Recordati S.p.A

"First Quarter, 2023 Results Conference Call"

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

FEDERICA DE MEDICI: Thank you, George [ph]**.** 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 who will be presenting the 2023 first quarter results. They will be running you through the presentation. As usual, the set of slides is available on our website in the Investor section. After that, we will open up for Q&A.

Please, I now leave the floor to Rob. Please go ahead.

ROBERT KOREMANS: Thank you, Federica. And good afternoon ladies and gentlemen. Welcome on our call. This year's first quarter confirms Recordati's ability to consistently deliver outstanding performance and showed excellence throughout the year. And with revenues at €551.4 million, up 31.5% versus previous year, or 21% on a like-for-like at constant exchange rate with strong underlying moment across both business units and across all key markets.

I'm extremely encourage by the group performance. SPC double-digit ahead of the relevant markets, thanks to continuous improvement in competitiveness, and I am also extremely happy with Endo's growth of 44.7% on a year-to-year basis, and a really successful Onco franchise integration, but that business showed 24.2% growth on a year-on-year pro forma basis.

In the first quarter we also benefited from strong metabolic performance which was resilient and so far very low and slow penetration of the generics in the first quarter. It is really worth highlighting some phasing, some real one offs and some seasonal shifts, but we are still able and very happy to upgrade our full year guidance.

The strong underlying revenue performance, enhanced by the general movements in Turkey and Russia and phasing of shipments to international distributors, with total Q1 benefit of roughly €15 million to €20 million the largest part of which was in our SPC unit.

What was also quite exceptional in Q1 was a strong Cough & Cold the season…the flu season was very strong, and we were able to benefit from that in most of our markets. And also in Turkey we've seen throughout the year and again also at the beginning of Q1 notable price increases as a reaction to the constant evaluation and pricing that we see in Turkey.

The high volume also gave us a high operating leverage, and this allowed us to really deliver strong operating and bottom line results, with an EBITDA of €220.8 million, operating margins benefit from fixed cost, absorption level in COGS and a gradual ramp up of the R&D spend related to also gradual ramp up of R&D activities very much in line with our plan.

Adjusted net income of €155 million, were up 33.3% versus previous year, driven by the positive operating performance partially offset by higher financial expenses, due to higher net debt and increased interest rates.

Our net debt of €1,339.6 million [technical difficulty] were leveraged at 1.8 times of EBITDA, with strong free cash flow of €103.4 million, absorbing working capital increase which was in inventories and receivables from high business growth.

Also we are very happy with the key R&D pipeline projects progressing to plan and Luigi will explain on that a little bit more. And we are very happy to raise our full year targets for 2023 which are now expected to exceed top end of the guidance range that we set in February, both on revenue and on bottom line.

And with that, I am handing over to Luigi.

LUIGI LA CORTE: Thank you Rob, and good morning, good afternoon everyone. I'm always happy to provide more colour on our financial performance, and even more so on days like this when the performance of Q1 was so strong.

As usual, I will start by providing a little bit more perspective on our revenue growth drivers. I would do it by giving a little bit more color on the core therapeutic areas of each of our 2 business units, which I think is hopefully more helpful way to go through the numbers. You will find our usual disclosure on key corporate products in appendix.

But starting with Specialty and Primary Care on Slide 3, you will see that SPC was really a key contributor to growth in the first quarter, with all our therapeutic areas growing at double-digit and with growth really broad based, you know driven both by our corporate and local products, both our [indiscernible] clearly supported by strong underlying market growth, but fair to say we grew ahead of competition benefitted as Rob has said also some phasing benefits and obviously had the impact various high price increases achieved in Turkey over the course of the last 12 months, and the really exceptional Cough & Cold season and I will try and pick those effects as I go along.

You will see a strong growth of our core legacy cardiovascular franchise, which is still a biggest franchise in SPC, growing by 12.6% driven by lercanidipine franchise which benefited to the tune of around 6 million from a timing of shipments to some of our international partners, but grew in most of our direct market as well in particularly in the…in UK, and we had broadly stable sales on metoprolol and pitavastatin and a little bit of erosion in some of our local cardiovascular portfolio and saw the little bit the effect of the tenders in Germany.

Urology franchise grew by 29% led obviously by continued, strong performance of Eligard that not only grew, but gained market share in a number of our markets, and that's ahead of the roll out of the new device. So obviously strong performance there, robust sales of silodosin and also some of our key local brands, Tergynan in Russia, Mictonorm in Turkey and initial contribution from [indiscernible] in Italy of 0.8 million.

GI and also the non-sale of other therapeutic areas grew by over 10%, driven by products like Procto-Glyvenol, our probiotics franchise Magnesio Supremo in Italy just to name a few, once again across both our Rx and OTC products, but really the standout obviously here on the page is Cough & Cold with growth of close to 67% year-on-year. And we've seen we have guided on Slide 4 a little bit more perspective on the evolution of Cough & Cold that has been such a big driver of fluctuations over the last year.

And you will see that and the chart compares quarterly revenues of '22 and now Q1 '23 to pre-pandemic levels, so 2019, and you will see from the blue bar that Q1 last year was still quite a bit below pre-pandemic levels, but started recovering and progressively grew ahead of 2019, over the course of Q3 and Q4. Q1 this year was clearly an exceptionally strong season, well above pre-pandemic levels.

Once again, this was in the back of and you will have heard this from other companies as well, a very strong underlying market, which we were able to respond to and benefited from it. There was also a little bit of effect here from restocking on Russia on the back of strong sell-out in the market at the end of last year, all of which contributed to a really standout quarter for Cough & Cold. We don't expect these kind of rates to be sustainable and in fact, we expect the remainder of the year to be closer to the levels achieved in Q2, Q4 of last year, as some of those phasing benefits unwind. And factoring in also headwinds, which we expect based on consensus on the ruble.

Turning over to rare disease, on Slide 5. Rob has already called it out. All of our key franchises and future growth drivers are absolutely tracking in line with the targets that we had set. In endocrinology, we continue to see a strong uptake of Isturisa both in the U.S. and in EU, particularly in those markets where we recently achieved reimbursement, but also continuing to enjoy double-digit growth of Signifor. Isturisa was up over 70% in the quarter Signifor by just over 20%.

We also had a very strong start of the year on the Oncology franchise with Qarziba growing outside of Europe mostly and Sylvant really growing across geographies. And as Rob has commented, metabolic performance was also very resilient and ahead of expectations, thanks to the continued growth of Panhematin and Cystadrops, particularly in the U.S., but also in particular, thanks to more gradual erosion from recent generic entries in U.S., which we have, however, started to see impacting in Q2.

And finally on the rare disease, to note, we are continuing to progress on the various opportunities, which we talked about in Feb. I'll call out the work that we're doing to prepare for developing Signifor a new indication, PBH. We've had positive feedback from the FDA on our proposed development plan and are on-track to start that off in Q3.

And of course, look forward to providing more update on that and the other programs over the course of this year.

On Slide 6, you will see our usual chart with revenue by geography. You know, in brief terms, growth was solid across all of the areas, clearly reflecting the strong performance of the 2 business units and the addition of EUSA. I'll focus let maybe on the outliers, which really showed exceptional growth, and that are the key ones behind €15 million to €20 million benefits of one-offs and phasing that we've called out.

First one on the chart is Turkey, which you will see as in local currency terms more than trouble sales versus Q1 of 2022, and that's really down to 2 things. One very significant level of price increases that were both awarded by the authorities to the sector, but also achieved by our team in Turkey on some of our key products which drive a significant portion of the growth.

We do see continued good underlying volume growth in Turkey as well, but in this case in Q1, this has also been distorted by the phasing. In fact, the timing of those price increases, as you can expect when they happen, there's always a little bit of tug of war with the wholesalers around quantities shipped, I think that probably led to a somewhat soft Q1 2022, and now a somewhat strong Q1 of 2023 in Turkey, the pricing clearly has more than offset the devaluation in this period of the Turkish lira. But don't forget that under hyperinflation, what will count in the end will be the exchange rate at the end of the year.

Russia, and other CIS and Ukraine obviously also growing significantly by 87.3%, that benefits from around €5 million of FX. Particularly in Russia, you recall last year the ruble moved a little bit widely over the course of the year. The growth, they are driven by the strength obviously of the Cough & Cold portfolio, and also in Russia some of the pricing actions that were taken over the course of 2022. We are starting to see in Russia a bit of softening of volume growth in the market as a result of the impact of the economic sanctions.

And finally other international sales are also posting a strong growth of 48%, driven by around the €6 million benefit, which I've already mentioned phasing of shipments of lercanidipine in particular to our international customers, and the addition of the oncology portfolio, which in the international markets was particularly relevant, and which is also behind a large part of the growth, which we're seeing in other Western European markets.

And finally on this slide, the only other thing I'll highlight is obviously the continued strong growth in U.S. behind the rare disease franchise, with U.S., now accounting for just over 14% of revenue and getting very close to becoming our #1 market.

Turning to the P&L on Slide 7, hopefully you are as delighted as me to see that the strong revenue performance is flowing through nicely to the bottom line. Margins obviously reflect both the effect of the higher revenue and hence operating leverage. But also you will see a strong and very resilient gross profit margin, which on an adjusted basis, adjusting for the unwind of the EUSA fair value step up of inventory, is holding up very closely in line with last year. We are seeing the impact of inflation, but so far we've proven able to offset that through the mix of things that we said we would do last year, a bit of the pricing, obviously the high volumes also help absorb the fixed cost base of our manufacturing sites, and we do have a benefit from a good mix this quarter as well.

SG&A expenses at €150.4 million are very much in line, in terms of run rate with where we were post the EUSA integration starting Q2 of last year reflecting the benefit of some of the efficiency initiatives, which we kicked off and announced already last year, namely the SPC right-sizing the synergies, we're extracting from the user integration. Within that, selling costs are around 21.8% and G&A costs around 5.5%.

R&D expenses at €60.5 million, 38.4% increase, are a step up versus last year, of course, as expected, obviously reflecting the integration of EUSA, an additional roughly €8 million incremental amortization, but also the gradual step up of activities that we planned over the course of this year and which we expect will gradually increase as we progress our key development programs.

And the one negative line on the P&L, I think Rob called it out, of course, no surprises there. Financial expenses ahead of last year at €12.6 million. There's a €1.5 million benefit in there from FX and the benefit of net monetary gains from IES 29 [ph]. We will see financial expenses step up further in the remainder of the year as variable rate loans reset on the back of…as you all have seen, reference rates which continue creeping up.

But all that consider leads to very strong margins, EBITDA of 40% for the quarter, adjusted net income of 28% with high margins across both business units and both growing by over 30%. And that translates also in continued solid cash flow generation for the group on Slide 8. Cash flow…free cash flow of €103.4 million clearly reflects the strong EBITDA, but also, on the other hand, the increase in working capital purely driven by the increase in the volume of the business.

In fact, inventory days decreased nicely since the end of December to mitigate a little bit the impact. Always tricky on a quarter-by-quarter basis to call this one, but I do not expect you know, very substantial further increases in the remainder of the year. And the cash flow combined with our operating performance, and to finish off on my side, leads, as you have seen on Slide 9, to us showing still a very solid balance sheet with leverage at just over 1.8 times last 12 month EBITDA and very much in line with our planning guidance.

And with that, I'll hand over back to Rob to provide the perspective on our full-year outlook. Rob?

ROBERT KOREMANS: Thank you, Luigi. And as you can see on Slide 10, we are increasing now on the back of our really good first quarter, the excellent performance that we're achieving and the view that we have for full year 2023. We do expect to achieve the top end of both the top and the bottom line guidance that we gave earlier.

Revenue expected to be between €2.50 billion and €2.90 billion with top-line outlook for SPC to deliver mid-single-digit growth and our Rare Disease business expect to continue to deliver double-digit revenue growth. So, very, very good revenue development going forward.

EBITDA above the original range set in February, now between €750 million and €770 million. And the margins that also Luigi already alluded to, where we set them originally around plus or minus 36%, we now see them creeping closer to the 37%. We expect lower quarterly revenue run rate, increased inflation that will creep through on our COGS and the step-up in R&D activities that was planned and we're executing on, will also have a slight increase in the expenses.

And then, Quarter 4 historically has always been the lower quarter and I don't expect this to change in this year. And despite the fact that we see a financial expenses step-up as we alluded to before, we are now also raising the target for the…an upgrade through the adjusted net income target for between €490 million and €500 million. Momentum being really, really good, and I'm very confident for the outlook for our business and the ability for us to continue to deliver and to continue to thrive.

And with that, I would like to hand over to you and allow for questions.

Q&A

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 comes from Isacco Brambilla from Mediobanca. Please go ahead, sir.

ISACCO BRAMBILLA: Hi, good afternoon everybody. 3 questions from my side. The first one is on Eligard. Could you please confirm if there is anything, say, non-recurring supporting first quarter performance or if we should expect these days of growth even for the rest of the year?

Second question is on R&D. You mentioned some sort of phasing in spending. Could you please give us some color on the incidence on sales of R&D embedded in your guidance for this year?

Last question is on external growth with such a strong organic momentum this year, should we expect plans in terms of external growth to be set aside in the coming quarters? Thanks.

ROBERT KOREMANS: Sorry. Acoustically, the third question was very difficult for us to hear. Could you repeat the third question, Isacco?

ISACCO BRAMBILLA: Yes, last question is on your M&A strategy. Since you are experiencing a very strong momentum on an organic basis, should we expect some sort of delay in terms of urgency of your external growth in the coming quarters?

ROBERT KOREMANS: Thanks for the question. So let me maybe address the last question and the R&D question and hand to Luigi to address the first question. Our strategy on M&A hasn't changed. We will take the opportunities. We have a very clear defined strategy on the sort of targets we are looking at, both in terms of partnering and acquisitions. With the user and fully integrated and that work being done, we are really happy and able. And as you said, we are generating good performance out of our business. That enables us to really do the deals we want to do. And this is absolutely on our agenda. And this is actively being pursued. So that hasn't changed both the SPC and the Rare Disease business, as is our strategy.

What you see on the R&D is a step up. I think the 2 programs that I would like…and this was planned, one is the continued development on REC 0559 where we are in Phase II and enrolment is going really well. We expect to be able to finish and report results on that in line with our plan, but that also comes with increasing cost and the same is true for the plans studies that we now have aligned with the FDA on the so-called PBH indication, which we believe is very important and we shared with you when we did three-year outlook. And that is also fully in line with plan. So, all the things that we were planning to do are actually happening.

And with that come the cost, and we were strongly focused on our business portfolio where we have the opportunities to expand the indications. So there's no risk, fairly affordable, but it will creep up slowly and as we indicated before, we're talking about in total a year-end throughout the period not even 1% increase in R&D expenses. So it's quite moderate. And notwithstanding that, we're very able and confident to be able to keep our margins in fact even increase the guidance for this year.

ROBERT KOREMANS: Yes and I know Isacco, to your first question, short answer is no. There's no real one-off effects on any Eligard that as you know, I always caution people to taking a single quarter and extrapolating. Just to be absolutely clear for everyone on the call, where we saw the one-off was really in three areas, one on lercanidipine, two in Turkey driven by sort of different timing across the years of price increases and your channel dynamics that drive, and three in Russia. And you know, you can assume that €15 million to €20 million to be split pretty much equally across those three. And in Russia, it was mostly on the Cough & Cold portfolio. So I hope…hopefully that addresses your question and helps unpick those numbers.

ISACCO BRAMBILLA: Yeah. Many thanks.

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

MARTINO DE AMBROGGI: Thank you. Good afternoon and good morning, everybody. I'm focusing on the guidance. Because if I look at the change at midpoint, you're implicit incremental EBITDA is 70 plus percent. So I understand during your speech, you mentioned there is a higher absorption of fixed costs. But could you elaborate on what else had such an important impact on profitability for your changing guidance? This is my first question.

LUIGI LA CORTE: Martino hi, Luigi here. I'm not I'm not sure I captured the percentage that you quoted in terms of…I think I thought I heard you say 70, but I don't recognize the figure…

MARTINO DE AMBROGGI: It's at 60 plus, the change in…at the midpoint EBITDA from current…from previous to current guidance midpoint and compared to the change in sales always midpoint. So in any case, it's much higher than the 37% that you performed in Q1?

LUIGI LA CORTE: Yeah, so just to be clear, in terms of…the drivers of the over performance, the sort of the drivers of upgrade to the guidance are essentially really two. ≠1, it's revenue growth and operating leverage that comes from that and I mean of course, within that we've built an assumption of potentially some of those the benefits that we had in Q1 are sticking for the year and some unwinding. And then on the margin, slightly you know we were able to offset inflation in the first quarter, we won't be able to do that for the full of the year. But we did have a better **___ 31:00*** in Q1 that we would seek to repay. So far, apologies, maybe I'll see if I can sort of reconcile the numbers that you're quoting and come back, if you need more on this specific question, but the drivers of the upgrade are those.

MARTINO DE AMBROGGI: Okay, that my figure was very, very rough. The second question is still on the guidance, because if I look at full year '25 guidance, you are just at the midpoint of the EBITDA you are just the 6% below the low end of the guidance. So I perfectly know you will not discuss '25. But it's too early for sure. But is there any reason why you shouldn't state that are easily achievable or maybe potentially could be revised upwards, because it seems to be that the non-recurring event are not justifying the big portion of the upward revision this year?

ROBERT KOREMANS: Martino, you're absolutely right, we will not discuss '25. Right, that's really…so that's **___32:15*** so that's…the business is doing well, we're happy we have increased our '23 guidance, we're confident that we're doing not only in terms of financial performance, but also in preparing our company for the future, the right things like the R&D investments, like the commercial excellence, all those things that we're not going to discuss or change or…for that matter now the outlook for next year or the year thereafter. And there will be…we will definitely do this at some point in time. But I think at the moment for us it suffices to really stick to '23.

MARTINO DE AMBROGGI: Okay, and the last question on EUSA because you're guided €185 million, €200 million. I was wondering if you confirm this or probably considering the trend in Q1, it could be even higher and I don't know if you can share with us the contribution of profitability from EUSA?

ROBERT KOREMANS: Yeah, so in line with what we just had on looking forward, we just confirmed so far everything, by not explicitly mentioning it, I think we confirmed these things. And this is what we now call our oncology franchise in rare disease is really performing extremely well. We're happy with it. We're a little ahead of the plan that we had when we announced the deal and we continue to do better, but I would like to leave it at that.

LUIGI LA CORTE: And Martino that applies also to Endo, both of those franchises as I said, we're tracking in line with the guidance that we provided early in the year to be changing that. I think you were comparing that, as I understand now, correctly, you're comparing the €70 million imply the increase in the mid of the range and revenue to the €45 million on EBITDA. And of course, the difference between the two is the operating leverage, the €70 million comes at a gross margin, which is much higher than the average EBITDA margin. And you know that with our initial guidance was a margin of plus or minus 36. And as Robert said, we now see it moving closer to 37. So that's… so that's why you see that higher, let's say, relative upgrade on the EBITDA level, hopefully that makes sense.

MARTINO DE AMBROGGI: Yes, makes sense. Thank you.

OPERATOR: The next question comes from Jo Walton from Credit Suisse. Please go ahead.

JO WALTON: Thank you. A few questions, please. Just to start with, can you tell us what impacted foreign exchange you are including in your guidance, presumably, at the net level for the year not very significant? My second question is just a clarification, you've changed some of the way that you give us detail, it's nice and simple in big chunks, you're going to be able to do that, is that how we should be thinking of modelling going forward in terms of cardiovascular, urology et cetera or is it just a one-off illustration?

And then my main…I'm associated with that, in terms of Cough & Cold, how much of that is prescription and how much of that is OTC because at the moment, we model those 2 separately. And then my main question is, if I could please, just thinking about a couple of products you've got…you talk about your Qarziba, your Type C meeting with the FDA and the outcome of that in 3Q. Just…are there any issues the FDA has brought up, anything we should be aware of. I think we will assume that that's going to be fairly, I mean, a simple move forward. And you talk also about Carbaglu, getting ready for potential launch in China. Would you try and do that yourself? Is that with a partners, just a little bit is your broader geographic ambitions whether you would like to have more of a foot print in some of these other markets? Many thanks.

ROBERT KOREMANS: Okay. So maybe Luigi, you want to answer the first couple of questions.

LUIGI LA CORTE: Yes, happy to do that. In terms of FX, we've modeled as usual what's suggested also by consensus. It was fairly benign this first part of the year, but you know, ruble has moved against us and as has the Turkish lira has continued to creep up. I didn't check. By the way, we are announcing these results today on the day of the elections in Turkey. So we are going to…we are seeing at the moment FX for the full year close to around 2% in terms of [indiscernible] more closer to minus 2 than minus 1 for sure. Q1 to-date was very small because if you recall, ruble has its very funny movement beginning of last year.

For modeling purposes, Jo, to ensure that you had all the details, we did keep in the back. You will find all of the details that we've disclosed in the past on corporate products, local products, OTC. I don't believe, we ever gave a split of Cough & Cold between Rx OTC, but we can come back to you on that. And so you have all the details there. We believe, and it's a little bit in line with where we presented the plan that looking at the smart category, this is probably very well looking at the business, corporate products, you know, only was really pleasing to SPC and some of them are probably going to be flatter there about for the coming years but we have given visibility on both.

ROBERT KOREMANS: And maybe Jo, on the Type C meeting plan for Q3 this year on Qarziba with the FDA as you all know, these meetings are never walk in the back. You have to really prepare for the best possible outcome [indiscernible]. The confidence that we have to be really well prepared. It's not given that this will just automatically follow. But we are well on track and happy with where we are and that hasn't changed.

On Carbaglu in China, we do plan to do that ourselves. In the past, we've worked with the distributor for lercanidipine. We've also had a partners in our Onco business for China and we are very happy with that because we've really believed that's super-confident partner in the oncology space. But in endocrinology and metabolic, we want to build our own presence and we are doing that gradually during this year to be able to launch early next year which is in the plan. And so far everything is in line with that plan.

JO WALTON: And can I just follow up please with a broader question. Is part of the reason that you are able to have a small upgrade in sales. The fact that the market environment has just been a bit more benign. I know in the UK, we had some nasty rebate on things but that's not the market that you are particularly involved with. Would it be fair to say that in general pharma market, particularly in the countries that you are operating, you know, we have not seen any extra authority measures and things are relatively benign and you are just a little bit more confident about things or is it something whereby you have outperformed the market more.

ROBERT KOREMANS: It's more than that really Jo. We have outperformed the market in just about every of the markets where we compete. The pack of the…portfolio that we do not promote, obviously, benefit from a good market. That's right, but all the areas where we do promote and all our focused products are outperforming the markets without exception. So it's a bit of combination of both. And of course, thing like the Cough & Cold season is not something you can ever predict, and as Luigi shared, this one was exceptionally good so that's not something we wanted to budget for or share with you before the year starts as a target, and we've benefitted from that. But you also have to able to benefit from it, right. We've seen that some of our competitors that they were not able to react fast and deliver and we've been able to really do that and very confident that our organization will continue to do…make use of opportunities as they come. But what makes me very optimistic and confident is the fact that we are outperforming the markets and that has increased our competitiveness with a much more focused and smaller team. We have significantly improved through commercial exercises and we are doing really well on that.

And then if you look…and that is mostly on the SPC side where we've done that exercise. If I look what we've done in the U.S., we've really a fantastic momentum, which is a really important markets going forward as you well know for Rare Disease. The key market I would say and the way that our Endo franchise…our Onco franchise and in fact even our metabolic franchise has held up or are growing that is very encouraging. So that's also part of the reason why we are able to increase the guidance for this year. These are things that we will continue or expect to continue and make us very happy and confident.

LUIGI LA CORTE: Maybe |Jo, if I can add to some of your this questioning earlier one. We are not immune from the fact that also others are seeing. In Germany, we called out already this quarter, and I am sure we will continue to see for the remainder of the year pressure from tenders in France. We have seen you know, increase in drawbacks. They don't impact us very materially in France, but what they do, you know, we have seen people most concerned as you said UK, MedTech in Italy but you know, we don't…we are not expose to those.

Finally, on the way of looking at the business and the number, you recall on SPC. We went through the plan with Alberto, Martin went through the plan. We spoke of the 3 therapeutic areas, you know, oncology, urology and GI as really being our core and that's how we look at the business and how we drive it. We think a little bit less in terms of corporate product versus local. So that's why we've decided to sort of present and hopefully provide a bit more color in the way we have just done.

JO WALTON: Thank you.

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

NICCOLÒ STORER: Good afternoon. Thanks for taking my questions. The first one is just a clarification. Is it right to say that the increase in your guidance has come entirely from, Specialty Primary Care with target set out during business presentation for Rare Disease business broadly unchanged?

The second question is on gross margin. Luigi as you highlighted before, net of inventory uplift, we are flat year-on-year so my question here is why should we expect this to worse and over the coming quarters if we have to?

And last question is on the evolution of Lercanidipine and Silodosin. I think that also if we take out the pre-buying effect on Lercanidipine you mentioned the performance of the 2 Zanidip and Zanipress was not the less very strong. Urorec was very strong. So maybe if you can give…shed more light on why that? Thank you.

ROBERT KOREMANS: Okay, thanks for the question Niccolò. To answer your first question, the increase in guidance is on the back of both businesses, Rare Disease and Specialty, Primary Care performing really well in terms of market shares, in terms of everything, and it makes us confident to increase the guidance for both, like I just said also in answering Jo's question, if I look at our Rare Disease performance, for instance in the U.S, but also in Latin America, in Asia and across the board, it's really doing extremely well. And that allows us to increase the guidance.

Maybe Luigi you want to take the question more on the margin remainder of the year.

LUIGI LA CORTE: Yes, sure. And then, no thanks…it's an obvious question Niccolò on gross margin. So gross margin in Q1, as I said, is benefiting from a number of things that are helping offset inflation impact, which we are seeing, and we'll continue to see. #1, we have the benefit of pricing we took particularly last year, if you take Turkey aside, there's a little bit of an outlier. Remember, I said last year, over the course of the year, we took a bit more pricing that we've done historically, so far this year, excluding Turkey, we're only marginally positive, so we're taking some price action, but we also see the impact of erosion in Germany, so that it's like that pricing benefit and offset to inflation will become a little bit lower. Another source of benefit in Q1, is the fact that we had extremely high volumes, and you'll recall 60% of our products are manufactured internally, we have, you know, that comes with a portion of costs, which are fixed, which in Q1, you know, we're absorbed and amortize over great volume. So that provides a benefit. If you recall, we also said that in the plan presentation that we benefited last year and would benefit in the first half of 2023 still from some of the hedges and energy cost, which were taken out in 2020.

Now energy costs have been coming down versus the peak they achieved, but still, they're higher than, you know, certainly was…**s**ignificantly higher than where they were in 2020. These things do take a little bit of time to then creep through inventory. But, you know, we do still expect what we said at the start of the year to hold true. And that is that we expect to see, you know, gross margin for this year below the level of 2022, and however, that impacts to a large extent offset by the operating leverage benefit from higher sales on SG&A and the benefit obviously, of the higher efficiency initiative that we have been taking.

Okay, hopefully Niccolò that addresses your question that really?

NICCOLÒ STORER: Yes.

ROBERT KOREMANS: Yes. And then maybe the last on the base products like lercanidipine that has benefitted the sales in Q1 more higher in the international division, where we export, for instance, to Russia or to China, and there was a very good benefit. In general for these products like we have indicated we are really seeing good stabilization with well after the loss of exclusivity for these products. There is a low single-digit volume growth that is basically on the back of the increased prevalence and incidence and number of cases that require treatment for diseases like hypertension, which is what we expected. And we're able to really hold our shares there really well. So going forward, we expect this to stabilize or continue to stabilize and allow for growth through the products that really drive our growth, which are not in this…which are not lercanidipine and products like that.

LUIGI LA CORTE: And maybe I just add silodosin, Niccolò I think, you know #1, this is one of the products were actually in Turkey. Our colleagues were able to negotiate a level of our pricing over and above you know, what we generally awarded to the market and that was on the back of, also the fact that we sourced the cost of goods in [indiscernible] and also on the authority there's a bit of background noise someone is not…doesn't have [multiple speakers].

NICCOLÒ STORER: Let me put in mute.

LUIGI LA CORTE: No, and also, I'd say, you know, there is a little bit of a positive halo effect when you're out in Urology with a field force excited by the positive performance on Eligard, you know, obviously you see a little bit of benefit on the other products in that same franchise, that those same reps promote, which again, why we think looking at things by category, you know, it makes… makes sense from our point of view.

NICCOLÒ STORER: Thank you.

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

CHARLES PITMAN: Hi, thanks very much for taking my questions. Sorry, there's a bit of background noise here as well, and if my questions repeat. And the thing I joined conference a little late. But my questions relate to, first just on M&A and kind of your intentions for debt or good, free cash flow, you like paying it down to a kind of 1.8 times now, I'm just wondering if you could give us an update on kind of how you're thinking about covenants, and maybe what levels you want to bring that leverage down to before you thought about the kind of M&A in kind of more holistic sense?

And maybe just one a little bit more kind of theoretical obviously we recently saw the EU proposals for reform that highlighted that companies that needed to launch their products in all markets, given you have very good geographic reach, I was wondering if there's any implications for Recordati into the longer term as a result of those proposals? Thanks very much.

ROBERT KOREMANS: Thanks Charles. Let's start with the latter, now we don't really see a good…an implication of the…of these reforms. Of course, we monitor this carefully and like you said, we have a really good coverage of all of our European markets and not that sort of as far as we can judge. Now, this is not going to be something that is going to impact us too much.

As to M&A, our strategy hasn't changed, neither has our willingness to take on rest. We have, the government hasn't changed either. So we keep with…at the moment we are at 1.8 and that is something that we are quite happy with, but of course we aim to bring that down to the right deals will go up and we'll go for the best deals in the… in class as high as 3 and that's it, nothing change.

LUIGI LA CORTE: We're not working to that specific sort of target leverage before we would do a deal, we really also depend on the opportunities**.** We are [indiscernible] the place right now is within the guidance that we said and we look at opportunities all the time, as we have always said.

CHARLES PITMAN: Thank you.

ROBERT KOREMANS: Welcome.

OPERATOR: As a reminder, if you wish to register for a question, please press "*" and "1" on your telephone.

ROBERT KOREMANS: I think, if there are no more questions and everyone having full agendas. Thank you for joining. We were very happy to share this, what we believe very good base for the remainder of the year, very happy with the results, very happy with what my colleagues are delivering all over the world, and confidence about the future and our ability to continue to deliver. So thank you for joining us today and looking forward to interact with you and keep you updated. Bye.