Recordati S.p.A.

"2022 First Nine Months Results Call"

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MODERATORS: ROBERT KOREMANS, CHIEF EXECUTIVE OFFICER
LUIGI LA CORTE, CHIEF FINANCIAL OFFICER
FEDERICA DE MEDICI, INVESTOR RELATIONS & 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 & Corporate Communications. Please go ahead.

FEDERICA DE MEDICI: Thank you, Sherry [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, Robert Koremans and Luigi La Corte our CFO that we'll be presenting the 2022 first 9 months results. They will be running you through the presentation. As usual, the set of slides is available on our website under the investor section. After that, we will open up for Q&A.

And I will now leave the floor to Rob. Please go ahead.

ROBERT KOREMANS: Thank you, Federica. I'm happy to say that Quarter 3 results were extremely strong confirming the strong momentum across both our businesses. And this on the back of continued recovery of our markets and also outperforming basically the relevant markets where our portfolio competes resulting in year-to-date revenue and EBITDA ahead of expectations.

Net revenues for the first 9 months of 2022 were plus 19% versus prior year or on a like-for-like basis plus 10.4%, where we have adjusted for the newly acquired EUSA Pharma and for the Eligard 2021 accounting.

SPC business continues to grow at a high single-digit ahead of relevant markets, driven by continued strong sales of flu products, our cough and cold range. GI the OTC and strong performance of Eligard. Our legacy rare disease portfolio showed double-digit growth with strong growth of both endo and also particularly strong performance of the metabolic franchise in Q3, led by Panhematin and Cystadrops, but also very resilient sales of Carbaglu with almost minimal impacts of the generics in the US.

Our new rare oncology franchise contributed in Q2 to Q3 with €91.1 million revenue. And this is nicely ahead of our expectations. EBITDA €560 million is up 15.2% versus prior year, with a margin at 37.5%, which remains strong, thanks to multiple proactive actions taken to mitigate impacts of inflation and despite diluted effects of the hyperinflation accounting in Turkey. The strong free cash flow generation of €346.3 million is in line with last year despite high non-recurring expenses with net debt just below 2 times EBITDA confirming the ability of the group to integrate acquisitions quickly and deleverage.

As you already know, and I will let Luigi spend a bit more time on it and give more details starting from first half of 2022. Our reported results are impacted by fair value IFRS 3 adjustments related to EUSA Pharma acquisition and non-recurring expenses and some FX volatility, which impact the reported operating profit and the reported net income.

Adjusting for the non-recurring costs and purchase price allocations, adjusted income…net income is plus 13.5% absorbing higher financing expenses and FX losses recorded in the first half of the year. And we've also achieved 2 important milestones that are going to help with our growth platforms. One is the new Eligard device approved by the Reference Member State Germany with national registrations and

transition planning ongoing. The device will definitely create positive momentum around Eligard.

And second, the transfer from Novartis of our production steps key for us Signifor LAR, we successfully completed the production transition into our hands. And there's also good news from the ECG side. Our efforts continue to be recognized by MSCI rating, A confirmation and an upgrade to robust level in rating provided by Moody's ESG solutions in September. Before I hand over to Luigi, I'd like to also give a little bit more detail on 2 of the key rare disease franchise performances.

On the next slide, you will see both franchises endo and oncology are growing very, very nicely. You can see the strong growth for both endo and Onco franchises fully in line with plan and on track to deliver for the full year of 2022 with respectively €160 million to €180 million for the endo and around €130 million for the Onco franchise.

For endo, the growth is 40% in the first 9 months of 2022 at a constant exchange rate this would be 30%. We see continues double-digit growth for Signifor and also almost revenue doubling for Isturisa. So, we're really on track to deliver for both products.

And also oncology, I'm happy to report continues to grow nicely at 13% year-on-year ahead of our expectations with particularly strong performance in LAC and EMEA. The full revenue for this year and I remind you that only 9 months or 3 quarters is going to be close to €130 million.

The interaction with the FDA on Qarziba US clinical development and the regulatory pathway ongoing with the targets filing in 2024 as previously communicated. So, both franchises are on track to deliver long term ambitions with the endo franchise and combined €400 million to €440 million for Signifor and Isturisa €100 million

for…over €100 million for Signifor and €300 million to €350 million for Isturisa and €250 million for the oncology portfolio as a long term peak. There's additional potential upsides from additional indications on revaluation, particularly one for the potential post-bariatric hypoglycemia, the indication that we're exploring for Signifor.

And with this, I'd like to hand over to Luigi to take us through the financial figures.

LUIGI LA CORTE: Thank you, Rob and good morning, good afternoon, everyone. I am guessing most of your interest will be on discussing our full year outlook. So, I'll try and go quickly through our usual slide deck, providing a bit more color on what I hope everyone will recognize as being a very strong set of results for the quarter and the first 9 months of the year.

Picking up on Slide 4, with the sales of our main products and franchises hopefully replied we really sort of show 3 things. #1, once again, the group confirming its ability to sustain and even grow the revenue of mature products post loss of exclusivity. And I think we're particularly proud of this achievement this year, done whilst at the same time refining our go-to-market model for the specialty and primary care organization. It highlights obviously, as a part already mentioned, by Rob, the strong growth of our new franchises and also the continued rebound and growth ahead of relevant markets of our other corporate products, particularly cough and cold, gastrointestinal and OTC portfolio.

Just very quickly touching on the highlights. You see the stability on the mature portfolio Zanidip and Zanipress franchise down by 4.7% with…but as you can see recovering some of the decline in the first part of the year due to the loss of tenders in China, which is in part offset by growth in many of our direct markets.

Revenue of the metoprolol franchise essentially flat with growth across many of the Central and Eastern European markets offsetting single-digit decline in some of the Western Europe markets. And both silodosin and pitavastatin returning to growth following loss of exclusivity in 2020 with actually pitavastatin growing double-digit, both of those driven by you know, growth in Russia, Turkey, Switzerland, Portugal and in other markets. Once again, I think the key strength of the group in sustaining these products.

Obviously Eligard adding over €18 million of revenue in the first 9 months of the year, on a like-for-like basis growth is around 12% or €8.4 million with the products having not stabilized, but starting to grow in a number of our markets on the back of our promotion, notably in Spain, France, Italy, Turkey and we hope to see other markets now following the trend in the next month. We're also very happy as Rob has mentioned that we hopefully will see new momentum...and further momentum in Eligard next year with the introduction of the new device.

Other corporate products growing by 16.5%, as I mentioned, driven by first and foremost the growth of our cough and cold portfolio products like Isofra, Polydexa, the Xspray franchise. These products have now pretty much going back to pre-pandemic levels and in fact in some markets are ahead. But we also saw very strong growth of our, gastrointestinal franchise, CitraFleet, CasenLax, [indiscernible] Probiotics, Reagila and a lot of OTC portfolio including local OTC products.

With regards to rare disease, obviously, Rob has already talked about the endo and the oncology franchise growth in the period which remains strong. Pleased to say that also metabolic franchise ensuring growth north of 10% with some growth particularly in US behind Panhematin, Cystadrops and Carbaglu revenues remaining resilient despite its first generic entry beginning of this year.

Nice to also see the growth…continued growth of our broad revenues portfolio in some of our international markets, Mexico, Brazil, and Japan to name a few. So very broad-based strong momentum in the business which as you will see on Slide 5 is now over 30% represented by drug for rare diseases. OTC overall is 16.4% of the business growing double-digit and local product portfolio is now below 13%.

Moving on to Slide #6, and looking at revenue by geography really all markets are benefiting from the same drivers that we trust and obviously also the addition of the EUSA portfolio. Nice to see and potentially in historic moment the US is starting to be neck and neck with Italy for becoming the #1 geography for the company with as already commented obviously US, which is focused on rare disease growth of close to 50% part benefiting from the strength of the US dollar, but really driven by broad growth of all of our franchises in U.S.

Italy at €206.8 million growing by 5.6% with a strong performance and growth again here of our seasonal flu products, [indiscernible] portfolio particularly Magnesio Supremo, plus probiotics and obviously growth of rare disease is partially offset by slight decline in some of our cardiovascular drugs.

I won't go through all markets, dynamics are pretty much the same. I will call out Turkey, where you see revenue growth in Europe 12%, just under €60 million. Growth really driven by volumes both on SPC and the rare disease business with a very sharp devaluation of the Turkish lira, essentially offset by equally significant level of price increases, which were awarded by the authorities over the course of the year.

Russia, CIS and Ukraine revenue up close to 40%, that goes to €89 million. Of that revenue in Russia was around €70 million growing

also in the back of obviously the strength of the ruble, which contributing year-on-year a tailwind of €9 million revenue in Ukraine down close to 12% versus last year just below €9 million. Other ones, I'll comment North Africa revenue growth of roughly 5% with high single-digit growth of our subsidiary in Tunisia, Opalia, partially offset by decline in Algeria.

And finally our international sales in other geographies up 15% to close to €177 million with the contribution of our growing rare disease portfolio in addition they will more than offsetting the decline of sales of lercanidipine in China.

So again also on a geographical basis, a strong performance across all of our markets, and you'll see on Slide 7 that our...legacy market, Italy now represents just over 15% of revenue not so long as we're close to 20% and us now at 14%.

Moving to the P&L, on Slide 8, as we said overall revenue of €1,277.5 million up 19.1% or 10.4% on a like-for-like organic basis, adjusting for exchange rates, adjusted gross profit, which adjusts for the online of the uplift to the acquired inventory of EUSA of €35.6 million is €990.4 million, growing by 17.5% and margin of 71.9% with the decline versus last year being fully explained by the diluted effect of both the transition over the course of 2021 on Eligard to direct selling and the effects of hyperinflation accounting in Turkey, which have added €5.6 million through the revenue line, and the track that on gross profit, because of the evaluation of inventory and cost of goods by €6.8 million.

SG&A expenses and obviously other lines of P&L, you know, obviously are growing you know, I think part also due to the integration of EUSA, but you'll see, SG&A expenses remain pretty much in line with last year in terms of percent of revenue just under 30% with selling at 24% of revenue and G&A at 5.8% of revenue with

obviously the benefits of the right-sizing actions that we took over the course at the end of 2021 and over the first part of this year offsetting return to pretty much full-fledged activities in the field following the end of lockdowns and obviously disruption during the pandemic.

R&D expenses of €155.7 million 11.3% of revenue, but the growth includes €19 million of incremental amortization mainly coming from EUSA but also from our other acquired assets. And the expectation is of slightly higher R&D expense rate of percent of revenue in Q4, as we continue to progress as some of our R&D programs in particular real world evidence study and/or interventional studies to support Isturisa. The progression of MCA's and additional effort on the MCA programme to accelerate the recruitment and the initial preliminary activities on the potential new indication in post-bariatric hypoglycemia on Signifor.

Other expenses of €31.4 million are, as you know, to reflect the non-recurring cost that we signalled at the beginning of the year, both related to the EUSA acquisition to the tune of €19.2 million and relating to the continued rightsizing and improvements of the of the commercial organization and SPC to the tune of €11.1 million with an additional close to 90 FTEs impacted this year, you know, mainly in Italy. We do expect these actions to deliver on a full-year basis roughly €19 million of savings.

This result in adjusted operating income and EBITDA of €423.7 million EBITDA of €516.2 million, a large EBITDA margin of 37.5% remaining very strong in current environment. Financial expenses obviously significantly increased versus last year as we commented at Q2. These reflect roughly €18.2 million of FX losses, you know, incurred in the first part…in first half of the year and compared to €6.8 million of losses in 2021. These are almost to be unrealized and arising from the strength of the ruble and in part of the US dollar. Also

included in financial expenses, the €5.6 million net monetary loss due to hyperinflation accounting in Turkey.

Bottom line result, net income of €241.5 million and adjusted net income of €355.9 million once adjusting obviously for the non-recurring items and the unwind of the purchase price allocation, you will see in the appendix we have added some tables to reconcile between net income and the adjusted figures.

As you can see on Slide 9, whilst accounting only for 31% of revenue, rare disease now accounts for over 36% of EBITDA and margins on both they just say it is remaining strong slightly lower on the rare disease compared to previous year reflecting the consolidation of EBITDA which as announced since the acquisition is running clearly at a slightly lower EBITDA margin is still expected to be around 25%-30% this year, but to grow in future to be in line with the balance of the rare disease portfolio.

On Slide 10, cash flow performance was also very strong, absorbing both the non-recurring costs incurred in the first part of the year and some high working capital due to the growth of the business. You recall we commented in 2021, cash flow performance being very strong and you know, given the non-recurring…the one-off cost and the growth of the business, very pleased that we are able to retain sustain a free cash flow delivery very much and only marginally below last year.

Honestly on the bottom part of the cash flow statement, you know, showing the acquisition of EUSA, net of the cash required and relative financing, and some of the other payments for intangible being mainly €35 million paid to Eligard earlier this year on the removal of the application for the new device plus residual milestones on Novartis and €10 million also included of clinical studies which meet criteria for capitalization.

Thanks to this strong cash generation and the operating performance of the group, at the end of September very pleased to say net debt to EBITDA ratio is just below 2 times obviously on for the last 12 months EBITDA basis. This is a very strong result. It demonstrates once again the ability of the group to quickly deleverage after doing acquisitions even significant ones like the one we just did completed this year with EUSA, and clearly is what gives the company ability to maintain a strong balance sheet and clearly the flexibility to continue making BD and M&A an integral part of the strategy.

And finally to close, prior to opening up to Q&A, you will see on Slide 12, our financial projections for 2022, very pleased that on the back of the strong performance to-date, we are able to increase our targets on revenue and EBITDA. With revenue now seeing around €1,860 million for the year and EBITDA at around €670 million, this on the back of the strong underlying performance across those businesses is slightly positive year-on-year effects versus original assumptions effect is fairly neutral year-to-date with the strength of the US dollar and Euro offset by the devaluation of the Turkish lira. We expect it to turn marginally positive in the balance of the year and proactive actions obviously to sustain our margins.

EBITDA margin implied of 36% reflects roughly 0.7% adverse effect…dilutive effect from hyperinflation accounting of Turkey. We expect application of IAS29 to have roughly €15 million on revenue detract roughly €8 million at the level of EBITDA. But it also reflects in Q4 which has historically always been, you know, slightly softer quarter in terms of margin. As I pointed out earlier, some target incremental investments, you know namely being preparation of the introduction or activities to prepare the introduction of the new device in Eligard.

We are preparing for fuller, if you like, launch of Isturisa in Italy. Isturisa is a regular market in Italy but we do not expect reimbursement to be approved in Q1 of 2023. We have initiated real-world evidence and non-interventional studies to you know, invest behind the strong momentum of Isturisa and/or adding some resources to the MTA program to accelerate a recruitment. And we have also decided as other companies in current environment to foresee a one-off payments to our employees on somewhat lower incomes as a contribution towards obviously growing cost of gas and just inflation and also as recognition of the very strong performance they contributed to for this year.

Financial expenses are now expected to be around €60 million due to the enduring strength of the ruble. With 72, we were expecting some of the FX losses to unwind. That doesn't…no longer seems realistic, and we also still foresee net monetary losses from IAS29 to be in the tune of €10 million. And finally we expect adjusted net income to be in the middle of the target range at around €460 million with higher operating results offset by the higher financial expenses.

And with that, I will close the prepared remarks part of the call and open it up for Q&A.

Q&A

OPERATOR: Thank you. Excuse me, 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 your question, please press "*" and "2." Please pick up the receiver when asking questions.

The first question comes from Niccolo Storer of Kepler Cheuvreux.

NICCOLÒ STORER: Hi, good afternoon everyone. And congratulations on results, which were very strong. I have 3 questions, if I may. The first one is on profitability. And so, if I further adjust gross profit for all the hyperinflation staff in Turkey, I end up with a number which is closer to 74%, which is one of the strongest print over the past many quarters. Is this possibly a new base upon which building our estimates for the future. And I add that these results have been achieved also notwithstanding inflationary pressure, of course, in countries other than Turkey, which were mentioned in previous calls. Related to still the profitability, maybe if you can quantify the one-off payment to employees you expect to disburse in Q4?

The second question on Russia, I was particularly surprised by the strength of Russia. Last year, we had a very strong second part of the year. In the 9 months, we are already at €90 million versus €100 million for the full year last year. So which are your expectations for the country for the area, Russia, Ukraine and former Soviet Union countries for the year?

And third question is related to your cost of debt. If I'm not wrong, debt you have taken on is mostly variable and not swapped into fixed. So as interest rates are growing, what should we expect as pure financial charges for 2023? Thank you.

LUIGI LA CORTE: Thank you, Niccolo. I'll take maybe the first 2 and the cost of debt one. And I think Robert will comment on Russia. Our gross margin, I think the calculation you're doing, you're doing on sort of the single quarter, Quarter 3, and you know, I'd always be careful of taking a single quarter as a proxy for the future. Metabolic revenue on other released portfolio was quite strong in Q3, which contributed to the positive performance. And as you said, we will see, and we are seeing and we already see today a little bit of sort of the effect of inflation coming through. The good news is so far, some of the actions we've taken on pricing have helped offset that. But no, you shouldn't take the

single quarter as being absolute representative of a full year. In terms of the one-off payment, you know, I assume that impacts the Q4 margin by slightly less than 1%.

And in terms of the cost of debt, actually, we're closer to 65-35 in terms of variable versus fixed you know, at the moment, depending on the view you take on the speed at which RIBOR [ph] further climb, there's not that much of a benefit on the fixed from my perspective, but we'll see, I mean, I won't give specific guidance for 2023 today, but obviously, you should expect that we're not going to...there's a big chunk of financial expenses in our P&L this year, which are related to the FX losses, which will not be recurring. I mean we don't treat them as nonrecurring items, but effectively, they are one-off. So we sold rubles at the wrong moment.

NICCOLÒ STORER: And Rob on the Russia?

ROBERT KOREMANS: Yes. Niccolo, on the Russia, so what we said also in the last call, the last quarter is, we do expect and we are seeing a slight decline in volume in Russia. And we've seen that clearly also in Ukraine with throughout the year. And this is happening. So it's less than 10% in volume decline. We've been able, at the beginning of the year to increase our prices somewhat. And at the moment, we continue to see the same trend nothing new in that sense coming from Russia. And the business continues to do really well in that sense. Nothing else to add on that.

NICCOLÒ STORER: Cool. Thank you.

OPERATOR: The next question is from Jo Walton of Credit Suisse.

JO WALTON: Thank you. 3, please. The usual one that somebody always asks, so I'll get it now, in terms of opportunities for acquisitions, particularly for biotech like products in the US, evaluations are very low. Is that

being transferred yet into people's expectations for doing deals, the success that you've had with the Isturisa deal must be bringing more people to the party thinking you know, you're a good steward of their product. So just getting a sense of the pipeline that's available there. You mentioned Eligard and how you've got the approval with the reference state of Germany? As you move through to the other countries in Europe, is there anything you would point out to us that maybe you are surprised on the label that you got. Is there anything that you can do in terms of repricing this product? So just give us a little bit of more on Eligard and if you could also talk more generally, you've highlighted inflation. You've obviously got to pay your staff more in the fourth quarter. I'm sure they will also need more money at the beginning of next year. What sort of proportion of your portfolio, do you have some flexibility on pricing with? I appreciate all of your OTC, but you seem to have done incredibly well to regain devaluation pricing, et cetera, in some of those markets. So just if you can give us a sense of the price flexibility you may have to absorb some of the inflationary pressures that we would expect for next year. Thank you.

ROBERT KOREMANS: Thanks Jo. So yes, we continue to look at deals. And you're absolutely right that there's...we were quite busy. But like I stressed a couple of times already, we maintain also our discipline. They are beautiful opportunities. We first wanted to really make sure that we had fully digested the acquisition of use and integrated the company, which is...I'm happy to report really almost complete. In reality, this business is running as one. It's not really our Onco franchise and we're very happy with our new colleagues in that respect and they found their place and business continues to do really well. So yes, we are able and willing to take on a next opportunity, but they will always have to meet with the same fairly stringent criteria as we did in the past, looking at ultimately the return of capital employed and looking at the opportunities. And clearly, I think for rare disease, where the biggest opportunities in the future will be in the foreseeable future is in

the US. So that has our focus. But you might appreciate that I'm not going to be more specific than this on any specific deals.

On Eligard, I see this rather as positive news for the franchise. We have something really good to say about our products, it will improve the handling by nurses and patients in that sense, it's just a positive boost in general. Germany will be the first country where we'll start to do this, and I don't expect this to be before Quarter 2 of next year. And you'll see it roll out through the rest of our countries. But there's not a specific additional label or claim. And I also do not expect that this is an opportunity to reprice. It's really more giving energy and enthusiasm behind our products. And what we've seen is stabilized in some countries already growth of Eligard. And I'm confident that with this, we can continue to see a very positive trend around Eligard going forward.

On the pricing, there are some countries where we can increase our prices, and we have, and notably the US on the OTC portfolio, we've done it in Turkey, traditionally has been a country that you can increase prices and we've done it this year. But I'll let Luigi also add his 2 pennies of thought around the flexibility there.

LUIGI LA CORTE: Yes. No. I think Rob has covered it. I mean, obviously, we have flexibility also in the US OTC portfolio. I mean just to give a sort of indication, I think you have heard me in the past say that you know, pricing pressure on Recordati on sort of normal years outside of major interventions or lots of exclusivities, year-on-year can I say between plus 1, minus 1. This year, it's actually even excluding Turkey, which is like is an outlier, we are running at around plus 1.5%. So we've clearly done a little bit more this year and you're seeing the benefit of that in terms of ability to sustain margins. We're not going to provide sort of specific guidance for next year. We're just starting to go through the budgeting process with the team, and we'll see. But so far,

very pleased with how we've been able to also use that lever to offset the impact of inflation.

ROBERT KOREMANS: And maybe one word to add Jo, I think it's not just the pricing, but also the ability. We have over 60% of our products were fully integrated and produce ourselves. And that has helped us really to address this. And we did report in the past and we continue to look at commercial excellence in trying to increase and enhance the impact we make in the market, but we're also doing that by using opportunities to be more effective and efficient. And that has been able to also, like Luigi also said in his prepared statements, with fewer people. We are actually seeing that we increase our market share in all of our relevant markets for the business. So this is not a program that is over. We'll continue to do a bit more going forward. And that gives us confidence going into the future.

OPERATOR: The next question is from James Gordon of JP Morgan. Mr. Gordon your line is open sir.

JAMES GORDON: Hello, James Gordon, JP Morgan. Thanks for taking the question. Hello, thanks for taking the questions. Just a about profitability, so the implied Q4 profitability using the updated guidance, it is about 550 bps of sequential EBITDA margin contraction, which is quite a lot bigger than the normal contraction we see in Q4, which is about 200 bps. And I heard the comment about some one-off employee payments you mentioned. But is some of it higher R&D spend, and is there anything one-off in the R&D spend like one-off milestones. How much of the extra should we put into R&D versus SG&A for Q4?

And looking into 2023, so you're exiting this year at about a 32% margin for Q4 and 36% for the full year. I know you previously issued '23 guidance, which suggested more like a 38% margin. Are there things you can do that mean you are going to see significant expansion next year, such as activities on pricing and some of the stuff that

happens this year being one-off or do we need to reset our expectations a bit in terms of inflationary cost pressures, et cetera, and investment plans when we think about modelling '23?

LUIGI LA CORTE: Thank you James. I'll have a first stab at that and then let Rob add on. So short answer is, no, you should not be taking Q4, obviously, as a sort of proxy for next year. As you've said, Q4 has always been a little bit softer quarter by about 2 percentage points. And I'll talk to sort of the slightly higher step down that you're seeing now. But maybe just taking a step back, beginning of the year, we set an expectation for 2022 of the margin of 37%. The beginning of the sort of like escalation of the conflict and the hyperinflation [ph], we said we'd probably see about an access of 50 basis points of pressure. Once you adjust for hyperinflation, which clearly was not in the sort of included in the guidance that we're not adjusting for. We're pretty close...we're pretty back online with that, confirming once again the group's ability to deliver on the targets. We're not going to set a target now for next year. As always, we will do that early in 2023, of course, we'll continue looking at pricing, rightsizing, leveraging all the things that we've leveraged this year. But on the somewhat higher sort of drop of margin in Q4, some of it is phasing. I said you know, Q3 was particularly strong in terms of the mix. We have the initiation of the programs. And whilst they don't sort of strictly end at the end of the year, as you may know, but even in R&D, there's a level of spend which you pay an initiation of the study, which tends to be a slightly more substantial part of the overall study cost. And when you sort of you know, consolidate that in a single quarter, obviously, it can make more meaningful sort of distortion to that single quarter profitability, we should not actually never focus on profitability on the single quarter. And things like preparation of the new device introduction in Eligard, the Isturisa launch in Italy, the one-off payment that we have discussed and recently decided that we're likely to do all after that. But again, many of these are one-offs or higher in the incidents when concentrated in a single quarter. But in terms of full year guidance for

2023, you'll have to wait, as always, the February when we'll get back together with the final results for '22.

I hope that gives you some flavor and some sort of more insight into the trend. But again, we feel very happy in terms of what we're delivering. We should not take Q4 as a proxy and we continue to stay committed to sustaining what we see as being margins at the very high level of the sector. Rob.

ROBERT KOREMANS: Nothing to add, Luigi.

JAMES GORDON: Thank you.

OPERATOR: The next question is from Keyur Parekh of Goldman Sachs.

KEYUR PAREKH: Hi. Thank you for taking my questions. If I may, please. The first one is, given the increased revenue expectations for this year, how should we think about the trajectory of the revenue line as we think into 2023? And then separately relative to your midterm guidance, again, kind of the same question as we think about how much stronger the revenue line has been this year, but when would be a good time for you to think about updating your longer-term or mid-term guidance? Thank you.

ROBERT KOREMANS: Thanks for the question. Like Luigi already stressed, we're going to give guidance for next year at the beginning of early next year, so probably do that early February. And our momentum continues to be good, business is doing well. Throughout the business, both in the SPC and rare disease continued good growth and are able to translate that into high margins. And we'll give you more update at the beginning of next year.

LUIGI LA CORTE: We're obviously not very far, okay view it from the bottom end of that guidance right for 2023 with this portfolio, but we haven't had a date yet for the update, but it will be in the first part of next year.

KEYUR PAREKH: Thank you.

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

ISACCO BRAMBILLA: Hi, good afternoon everybody. A couple of questions from my side. The first one is on top line organic growth, it is now at least 3 or 4 quarters, you are running with organic growth, even excluding the switch of Eligard recognition in the high single-digit as well as low double-digit territory. Can you help us understand how much of this is a source of pent-up recovery compared to last year, subdued trends and how much is sustainable growth, even looking forward?

Second question is focused on the rare disease franchise. You reported EUSA growing plus 13% in the 9 months. Isturisa, if I'm not wrong, posting the same revenues of Signifor this quarter and also the so-called legacy business growing double-digit. Is there any non-recurring driver supporting performance of this portfolio during this quarter or is this trend sustainable? Thanks.

LUIGI LA CORTE: So I think, first of all, in terms of that organic growth, I think rare disease was not significantly impacted by the pandemic, as we've always commented. So I don't see any need to do major adjustments to the growth rate there.

On SPC, I would just point back to comments we've made in the past, where we said you know, we see the SPC portfolio having the potential to grow around mid single-digit...low to mid single-digits. So there's obviously an element of recovery this year and strong growth in a few markets. Again, without yet sort of giving sort of full updated guidance for the future, you know, for us that remains a little bit the guideline for SPC, of course, you have parts of the business that will grow at a higher rate than that. We hope to see Eligard within the SPC portfolio continuing to grow at high single-digit, hopefully next year,

but we're not going to give more detailed guidance on 2023 or beyond now, Issaco.

ISACCO BRAMBILLA: And maybe one on, to what extent there has been something which is a one-off in the current quarter sales. I think mostly it's been normal business, if you'd like, sustainable business. What we did have on the Onco franchise in light of the launch of Signifor in China, we had shipments of that in oncology in China. And that is...yes, in terms of loading the channel, so that's a bit higher than what you would expect in a normal quarter.

LUIGI LA CORTE: But it's not much Isacco. I think you know, clearly, the metabolic portfolio performance in Q3 stood out, delivery a bit weaker on the other hand. But again, I think as we all know SPC, we stand by comments made in the past around seeing the potential to continue to grow at around low to mid single-digit, depending on the year and with some part of the portfolio likely to grow more and some likely to grow less.

ISACCO BRAMBILLA: Very clear. Many thanks.

OPERATOR: The next question is from Emily Field of Barclays.

EMILY FIELD: Hi, thanks for taking my questions. Just 2 from me. Obviously, with the debt-to-EBITDA ratio now falling below 2, and you mentioned that there's still a lot of attractive opportunities out there from the M&A side, particularly in rare disease. Just curious, you know, if you have an upper bound in terms of leverage ratio that you'd be willing to go to, just obviously, given the broader macro environment those are numbers that are being watched closely by the market. So just any color you've give around that.

And then I believe you mentioned in the prepared remarks that cough/cold flu has returned to pre-pandemic levels. Some of the

earlier data, particularly out of the US indicates that we could see very high levels of influenza in particular, this year. So I know it's a tough comp with numbers getting back up there, but sort of how are you thinking about this season, maybe potentially offering some growth on top of that. Thank you.

LUIGI LA CORTE: Emily, thank you for the question. On BD [ph] and M&A, our sort of guidance has not changed on that in terms of us wanting to operate at levels not too different from the current ones, but with the flexibility of going up to maximum of 3 times, you know, it's really a compelling opportunity of scale came up. The good news obviously is the result that we achieved in this first part of the year with that leverage going very quickly down from 2.4% to just under 2 times, which similar to what we did already after the Signifor/Isturisa deal where it went from very quickly from 1.9% to 1.2%.

On the flu, yes, we also see, as you said, the potential for...this is reason [ph] to be a strong one and that's reflected, if you like, in the updated guidance that we provided. And one of the things that we have, obviously, more visibility on today, and one of the drivers of...amongst others, obviously, the sustained performance, the resilience of our metabolic portfolio, the recovery in some of the markets that has led us to upgrade the guidance.

ROBERT KOREMANS: And maybe Emily sorry, just one comment on M&A, it's not just on rare disease where we're looking to make acquisitions right for us going forward, both businesses, we want to continue to invest. And also on the SPC side, we're actively looking at, what potential things and we will continue to pursue opportunities there.

EMILY FIELD: Okay. Thank you.

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

We have a follow-up question from Jo Walton of Credit Suisse.

JO WALTON: I'm sorry, the line is a little bad. So I may be asking you to repeat some of this, but you talked about higher clinical trial start-up costs, which would be impacting in 4Q. I wonder if you could just tell us a little bit about R&D spending as we're going forward. I know that you keep a lot of your amortization charge you know, within R&D, and that's expanding it a bit. But could you just talk a little bit about the underlying numbers of trials or what you're actually planning to do over the next few months that might see the R&D as a percentage of sales increase? Thank you.

LUIGI LA CORTE: Hi, Jo. Yes, I mean, I will reiterate what I said. I think, first of all, as you've rightly highlighted close to more than 40% of our...the cost in R&D line is amortization and it is increasing on the back of the recent deals.

In terms of the key programs that we are running, of course, about the MTA program in Neurotrophic Keratitis where the Phase II is running, has been enrolling. The pace has been a little bit slower than we would have liked. So we have made some...we've initiated some new sites and also made some tweaks to the protocol to accelerate the recruitment. We have, but we have spoken before about the intent to complement the data package that we have on Isturisa with real-world evidence that should further support potential feature application for the expansion of the indication in the US. We're also running non-interventional study to help provide the physician with further experience on Isturisa, which should also support the further rollout of Isturisa in Europe as we progressively get reimbursement.

At Q2, you recall we talked about us seeing potentially new opportunities for additional indications also on Singapore, post-bariatric hypoglycemia, where we've seen some interesting data in a different population run by Novartis, and we are currently discussing with the FDA with a potential clinical path for developing Signifor and that additional indication could look like. We haven't finalized those discussions yet, which is why we've not provided yet a lot more sort of guidance or set a lot more expectations on that. We want to have those discussions finalized. And we're also still exploring on Sylvant potentially a new indication. We talked about a potential use in the patients with cytokine response in conjunction with CAR-T therapies. And there's other things that we're evaluating. So hopefully, that...I'm not going to go into more detail than that in terms of the study by product or specific timelines. I think we're probably more likely to do that when we give a broader update on the mid-term outlook, if that makes sense.

ROBERT KOREMANS: Beginning of next year, yes.

LUIGI LA CORTE: Yes, which, again, will be at some point in the first part of next year. We've done it in May historically. We'll see a recent...last couple of years, we still have to sort of finalize the view as to what is the right time to do that. I hope that it is okay for now Jo

JO WALTON: Yes, Thank you

OPERATOR: Gentlemen, Ms. Medici, there are no more questions registered at this time.

FEDERICA DE MEDICI: Okay. Thank you very much.

ROBERT KOREMANS: Thank you all for your time and interest, and looking forward to engage and continue to share our progress.

LUIGI FELICE CORTE: Thank you.

FEDERICA DE MEDICI: Bye-bye.