquisition of EUSA, net of the cash

acquired. And we have defined a new financing that was taken on to finance that acquisition.

And on Slide 12, in terms of net financial position, clearly from our perspective, continue to remain a very solid balance sheet with net debt of just over €1.4 billion, being slightly over 2.2 times the EBITDA or slightly below 2.2 times the pro forma for EUSA results for the full 12 months, should add in terms of that increase in loans as Rob has briefly commented, we are very happy with the terms of the financing we have achieved for the EUSA acquisition.

And now finally, from my side, switching over to Slide 13, and looking at the outlook and the projections for the remainder of the year. As we said, business momentum is strong and on the back of that, we expect overall revenue to be at the top-end of the guidance range that we set at the beginning of the year with slightly favorable FX in the second half, which should offset the slight headwind that we had in the first part.

We've been transparent about the assumption that we've used further ruble given the higher volatility, and expect our Specialty Primary Care business to grow low to mid-single-digit. Obviously grew high single-digit in the first half but we all know that the second half will provide a somewhat tougher comparable, and we do, as we said, expect somewhat softening of demand in Russia and the limited contribution from Ukraine in the second part of the year.

We do expect our legacy Rare Disease business to continue to grow at a sustained double-digit, albeit, we will start to see a little bit of an impact, as we said, from the start of the year from generic erosion on Carbaglu in the second half. We do expect that both of our key growth drivers, Eligard and Endo to achieve the objectives that we set. And as you will see, we

expect slightly higher contribution from EUSA, close to €130 million revenue for the 3 quarters that we are consolidating.

We expect EBITDA and adjusted net income around the middle of the guidance range, as we do expect, since targets were set a little bit higher inflationary pressure, particularly in the second half. And as I've commented, the impact of IAS 29, I do expect adjusted net income to be a little bit volatile because of the FX impact on financial expenses.

And to help with modeling, we have set out, on the bottom part of this slide, the assumptions we're making around both financial expenses, the non-cash charge, charges arising from the purchase price allocation of EUSA, and finally, the non-recurring cost of around €40 million with a slight acceleration of the rightsizing in SPC.

And with that, I'll turn over to Rob with some closing comments.

**ROB KOREMANS:** Thank you, Luigi. So, overall, very pleased with the performance of the business today. Yes, there are challenges but we continue to be able as Recordati has always done to address these and do a really good business. We confirm all our targets for 2022 with revenues at the top-end of the range as Luigi already commented.

The momentum is really good and I'm very confident for the outlook for the business and our ability to continue to drive. Yes, they're volatile times, but Recordati has been able to demonstrate also this year that we're able to deal with the challenges and the volatility and we have a very, very good solid base for our business that is really growing nicely, and we expect to continue to do so.

Thank you for your attention. This is the end of the presentation, and I'll open the floor to questions.

## Q&A

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

The first question is from Harry Sephton with Credit Suisse. Please go ahead.

HARRY SEPHTON: Great. Thank you very much for taking my question. I have 3, please. So firstly, could you please touch on the dynamics that you're seeing in the underlying Rare Disease portfolio? So excluding the Endo franchise and EUSA, it looks like it's growing around 5% year-on-year. Just wanted to understand some of the dynamics, whether there's anything dragging on growth there?

My second question is on EUSA. Clearly, it's progressing well. Would you say that the improved performance will follow through into 2023? Or are you comfortable with the previous guide that you gave of €150 million in sales? And then my third question is, well we rarely get an update on the pipeline. So I just wanted to ask on some of the assets you have there, specifically, the REC 0545 in maple syrup urine disease. What can we expect in terms of timing for that asset and any contribution? And then also your preparations for the nasal epinephrine spray with the expected decision from the EMA in the second half of this year? Many thanks.

ROB KOREMANS: Thanks, Harry. Happy to address some of the questions. As for the Rare Disease, the metabolic, say, the traditional franchise, as we have highlighted, we do see some generic impacts on 2 of our products there. We've seen for both products there, first generic entering the market already now, and we expect that for both of them, we will see additional generics coming into the market in the second half of the year.

The first generic hasn't really surprised us, quite frankly, the performance continues to be strong, but we believe it's a bit too early to now say this is also going to be the case for the second generic, right? So we have a very good position with our patients as close as you can get in all the legal frameworks and limitations there. And the business is holding on strong. And we're confident that we can continue to do well. But just to that extent, there will be most likely second generics coming in on the metabolic franchise.

For EUSA, we're absolutely happy with this business at the moment, its performing really well. Frankly, I do believe that the momentum is good, but it's a little too early to call out any guidance for next year. We now own this business for 3 months. I'd like to...we will give guidance definitely on that, as we've always done towards the end or beginning of next year. And we'll also take the time and the chance then to talk a little bit about some of the pipeline opportunities that we have with some of the current assets that are not in development but actually already on the market and we see additional indications as an opportunity for fairly affordable and nice opportunities there.

I acoustically couldn't quite get your...the other part of your question, quite frankly, because the line broke a little.



HARRY SEPHTON: Yes, sorry. So it was my third question, which was just around an update on the pipeline. So I think really, the assets I was looking at were REC 0545, which is your Rare Disease assets in maple urine syrup disease...sorry, maple syrup urine disease. And I just wanted to just get an update on the timing for that and any potential contribution for that? And then also your preparations ahead of the nasal epinephrine launch in the second half of this year?

ROB KOREMANS: Well, on net, we're progressing as planned. So the project is going according to plan. There's no...in that sense, no update to give, but then its good news. We're progressing as planned. The other, Luigi, do you mind?

LUIGI LA CORTE: Harry, I think on MSUD, we're on track with what we said in the past. I think we expect the filing at some point late this year, early next year. We've always said that it's a fairly small sort of patient population that we're looking at here. And I think your other question, if we've understood correctly, was around ARS, the epinephrine spray. We are addressing questions that we had from the European authorities, and we plan to...as you may have seen, we pulled the dossier and prefer to resubmit. We're collecting additional data that was requested and expect to do that in the second half of this year. And then we'll have to see the...when we get the final green light from EMA. Hopefully, that addresses your questions, Harry.

HARRY SEPHTON: Absolutely. And thanks very much, Luigi.

OPERATOR: The next question is from Keyur Parekh with Goldman Sachs. Please go ahead.

KEYUR PAREKH: Thank you for taking my questions. Two, please, if I may. The first one is you're talking about reducing 64 kind of full-time employees kind of from an SPC perspective. Just wondering if kind of how you guys are thinking about this kind of going forward? Is this kind of one and done? Or do you think this is the kind of restructuring and reshaping of the business that we should continue thinking about as we go forward?

And then separately, kind of from an FX perspective, apologies, Luigi, I know you spend a lot of time explaining this. But just trying to get my head around what kind of current levels of FX imply for your second half up and down the P&L? So obviously, on hyperinflation, you will get a benefit kind of on the top line, but should we continue to expect kind of levels of impact further down the P&L? And when does that reverse out? Thank you.

LUIGI LA CORTE: Hi, Keyur, I'll start with the second piece, if you like, on FX specifically at inflation, you're right. And hopefully, we called it out, hyperinflation added roughly € million to revenue in the first half of the year. Unfortunately, we hold at the moment thoroughly robust levels of inventory, let's put it like that in Turkey, which means that the revaluation effect on inventory is slightly higher and offset that so that at the gross profit and operating income level, the impact is around sort of € million.

Now that's offset is clearly in monetary gains and losses, which, however, are impacted by the revaluation of the balance sheet and particularly of shareholder equity, which more than offset that to the tune of...which result in a net € million that I spoke of. We're making some assumptions, obviously, around inflation in Turkey. And our estimates as we set out, is for that to impact to the tune of around €10 million in the...for the full year. I may comment that, but then I'll turn over back to Rob. I mean, the rightsizing in SPC will be a continuous improvement.

ROB KOREMANS: Yes, very much. Of course, I think you've seen the biggest...the rightsizing in terms of numbers of people in this year. And...but we will continue to improve our commercial not only footprint but also ability using more and more multi and omnichannel, and this has impacted. And then depending on whatever products we bring in additionally to launch, we might have to adapt to some extent, slightly our structures. And so we continue to evaluate the market, the environment, the commercial effort we need and the opportunities at hand. But it will be ongoing, but expect the biggest are behind us.

LUIGI LA CORTE: And then, Keyur, I guess we should say, whilst to some extent we are rightsizing, particularly in the sort of primary care lines. We're also in the Rare Disease side and the specialist line, we are evolving the organization. So it's not just a net minus.

KEYUR PAREKH: Thank you.

OPERATOR: As a reminder, if you wish to register for a question, please press “\*” and “1” on your telephone. Once again, if you wish to ask a question, please press “\*” and “1” on your telephone. The next question is from Bruno Permutti with Intesa Sanpaolo. Please go ahead.

BRUNO PERMUTTI: Hi, good afternoon. I have a few questions. The first one concerns the prices. So I was a little bit surprised that you succeeded in increasing prices and to offset inflation. So if you can give us some details on this. And on the size, more or less the size on average, which you had in the first half?

And the second point also on prices concerns the outlook. So what do you expect in the coming months? And do you expect any impact from events

for regulatory initiatives in the US? And the last one, it's regards the FX impact. If you can share with us your budget at US dollar foreign exchange and also if you made some guess on the Turkish lira.

LUIGI LA CORTE: Thank you for the questions, on price, particularly on pricing. Now, first of all, we didn't say that it's sort of necessarily fully offset. But I think historically, I've always...I've commented that barring major new losses of exclusivity or major events, the company has seen a sort of level of year-on-year price change of between plus/minus 1%. I think what we were able to do this year is go a little bit beyond that, I'd say if I exclude Turkey, because Turkey is a little bit of an outlier and obviously hyperinflationary environment on the cost side as well.

We are probably somewhere between plus 1% and plus 1.5%. So it's obviously positive. And on our P&L, that helps given the structure. And on FX, we've never really given...we typically budget on the basis of consensus in January. We don't typically set out or publish budget FX assumptions. We've now shared our assumptions, the planning assumptions for the ruble because the very high volatility that, that currency has had and the impact that it's had on FX losses. Hope that makes sense.

ROB KOREMANS: Yes. On the question on the, say, expected regulatory impact, frankly, in the US for our Rare Disease business, we do not see any impact coming from any of the measures in the coming periods. And of course, there are always discussions in Europe on what can governments do to help them manage all of the health care expenditures. But I don't think that they get specifically for our business any more strict or restrictive than what we've seen so far. So far for...but it's a bit of crystal ball, frankly. And so far what we've seen is very clear from the US, we don't expect any real impact.

BRUNO PERMUTTI: Thank you.

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

GIORGIO TAVOLINI: Hi, good evening. And thanks for taking my questions. I was wondering if you can elaborate more on the 40% increase of Eligard in the first half, what is driving this performance. And the second one is on the bridge of the organic growth since I'm struggling to reconcile the 8.6% organic growth starting from the reported €15.8 million. If I strip out 6 percentage points for M&A, I mean, in EUSA €46 million, basically, and also the FX, I don't get the 8.6%. So I was wondering if you can double check the numbers. And also for the second quarter, what is the corresponding organic growth?

And the third question is on the impact on some inflation, in the first quarter presentation, you talked about 50 basis points on top of the other 50 basis points that you already anticipated, so roughly 1 percentage point impact from inflation. I was wondering if it's still valid, that this indication or not? Thank you.

LUIGI LA CORTE: Giorgio, I thank you for the question. Yes, of course, we have double checked the figures. And I think actually, the answer to your first and second question are related in the sense that I think the piece which you're missing in your reconciliation is, when I commented Eligard revenue, I mentioned that roughly 11...so the €1 million, €2 million of the growth is actually a function of the fact that in the first half of 2021, we did not yet, in many of our markets have direct selling. So basically, we booked in revenue just the gross margin that was transferred to us by Astellas.

And I think we're being here extremely transparent and honest in stripping that out from our reported growth. And I think if you sort of add that to your numbers, you should come to the same figure that we come to because those are the things that we're stripping out basically, EUSA, Eligard and the minor FX erosion.

In terms of...and again, the Eligard growth of 40%, as I said, for a big chunk is due to the difference in sort of selling models in the 2 halves. But obviously, we are starting to see growth in...as I commented in a number of markets on a product that was declining when we took it on, particularly good growth in France, Spain, but also Portugal, Turkey and Italy.

With regards to inflation, our view on that has not changed. As we said, though, we're not just going to sort of lie down and take the impact on the chin, but we have been doing what we can in terms of our pricing and maybe to fully address the previous question, we've taken pricing up on our OTC portfolio across the region, where we can and where we have more flexibility in some of the Central and East European markets, including Russia, we are taken pricing up. We regularly take single-digit price increases in the US on the portfolio as most other companies do. So all that is...that together with some of the measures we've talked about in terms of rightsizing are helping offset those headwinds. We will reiterate what we said in the past. We're not immune from inflation and everyone sees the spike that we've had over the last 6 months. Hopefully, that answers your questions, Giorgio.

GIORGIO TAVOLINI: Yes, very clear. Thank you, Luigi.

OPERATOR: Once again, if you wish to ask a question, please press “\*” and “1” on your telephone. Ms. De Medici, there are no more questions registered at this time. I turn the conference back to you for the closing remarks.

FEDERICA DE MEDICI: Okay. Thank you very much for joining this call, and we wish all of you a very pleasant day. Robert....

ROB KOREMANS: Yes, thank you all for joining. For those who will have time to go on a summer break, wish for a great break and speak soon. Thank you all.

FEDERICA DE MEDICI: Thank you.