Recordati S.p.A

"Investor Conference Call"

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

FEDERICA DE MEDICI: Thank you Sabrina, and good afternoon or good morning, everyone, and thank you for attending the Recordati conference call today. I am pleased to be here with our CEO, Andrea Recordati and Luigi La Corte, our CFO that will be presenting the first quarter 2021 results and the strategy and outlook update for the next 3 years. They will be running the usual 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.

I will now leave the floor to Andrea. Please go ahead.

ANDREA RECORDATI: Good afternoon, ladies and gentlemen, and thank you for having joined us for the Recordati first quarter 2021 results and a 3 year plan update investor presentation. So please move to the second slide, the agenda. The agenda today would take us through our company overview and strategy, our 2021 first quarter results, the key assumptions around the drivers for organic growth, a focus on further growth opportunities, internal and external, and finally our financial projection for the next 3 years. So if you can please turn to the first slide of the presentation, Slide #3.

So let me start with Recordati in a snapshot in one page, for those of you who don't know our company, to give you a quick profile of Recordati, and where Recordati is today. An international specialty Pharma Group with its root and legacy in Italy that has successfully grown in international markets, mostly through acquisitions and business development over many years to the point that Italy now accounts less than 20% of revenue. We manage the business through 2 business units, SPC [ph] which stands for Specialty and Primary Care that account for 78% of revenues and includes Rx, OTC and Fine Chemicals and our Rare Disease business unit, which is mainly focused on the treatments for metabolic deficiencies and rare endocrine conditions, that accounts for 22% of revenues, but accounts for more than 25% of consolidated EBITDA.

Our SPC legacy is in cardiovascular, and we are also present in a number of other therapeutic areas such as urology, gastrointestinal, [indiscernible] anti-infective to mention the key ones. We have a well diversified footprint and strong vertical integration with 8 manufacturing facilities of which 2 are API production sites and one is specialized packaging and distribution facility dedicated to Rare Diseases. This diversification has served us well in 2020 during the COVID-19 pandemic. Although we were not immune from the impact that COVID had on several categories and markets, our organization was quick to react in showing continued availability of our products and the safety of our employees. Despite the disruption, we were able to deliver revenues which were broadly flat versus the prior year. In EBITDA and adjusted net income, they were very closely aligned with the targets that we have set at the beginning of 2020.

Moving on to the next slide, those of you who are better or more familiar with the business will know that we have a relatively straightforward and

successful and proven business model, which is summarized on this slide. We are a unique company with a very broad portfolio and geographical footprint that minimizes exposure to single product and markets, and therefore a limited exposure to single reimbursement systems. Organic growth is primarily fueled by volume driven growth rather than price and good exposure to markets, with positive long-term growth outlook, such as in North America, LATAM, Turkey, Russia, North Africa, to mention a few. A proven success of strategy of stabilizing key products post-loss of exclusivity through active promotion and no major corporate products taking a lead over the next 5 years. We have a fully vertically integrated platform from APIs to commercialization for key products, driving margin and protecting the supply chain, with approximately 60% of volumes manufactured by Recordati plants.

We minimized R&D risk with selective investments with a majority of our net revenue coming from mature products and products sourced externally by a licensing and business development activity. And finally, we have a strong and proven M&A track record to complement and strengthen our portfolio and geographical footprint, with a very disciplined approach and the long-term focus on value creation always pursuing a mix of growth and accretive deals.

Moving on to Slide 5, our business model has delivered a consistent history of growth and margin improvement. As shown in this chart, revenue CAGR for past 10 years was plus 7%, and this was achieved through a well balanced mix of organic and inorganic development. We consistently improved our profitability with strong margin expansion from 25% EBITDA to over 38% target that we have set in our prior full year plan, reaching 39% in 2020, a margin result which, however, then we remind you we know was enhanced by the impact that the COVID pandemic had on revenues, but also on the cost base of the company.

Moving on to the next slide, so we are planning to keep on doing this in the years to come, maintaining a strategy, de facto unchanged from the last reservation of a 3-year plan that we presented in 2019. For those in fact familiar with our company, you may recognize that this strategy slide is fundamentally the same as the one that we shared in May ’19, a strategy that we believe remains valid today and going forward. We’d like to confirm the continuation of our successful strategy with a steady organic growth, generated by a well diversified portfolio, and the balanced exposure to emerging markets, enhanced by accretive and strategic deals in both SPC and Rare Diseases, and leveraged on our capabilities across both businesses. As you can see from the bottom of the slide, we also feel that as a Group we are well positioned and exposed to positive macro trends driving our relevant markets.

Moving on to the next slide, in Recordati, we believe that integrating corporate responsibility into our business approach and strategy by uniting economic, social and environmental aspects, will create long-term value for all creation, for all relevant stakeholders. Our commitment to this is summarized in this slide. Given the growing importance of sustainability issues within the company dynamics, we have created a dedicated environmental, social and governance, ESG function, with the task of integrating and managing sustainability as an integral part of all the activities and initiatives of the Recordati Group.

Our sustainability strategy is based on 5 priority areas. For all of them, we have defined specific commitments. Regarding patient care, our attention is focused on access to medical products, quality product, safety and R&D, as for employees we are committed to creating even more safe, responsible and inclusive workspace. We consider also very important supporting local communities. We want to take conscious action to reduce

our environmental impact, fighting against climate change, increasing the circular economy, and promoting waste reduction initiatives. Concerning responsible sourcing, we are committed to constantly promote and respect for ESG aspects along the entire value chain. And finally, integrity is our founding value and we are committed to maintain the high standards of ethical products. Our remuneration policy is closely involved in our sustainability plan, in order to have a strong commitment we have included also the sustainability target in our Group's management by objective system. The plan will present how we want to create sustainable and shared long-term value. We can move to the next slide, please.

So now, before we actually move to the 3-year plan presentation, I will leave the floor to Luigi to present the 2021 first quarter results. Thank you, Luigi.

LUIGI LA CORTE: Thank you Andrea, and good morning, good afternoon, everyone. I will take you through the quarter one financials and we will try to do so clearly but also with pace given that I am sure everyone is keen to hear more about the 3-year plan, and also given that as you already know from our press release a few weeks ago, Q1 financials are somewhat distorted by stock movements both this year and the last.

So starting from Slide 9, and in terms of key highlights, revenue as we've already disclosed was down 10.3% for the quarter at just under €385 million. This reflects adverse foreign exchange of 3.5% and obviously the continuation of COVID pandemic pressures on some key categories as we saw in the second part of last year, but also reflects the year-on-year impact of loss of exclusivities that we faced in 2020, on pitavastatin and silodosin. But once again, it also…it also reflects an estimated €20 million of stocking in Q1 of 2020, where we benefited from advanced purchases of wholesalers and pharmacies at the start of the pandemic.

And we also said a few…a couple of weeks ago, we saw on the other hand in 2021, a level of destocking in some of our markets, particularly impacting cough and cold, an ear and nose and throat medicines, which were particularly acute in Russia, where this portfolio makes up a significant part of the business.

To note, we made good progress in the quarter, both on our endocrinology franchise with revenue of €26 million versus €14.7 million in the same period last year. And also with Eligard, where the integration of the business is on-track and in fact in terms of transition from Astellas moving slightly faster than planned with revenue in Q1 of €16.8 million. Andréa will come back to cover these in more detail later on.

The reduction in revenue is obviously reflected into the P&L, with both EBITDA and net income, showing a double-digit decline in the quarter, but with margins remaining at robust levels with EBITDA in particular at 39% of revenue and adjusted net income around 27%, reflecting the impact that the COVID also has on our activity spend in the market.

Free cash flow in the quarter was €110 million, €21 million higher than same period of 2020. Thanks primarily to lower absorption of working capital. Most importantly, despite the lower revenue and the somewhat weaker demand on cough and cold medicines, which we expect to persist for the rest of the year. Our financials are in line with expectations. And as you will see later on in the presentation, our financial guidance for 2021 is unchanged.

Moving to Slide 10, in terms of key product sales, as you will see from the slide, most of our specialty primary care products, which are the ones that which most…were most impacted by COVID, and also which have most of the benefit of stocking last year showing a decline. Zanidip is fairly

resilient, up actually 3.2% versus last year. And that is driven by double-digit growth in international markets with a decline in direct where we sell the product directly.

International markets, we're not very affected by the pandemic last year, given the longer order cycles, and they do represent over 50% of Zanidip revenue. This was in part through also for Zanipress, with growth on the international business, which, however, makes up a lower percentage of the total. And we did have, although we are starting to see the business stabilize a little bit of pressure in France because of measures introduced at the beginning of 2020.

The distortive effect of purchasing patterns across the 2 years is clear, obviously on metoprolol, you will recall Q1 2020 metoprolol showed revenue growth in Q1 of 30%, and is down 18% in the first quarter of this year, against that comparable. Silodosin and pitavastatin also to some extent reflecting the impact of stock movements, but clearly also reflecting the loss of exclusivity, which they each went through last year. Our view for these 2 for 2020 remains unchanged. And as we said, at the beginning of the year, we expect on both products a year-on-year erosion for the full-year of around €10 million. To know that pitavastatin is continuing to grow in markets where we don't face generic competition, mainly Turkey, Greece, and Switzerland.

Other corporate products continue to be the area where we see the brunt of the COVID impact. And this is where we see really the effect of the restrictions impacting on our cough and cold portfolio, and also where we've seen the impact of destocking, particularly in Russia. The reduction of 31% is driven by products like Polydexa, Isofra, and TERGYNAN, which are significant particularly in Russia and some Central Eastern

European market, Lomexin, Hexaspray, and our probiotics. In addition to Russia, we see some of this effect in Italy and France as well.

Rare diseases is…as already commented, is continuing to grow well with growth in the quarter of close to 10% and revenue of close to €85 million. Clearly, the growth is driven by our endo franchise, which at just over €26 million grew significantly versus Q1. Now, clearly, this is on the back of the addition of Isturisa, which had no sales in '20…in Q1 of 2020, and continued growth of Signifor, which on a like-for-like basis continue to grow at around 10%.

The small decline on the base…on our legacy business is really being driven by the weakness of the U.S. dollar in the quarter and the erosion of Panhematin, which as I commented in the past, has started to stabilize. But faced competition starting later in Q1 of last year, which offset the growth of pretty much the bulk of our portfolio and again, Andrea will speak more later on.

Slide 11, and again, I won't go market-by-market in the interest of time. But clearly our core European markets reflect some of the dynamics, which I've just mentioned, and therefore, are showing a decline versus prior year. And that really applies to most of the Western European markets.

Spain, we're actually starting to see signs of stabilization of the GI franchises, which were impacted over the course of last year. But also we will see the benefit of the contribution that Eligard is making to the revenue in the market where Eligard does have a significant business.

Turkey is suffering from the tighter restrictions, which have been imposed in the country really from the start of this year. You see Turkey in local

currency terms showing mid single-digit decline of 5.5% with revenue in euro terms down 26.7%, due to adverse effects over 20% in the period.

Russia, CIS, and Ukraine, as mentioned already, clearly reflect the impact of cough and cold weakness, but also, as mentioned, the level of destocking historically Russia, the Russian market, as we see it has been running with stocks in the channel of between 11 and 13 weeks. And as a result of the pandemic and the economic pressures there, we're seeing distribution channel moving towards 8 to 9 weeks of stock, and you've seen the results reflected there with revenue in local currencies down 50% in Russia for the quarter. And we clearly expect some stabilization now in the months to come.

U.S. business growing by 26.7% in local currency or 15.9 in euro terms, once again due to the weakness of the U.S. dollar at the start of the year, with the growth driven by both the ENDO portfolio and all of our promoted products, with the exception of Panhematin.

Other Central Eastern European and other Western European countries are broadly stable. You recall last year these countries were less impacted by COVID, this being countries where we have established our presence more recently and also countries where Eligard is also making already a good contribution. And therefore showing relatively stable year-on-year revenue trend. The same is true of our business in Tunisia, which is continuing to grow double-digit, with north…total North Africa's revenue down due to delays in import licenses for this year to some of our export businesses particularly in Algeria.

And finally, our international sales down due to the loss of exclusivity last year of pitavastatin and silodosin, which offset good growth as I said of the lercanidipine franchise.

Moving to Slide 12, and looking at the P&L. Gross profit at 73% is marginally up versus the levels achieved at the end of last year on the back of improving mix, but it's also slightly flattered from the accounting of Eligard that which I will remind everyone, we account for the net revenue level on a net gross profit basis until we transfer a market authorization and distribution from Astellas.

SG&A cost of €113.4 million are lower than prior year by 4%, really driven as we saw in the back end of last year due to the reduction in selling expenses, which stand at 24.3%. Sales down, because of the lower activity levels and spend in the field particularly on the SPC business with G&A slightly up just about 5% as we strengthened our structure behind the new franchises.

R&D costs at 10.8% of revenue are up 18.7% versus 2020. A third of the increase is due to the additional amortization charges on both the ENDO franchise and Eligard. Another third is due to the progression of clinical trials, both the ones we inherited from Novartis and the ones that we are progressing in our own pipeline namely the MTA project. And the other third is due to the strengthening of our medical science Liaisons in the field and additional pharmacovigilance and regulatory spend behind the new franchises.

As a result operating income and EBITDA as mentioned decline versus prior year by double-digit, but with margin levels remaining strong with EBITDA at 39% of sales. Net income at roughly €90 million reflects in addition to the operating results, also additional financing charges in the quarter due to unrealized FX losses of around €3.7 million which compared to Q1, 2020, where we actually benefited from around €1.9

million of gains related to currency swaps that were no longer treated as hedges.

Just a final note on the P&L, as you all will know, we completed in April, the reverse merger transaction with Rossini SpA, and therefore in Q2, we expect to record the non-recurring tax benefit of €12.9 million that came from that transaction as foreseen in the plan and as we said at the time, we expect no other impacts from the shortening of the control chain.

Quickly on Slide 13, we chose our rare disease business continuing to account roughly 22% of revenue, but around 25% to 26% of operating income and EBITDA. Margins levels on both businesses being broadly in line with the levels achieved in the full year 2020.

When it comes to…on Slide 14, you will see we've added to our standard quarterly reporting pack. An additional slide which we do plan to also include in our next quarters reporting, which gives a bit more visibility on the drivers of our cash flow, which we do believe is a key area of strength of the group. Of course, as always, there is a seasonality to the cash flows and Q1 is particularly positive, as we tend to pay very little taxes in the first quarter of the year. But that aside, free cash flow of €110 million is up, as I said at the beginning €21 million roughly versus the first quarter of last year, mainly due to a lower absorption of working capital clearly due to the revenue dynamics.

Intangible assets increased by €53 million in the quarter with the main items there being €35 million, we paid to Tolmar on completion of the deal to…for Eligard, and the €14.5 million paid to Almirall for the Flatoril rights in Spain. And we also in the quarter had net share purchases of €43 million. Financing flows of €49 million reflecting new 5-year loan that

we've taken out to benefit concurrently low interest rates and to increase the average duration of our debt.

And finally, before turning over to Andrea on Slide 15, you will see our net financial positions remained strong, net debt of €852.6 million is below end of 2020, and is 1.5 to 1.6 times last 12 months trailing EBITDA.

And with that, I'll hand over to Andrea.

ANDREA RECORDATI: Thank you, Luigi. So if you could turn to the agenda, please, Slide 16. So let me now take you in more detail through the 2…our 2 businesses and describe the key drivers of a plan from '21 to '23. I'd start with SPC which today still represents like we mentioned before 78% of total revenues and 74% of our EBITDA.

So Slide 17…next slide. So as you can see from the summary overview on the slide, our presence in SPC is focused on Europe, Central Eastern Europe, CIS, Turkey with direct selling organizations in over 30 countries and with approximately 1,900 strong sales organizations. But we've also an important business that we would like to remind, worth roughly €100 million, which is selling profitably on other international markets by licensors.

We have a very broad portfolio across a number of therapeutical areas, key ones being cardiovascular, urology, GI and anti-infectives [ph] like I mentioned before. We got product offering including both Rx products, but also OTC products. OTCs being roughly 8%...18% of total SPC. You will see here some of the key brands which is a combination of products we've developed internally and once we have acquired only license from our partners.

If you can move to the next slide please, Slide 18. So Specialty and Primary Care is the fact of a backbone of Recordati offering a robust and resilient portfolio with no loss of exclusivity exposure in the plan period, and very little exposure beyond that. It grows at 6% CAGR in the planned period or 3% CAGR when excluding Eligard with growth across all markets and all key categories in the next 3 years. Despite some assumed FX headwinds in the plan in Turkey and Russia.

We would focus our commercial efforts on accelerating growth from the assets with potential, namely Eligard Reagila and the forthcoming [ph] launch of ARS1, as well as, the selective promotion of key OTC brands like Procto-Glyvenol, Gynoxin [indiscernible]. In parallel for the period our large and diverse portfolio established brands in areas like cardio, uro and gastro are stable or marginally growing cost written LOEs. We focused promotional efforts, exemplifying the robustness and resilience of our SPC business.

With this diverse and well-balanced portfolio SPC offers a very solid and diversified platform with single-digit growth that can be leveraged with accretive business development deals that complement our capabilities and footprint, just like the recent one with Eligard. Hence our continued focus on inorganic acquisitions or new licenses to accelerate growth and sustain margins of this part of the business.

If you please move to the next slide. So looking into our portfolio by key categories, let's start with the areas that have suffered the most to like I mentioned before, due to the COVID pandemic being the cough and cold and ENT infection therapeutical portfolio. The lack of pathology due to the COVID prevention or restrictions measures has resulted in a decline in a reference market of roughly 25% in 2020, and almost 50% in the

January to February '21, 2021 period. This is actually IQVIA data in volumes. And this has been translated into a significant sales decline of almost 40% of our portfolio versus pre-COVID levels and that's for 2019. This has been impacted mostly those markets with a relevant cough and cold portfolio, and ENT portfolio, like Luigi mentioned before being Russia, Italy, and France.

We have taken, we believe a balanced view in our Plan, in our expectations of a recovery of pathology, over the next couple of years following the easing of restrictions and distancing measures and the reduction of the use of protective masks with our sales progressively recovering over the next 3 years, starting from the second-half of 2022, but still expected to be more than 20% below pre-COVID levels at the end of 2023.

Next slide, please. Moving on to the cardiovascular portfolio. Unlike cough and cold and ENT, our core portfolio of cardiovascular products has shown an extraordinary robustness and resilience throughout the COVID pandemic. We've a limited impact of LOE of pitavastatin, until 2021 and then low single-digit growth of a portfolio across the reproductive geographical footprint, but also through our international partners and particularly in China, thanks to the expansion driven by our new distributor for that market. We're expecting pitavastatin and metoprolol to be relatively stable throughout the time period, with some growth of lercanidipine franchise post Zanipress loss of exclusivity stabilization.

As you know, our cardio franchise is the largest cash flow generator, which supports the continued BD and M&A activities of Recordati and its robustness and resilience is a massive asset for our company.

Moving on to urology. Next slide, please 21. For the plan period we forecast a gradual similar stabilization of the sales of Urorec, silodosin after the initial top line decline, following the loss of the exclusivity last year. As you can see in the above graph on the right, we've been able to preserve its market share in units over the past months, and expect to sustain the sales over the coming years, thanks to targeted promotion to key customers, as well as the calls on your urologies with Eligard, and with an opportunity for some further growth coming from Turkey and Central Eastern Europe.

Next slide, please. Moving on to Eligard, our new addition to our SPC portfolio. This is the growth…we consider this to be a growth opportunity, it's a great asset that will benefit from our established presence and heritage in urology and that offers the opportunity to demonstrate our ability to reverse the declining trend seen over recent years, and we established [ph] a non promoted tenure and therefore revitalized its growth.

We kicked up promotion in March in certain key markets with very encouraging feedback from our customers. Transition from Astellas has been smooth with our year-to-date sales on track with expectations, and now all the markets are promoting Eligard. Our collaboration is progressing well with Tolmar around the development of a new easier to handle device. We expect the regulatory submission by the end of this year, and for its expected approval, we believe we will be able to further accelerate its growth going forward as you can see in this graph.

Moving on to Slide 23, on Reagila. So we believe that the end of the COVID 19 pandemic will offer an opportunity to relaunch a novelty product like Reagila, as and when, obviously, access to healthcare professionals by both patients and sales representatives is normalized. For

a majority of products launched or still in launch phase, around the COVID pandemic, physicians have been obviously very cautious and generally more reluctant to switch their patients to new drugs, especially in therapeutical areas with difficult to manage patients, such as schizophrenia.

This therefore limit substantially the potential in launch optic for this product. During these last months, we've been preparing the ground for the relaunch of the product on the, say, the day after the end of COVID, by repositioning the brand around both negative and positive symptoms and strengthening our network of local advocates and key opinion leaders, as well as expanding the opportunity into new markets like Greece and Austria where Reagila is expected to be launched later in this year.

As a result, we do expect an acceleration of Reagila's growth through the forecast period, which could be boosted, if we manage to unlock the access also in France and U.K., and which is actually not represented in this Plan and should be considered as an upside to the current numbers.

Moving on to the next slide. So before we move to Rare Diseases, we tend to seldomly talk about key products in our OTC portfolio, and we wanted to share the success story of Procto-Glyvenol, an asset that has seen continued growth in Central Eastern Europe, and Turkey since Recordati acquired it, growing from a brand with €9 million in sales in 2011 to…or just over €30 million by 2019, 2020 through the development of line extensions in omni-channel approaches leveraging DTC investments, we are confident to reach more €40 million by 2023. This is a success story that we expect to replicate with other OTC brands across our portfolio as I mentioned at the beginning of my presentation.

In conclusion, our diverse portfolio in SPC as well the COVID-19 [indiscernible] with you. And it sets up for growth across all markets and all categories over the coming years, providing Recordati with a robust and resilient platform to be able to further grow fueled by more accretive acquisition and new in-licensing deals that fits with our proven commercial capabilities and geographical footprint.

While we bring in certain big opportunities, we will continue to focus on accelerating growth through commercial focus on selected assets like Eligard, Reagila, ARS-1 and some selected OTC brands, and target a promotional activity aimed at sustaining legacy brands across all countries, especially those particularly sensitive to promotion.

So moving on to Slide 25 or I should just move to Slide 26 to take you through our Rare Disease business unit outlook. So first of all, as many of you know Rare Diseases is an area of still significant unmet medical needs, with only 500 of a total 7,000 designated conditions, having approved medical treatments. Thanks to advancement in sciences, both for the diagnosis, but also for treatment rates are increasing, supported also by supportive legislations are incentivized investment and innovation in this area for different initiatives, both in Europe and in the U.S. It is also an area with very strong growth fundamentals. Market expects to double-digit over the next years from an estimated €138 billion in 2020 to over €230 billion by 2025, and which therefore offers plenty of opportunities for growth for an established player like Recordati.

Next slide please, 27. Recordati has a long-established presence in Rare Diseases, starting with the acquisition obviously of Orphan Europe in 2006 and then the U.S. Rare Disease business from [indiscernible] in 2013. We have a growing global footprint with which currently encompasses North America, EMEA and key markets in South America,

Australasia, and Japan. But we have an ambition to expand further in our geographies, in order to become a fully-fledged global player in the field.

Our legacy portfolio is mainly concentrated in metabolic diseases. For example, products that fit in the area are Carbaglu and Cystadrops. And in the more recent times, as you all know very well, we have entered the endocrinology therapeutical area with the acquisition in 2019 of rights to Signifor, Signifor LAR and Isturisa from Novartis. Already in this space, we also pursue innovation by investing through our own research into potential new treatments for some rare and [indiscernible].

You can move to the next Slide 28, please. So in more detail, our key priorities and our 3-year outlook for Rare Diseases. We see potential for Recordati Rare Diseases to grow at a CAGR of around 15% through 2023, with a large portion of that growth coming from our Endo portfolio. Our list of priorities is extensive, but I want to focus on a few that are critical. We will continue to drive the uptake [ph] of Isturisa while we are still growing Signifor in the respective primary indications of Cushing's and Acromegaly, but we will also continue to grow Ledaga in EMEA and Juxtapid in Japan, and we will continue maximizing new opportunities in North America, especially Cystadrops and Carbaglu, a newly granted indication in organic acidemia.

While we're heavily investing in our growth of our organic portfolio, we are also committed to growing Recordati Rare Diseases through BD and M&A activities in order to reinforce our global portfolio and presence in the market. Regarding the revenue outlook, all regions are growing. North America is benefiting from the strong uptake of the Endo portfolio, and a decline of Panhematin would also be offset by the new product launches, uptakes, and new indications expansions in the metabolic

portfolio that I mentioned before, being Carbaglu in organic academia and Cystadrops.

Rest of world is maximizing opportunities in newly open markets including Juxtapid in Japan as mentioned earlier. With regards to EMEA, we expect to accelerate further from 2023 onwards positive to Isturisa reimbursement approval with growth of Endo, Ledaga and Cystodrops and some slowdown of Carbaglu. Finally, as you can on the bottom of the chart, we forecast ENDO portfolio doubling during the plan period…doubling in size during the plan period.

So if we can move to Slide 29, there is more focus on the Endo franchise. So if we take a deeper look at the Endo portfolio Signifor and Isturisa represent a significant opportunity for patient suffering from Cushing's and Acromegaly. In order to maximize the potential of these assets within reproductive rare diseases, there are several critical success factors that we need to achieve.

Let's begin on the left of the slide with Signifor on which we plan to grow in Acromegaly by accelerating the step up from first generation somatostatin analogs, but also continue to put new Cushing patients on therapy, particularly ones that can benefit from tumor shrinkage.

Regarding Isturisa on the right, we plan to differentiate the product, establish it as a new standard of care for Cushing's disease in the U.S. and Centrum in EU and Japan. We are also putting all initiatives in place to ensure that we have the appropriate level of access for patients to receive Isturisa, not just in the U.S. but also in EU and the rest of the world.

Finally, all this comes down to the execution by our country themes for strong engagement with KOLs and through leaders, and of course, through

the collaboration with patient efficacy groups all of whom approved very supportive [indiscernible] product

We can move to Slide 30, we will get a bit more insight on our expectations for the Endo franchise to continue on the topic. So taking all this into consideration, we expect that our global Endo franchise will deliver between 80 to 100 million in incremental net revenue by 2023, exceeding 200 million in net revenue by the same year or at the end of the plan period.

Most of the growth will come from Isturisa, but we also expect Signifor global net revenues to continue growing by around 10% per year with our ex-U.S., EU region growing by more than 50%. Understandably, there has been a lot of interest in better understanding Isturisa early uptake by all of you, and while we continue to want to be cautious in disclosing too much information since we deem it to be commercially sensitive. Before we would provide some insight on the traction today where the launch most advanced being the U.S.

On the right side of the slide, you can see the very positive Isturisa patient uptick we have in the U.S. from launch last year in May until the end of Quarter 1 2021. While we have close to 100 active patients on therapy and we expect the number of patients receiving treatment in the U.S. to exceed 500 by 2023.

Further momentum will come from the launch in Japan expecting in the second half of this year and for reimbursement in Europe. We will start seeing in key markets in the second half of this year and the first half of 2022. Our long term view remains for Isturisa to achieve a peak year sales estimate between €300 million to €315 [ph] million and with further potential outside beyond the plan years from the expansion of the

indication to Cushing's syndrome in the U.S. and the expansion in new territories globally.

If we move to Slide 31, please. So finally, on rare diseases, here is some additional detail around the other key products in the Recordati rare disease portfolio. As obviously, we have a very important franchise in metabolic diseases like I mentioned before, and here you can see on the right hand side of the slide some of the key assumptions underpinning the plan period product performance.

As I mentioned before, this portfolio represents significant portion of Recordati rare disease revenue. So I think it is worth mentioning that we expect to continue growth of several of these products over plan period including Carbaglu in the U.S. and Cystagon [ph] both in the U.S. and in the EU, Juxtapid in Japan and Ledaga in EMEA like I mentioned before, more than offsetting the erosion of pandemic in the U.S.

Overall, our rare disease business offers a solid and diversified portfolio with a global reach and demonstrated capabilities established over a number of years. Making Recordati rare disease also a strong partner of choice for innovative companies and research institutions investing in new therapies. We are committed to continue grow in the share of our business in rare diseases introducing new and innovative treatments for patients with academic [ph] very serious conditions.

So moving on to slide…I would say to Slide 33, so having forward our 2 businesses…business units specific of expectations and priorities for our existing portfolio. I would now briefly cover BD and R&D areas to explain how we plan to keep using them to further enhance our business over the coming years in long term.

So starting off with R&D, which as I mentioned when discovering our business model is a narrow we have historically made and we continue to make selective investments. Our SPC historically, the focus in SPC…historically the focus on…of our R&D activities has been primarily on life cycle management through formulation or indication expansions. With more clinical work done on rare diseases side with our own portfolio projects focus primarily on ultra-red [ph] conditions.

Following the recent deals, we do have a number of important projects on both areas of our business, even directly or through our partners. On SPC, the key ones are obviously around Eligard, with the development of a new easier to handle device where we are on track for regulatory submission by Q4 of 2021 and we have an approval expected by the second half of 2022. We clearly have also ours. We expect to engage the EU authority, regulatory authorities on the file [ph] submitted by Q3 of 2021 with an approval and launch expected by late 2022.

In addition to this also in SPC, we have pediatric investigation plan on going for an indication… pediatric indication expansion for Reagila and also…we are also looking to develop further our pediatric portfolio. On the other side on Recordati rare diseases focuses clearly on continuation of study supporting Signifor and Isturisa that we inherited from Novartis and supporting entry into new territories from a regulatory perspective while finalizing a plan to engage with the FDA on the potential indication expansion in the U.S.

We have 2 clinical stage programs always in the rare disease space, one is MT8 [ph] for neurotrophic keratitis which is in Phase 1/2 started with patients enrolled and we expect a study read out by second quarter of 2023, and also we have maple syrup urinary disease product which is expected to be filed in Q4 of 2021.

Moving on to BD, I think that…it is important that when we plan for the future, it is always a good idea to look at our history. In this chart, you can see clearly how BD…our Recordati's BD track record is an integral and fundamental part of our development history. We select 2007 as an entry in the rare disease business as an ideal starting point for the slide, even if BD journey of Recordati started even earlier in the late-90s when the group started to reinvest cash flows generated by Lercanidipine for the initial geographical expansion in the key Western European countries.

Since 2007 and the acquisition of Orphan Europe, we completed more than 30 transactions, both accretive and growth, both in SPC and in rare disease, with a total investment over 1.8 billion. And for us the period we have never stretched our net debt EBITDA ratio. Having in mind our history in the next few slides, we described what we plan to do for the future which is very much consistent as you will see with our development pathway and consistent with our already disclosed strategy in 2019.

So moving to Slide 35, starting with SPC, we will continue to look actively for licensing and acquisition opportunities, and we will continue to pursue the right mix of the innovation immediately accretive mature assets with turnaround potential and OTC brands. Also we will continue to invest preferably in our commercial or near to market opportunities. We do not plan to further expand our geographical region in the short term, but we would position ourselves as a regional partner of choice, leveraging on our commercial platform and proven integration capabilities.

Moving on to Slide 36, pertains to rare disease. In this space, we will continue to look actively for in licensing and acquisition opportunities

positioning ourselves as a worldwide partner of choice for development and commercialization of rare disease products.

While our preference remains for late stage opportunities, we are also keen to look at early stage assets for Recordati rare diseases partnering with other rare disease companies or research institutions. We will focus on our main therapeutical areas, well at the same time, we will remain opportunistic to explore different therapeutical areas leveraging on our solid experience in the rare disease space.

So finally, I will leave the floor to Luigi to take you through the core assumptions and drivers and targets for our 3-year plan. Luigi…

LUIGI LA CORTE: Thank you, Andrea. And you know on Slide 38, you will see sort of a summary of key assumptions and obviously I will not try and summarize everything that Andrea went through, hopefully we've given you, you know, some good color on both the key drivers of our current portfolio. But, also of the areas where we expect to focus…we will continue to focus our efforts from a BD and M&A perspective.

As you've seen, we expect a good underlying growth in both businesses despite FX headwinds which we will assume at round 1.5% per annum built into our forecast, with as we said, no material loss of exclusivities expected in the period. And of course we will continue to compliment our current portfolio with our M&A and BD, following a proven successful model and strategy and the share of Rare Disease as a percentage of the total business that we expect to continue to grow, from today 22% of revenue to over 25% of revenue by 2023. Now the exact split clearly will be subject to, you know the fact of deals that we will do and we have consistently said and as Andrea articulated, we are committed to continue investing in both of those businesses.

We expect margins to stay around their current levels of 38% in terms of EBITDA and 28% on adjusted net income reflecting our intent to continue investing behind the growth opportunities and particularly those that will materialize post-COVID. We of course, also expect to maintain the strong cash generation profile of the Group with free cash flow of around 100% of net income over the period of which we expect 60% per our dividend policy to be paid out and the balance being available for reinvestment in the business.

Thanks to the strong cash generation of the Group, we expect to achieve the objectives that we have set out with the net debt to EBITDA leverage ratio to stay between 1.5 and 1.8 times and clearly again here providing a small range as clearly it will depend on the timing at the time and the structure of the deals that we will do over the coming years. But as we have said before, you know allowing for and with the flexibility for that to temporarily increase up to a maximum of 3 times for real high quality opportunities which is consistent with the guidance we gave in 2019.

So then turning over to Slide 39, which summarizes clearly the key figures, we are reconfirming obviously the guidance for 2021, which is unchanged for this year and for 2023 including additional M&A and BD which we built into the Plan, we aim to achieve revenue of between €1.9 to €2 billion which at the base point of those ranges then we deliver a CAGR of over 10%; EBITDA of between €720 million and €760 million, again a CAGR of around 9% and adjusted net income of between €530 million and €560 million with a CAGR of around 10%.

And I will now hand it over to Andrea for some closing remarks.

ANDREA RECORDATI: So, if you can move to the Slide 40, of the presentation which are some of our financial projections and key takeaways. So in conclusions hopefully we have giving a good overview of the objectives we've set for the business for the next years and the key assumptions and drivers underpinning them. In summary, we aim to achieve appropriate growth of across both of our businesses current portfolios. We are close to 6% CAGR in SPC, up which thanks to the contribution of Eligard that we mentioned and a return to volume growth post-COVID of the rest of the business. And 15% CAGR for Rare Diseases with significant growth of our Endo franchise [indiscernible].

We aim to sustain a high level of profitability with a EBITDA margin of around 38% and adjusted net income of around 28% on revenues reflecting also continued investment behind our growth opportunities. We continue with our strong track record…we are planning to continue with our strong track record of turning the substantial part of those margins and profits into cash, with free cash flow to remain on average around 100% of the consolidated net income. We maintain a clear capital allocation policy with dividend payout of 60% of consolidated net income and the balance of the free cash flow reinvested in the business on both growth and accretive deals in both parts of the business.

And we aim to preserve a strong balance sheet, like Luigi mentioned just a moment ago, with the net debt around current levels of 1.5, likely to fluctuate between 1.5 to 1.8 depending on the timing, the structure and the type of deals being again growth for accretive, but ready to go up to max of 3 times for really and I underline, really high quality opportunities.

So, moving to the last slide of the presentation, so finally before opening to Q&A, in recent times, we have also worked to the strength the team in recent time and years, not only obviously across the organization, but also

at top management level, to obviously ensure the efficacious management of our growing and more complex organization and in order to drive more effectively towards the achievement of the goals.

So, with me here today, in addition to Fritz Squindo, whom all of you know, and is currently the Group General Manger and there is also Corrado Castellucci, who is the Head of our Rare Disease business and has been so far many years. Obviously, Luigi La Corte, our CFO, Group EFO since 2019, but also I have to…joining here today also Scott Pescatore who joined the Group in February 2020 as Head of Operation for Recordati Rare Diseases joined from AstraZeneca and before then having spent many years for Novartis in the Rare Diseases Division in Europe with a good and deep knowledge of our Endo portfolio. And finally, but not least, Alberto Martinez who joined the Group in January of this year to head our SPC business, joining from Mundipharm where he held in his latest role that of President and CEO of EMEA.

So, having concluded our presentation I think we can move on to the Q&A session. Thank you very much for listening.

Q&A

OPERATOR: 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 yourself from the question queue please "*" and "2." We kindly ask to use handsets while asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from Martino De Ambroggi of Equita. Please go ahead.

MARTINO DE AMBROGGI: Thank you, good afternoon, everybody. The first is an obvious question on the like-for-like growth, in the previous Plan, I know it's not unusual for you to include acquisitions in the long-term target. But in the previous plan you presented a 50% organic growth of 50% coming from acquisitions. Is it still the case, 50-50, or based on the existing portfolio you have a more visibility on the portion related to the like-for-like growth.

And the second question always on the guidance just to have an idea of where R&D costs are envisaged in your '23 target or what's the range over the 3-year period. And the third question is on just a clarification on what do you mean for acceptable valuations in your slide #38, when you talk about M&A you underline acceptable valuation for M&A. So, just to understand what you mean in the current market environment?

LUIGI LA CORTE: Okay. Thank you, Martino. In terms of like-for-like growth, I mean it kind of depends on how you consider Eligard, as Eligard was not in the 2020 base. So if looking at it on a sort of consistent base, with how you would have looked at it in 2019, I think you know, that 50-50 would still apply. And hopefully we have given you quite a bit of sort of color on the drivers of, you know, the growth of the portfolio, which we already have today, to be able to get a sense of the growth of the current portfolio.

With regards to R&D, you know we'd expect R&D to be between 10% and 11%. Now, don't forget, you know, close to over 40% of our R&D cost is actually amortization of licenses that will depend also on the type of deals that we do, it is an acquisition, with goodwill which is not amortized obviously will not add to that, if we do…if we acquire product rights which are amortized, you know, clearly the R&D line will be on the

higher end of that range. I think acceptable valuations means they will continue to be as disciplined as we've always been. I don't know Andrea.

ANDREA RECORDATI: It means keep our good discipline in not overpaying for acquisitions, whatever they may be, okay. So this has been you know part of our way of doing things until now, and we are not planning to change this. So clearly every deal or growth deal has different multiples from an accretive deals, but clearly you know every case is a different case. So the main kind of point is discipline and not overpaying. Hope that answers your question.

MARTINO DE AMBROGGI: Yes, thank you. Just a follow up for the first question Luigi. 50-50 is considering Eligard as M&A or organic?

LUIGI LA CORTE: No, if you were…you were comparing it to the guidance which broad guidance which was given in 2019, and I am saying…what I am saying is, if you are doing it like that, then you'd have to take into account that 2020 base that the CAGR is built on obviously didn't have Eligard in that.

MARTINO DE AMBROGGI: So if we include Eligard which is in the pocket today, you have more visibility than the 50% on that…

LUIGI LA CORTE: Yes, of course.

MARTINO DE AMBROGGI: And if I may, a last question on the strategic optionality. I clearly understand it is not an issue today, but would it make sense in the medium term to separate the rare disease business through as a spin off separate listing merger with another to become larger. I don't know, strategic optionality on the rare disease is something that could be taken into account?

LUIGI LA CORTE: At this moment in time, we believe that you know keeping the 2 businesses combined is fundamental for the development of both, and I think that also for rare diseases, you know, having a strong cash generation generated by SPC is a major asset for rare diseases, because it allows solvency to be more ambitious and invest in a more ambitious way on the development of that part of the business. So today you can never say never Martino, but you know today we are not planning, we are not evenly remotely thinking about something like that.

MARTINO DE AMBROGGI: Very clear, is there any size…ideal size for the rare disease business to think about it, or…?

LUIGI LA CORTE: No, we cannot generalize on assumptions around size, I mean, it depends on the opportunity. We look at a lot of opportunities. We get new opportunities over time. Today, I wouldn't kind of give you a ballpark number for size around opportunity, so we look for rare diseases. It depends on the product addition, it depends on the portfolio, it depends on us. So every case is different and gets measured and weighted ad hoc.

MARTINO DE AMBROGGI: Thank you.

LUIGI LA CORTE: You're welcome.

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

JO WALTON: Thank you. Firstly, can I say what an excellent presentation it was, you've really set out the parameter of the company, it will make it a lot easier for new investors to understand your company, so well done? My second…my 4 questions please. I have 2 product ones and 2 more strategic ones. So the product ones, the first one is on Isturisa, how confident are you that you don't need more studies in order to be able to

extend the indication to Cushing's syndrome in the U.S. I believe you've felt in the past that you haven't leaded those, but you are still going to have a discussion with the FDA although not until next year. So just a little bit on why it's taking you so long and what the risks are, and what you could be asked additionally to do, and perhaps if you are lucky enough to be able to file with what you have, what the peak additional sales might be?

My second question is on Reagila. You've said that the UK and France is not in your plan, it's an opportunity to you, an upside opportunity, but you need to be able to get a good pricing there. I wonder if you could just talk about some of the positives and negatives in the…you know so that we can try and handicap the likelihood that you would be able to get that within the planned timeframe?

And then my strategic questions, one of them is I think a little bit mean, but I'll try it anyway. So looking back in 2019, you were expecting to be able to do in 2021, clearly it was about 1.7 billion, you're coming in quite a bit short of that. And I appreciate there's been a massive pandemic in the meantime. But if we were to characterize crudely the mis there, would it be that you haven't been able to find as many acquisitions as you had hoped to be able to do over that timeframe? And looking a bit more forward, I wonder if you could talk a bit about the balance of your M&A objectives between getting new specialty type products to go into your rare disease franchise, and buying tail assets which are immediately accretive. And if you could just talk a little bit about the pricing, the level of opportunity that you have in that, that would be very helpful for us?

And my very final question, and I apologize for taking so long, just looking at R&D, as you've said yourself, your R&D 10% of sales are in that…that's lower by industry standards particularly low for innovative

pharma companies by industry standards, and yet within that you've got a high level of amortization. So looking forward, could you tell us a little bit about what your objectives are in terms of building up you know, a genuine development franchise or development capability, so that you are more able to buy, and let's say mid stage asset and finish them off for the market, rather than being somewhat more restricted perhaps to late stage assets like Isturisa which was just ready to roll or tail assets? There is a whole sort of section in the middle which you don't seem to be able to address at the moment? Thank you.

ANDREA RECORDATI: Okay, maybe I will let Scott Pescatore take the first question, Jo on Isturisa regarding the indication expansion in the U.S.

SCOTT PESCATORE: Yes. Good afternoon, everybody, and thanks for the opportunity. So it's always been, you know, our plan to have a possible global expansion to the U.S. for Cushing's syndrome. Any sort of peak opportunity or upside in the Plan, like we won't be sharing the details, but it would fall outside the planning period.

You know, as you mentioned, we don't have any current timelines for the approval of the Cushing's syndrome medication, we have to meet with the FDA first. We have a robust data package that we can bring to the FDA. But first, we need to understand exactly what the requirements would be in order for us to achieve that label extension. What I can tell you, though, is that we don't expect to start any new clinical trials to generate that data. But data generation through real world evidence and another means would be our proposed strategy for any [indiscernible] that would be needed..

ANDREA RECORDATI: Okay. Reagila, I will let Alberto Martinez speak on this question.

ALBERTO MARTINEZ: Thank you very much. Good afternoon, everyone. On your question around the opportunity for Reagila in U.K. and France, I am afraid the situation in France is difficult and is unlikely to get a reimbursement from a realistic perspective. And so I don't think, we should consider that as an option. However, we are actively working on it and continue to work on it with the French authorities and certainly will not give up for the patients with schizophrenia in the French market.

In the U.K., we are in the market, and we are actively promoting. However, we face significant hurdles in terms of access and the team is rethinking and revisiting the opportunity, they are looking at new ways of approaching the promotion of the product on lifting the hurdles that we're facing from a market access perspective. I would say the options in the U.K. to improve the position of Reagila are somehow more positive than those in France, as some potential upside. But we have been prudent and cautious in our projections for these products.

ANDREA RECORDATI: Yes. Exactly. What, I mean, so let… I reiterate what I said before, just to reiterate what Alberto said that we did not build this in our forecast, okay. So the U.K. and France for Regalia are out, and to say it's important. France, obviously we are…that we all know that it's extremely tough market, the market access wise than the U.K. We are on the market, like Alberto said, but it's just a matter of, let's say, the penetration of the different mental health costs has being taking longer than expected. But we are obviously working on it. And so that we are getting access to them. And so the uptake is slower than what we expected. But it is…we will get there eventually.

Regarding the 2019 objective of 1.7, we can respond [indiscernible], I guess. I can tell you that for sure. COVID has an impact. I think obviously, I don't remember honestly the FX impact that we had in our

Plan, but it's probably more or less aligned. Clearly, we have also…we've had our headwinds within the business. Regarding M&A, I will let….

LUIGI LA CORTE: Now, I think you know if you do this…if you do the math, if you take the 2021 numbers of Eligard and the contribution we've had from the endo franchise, I think you'll see and plus the other bits and pieces, the smaller bits and pieces with…we've gone. I wouldn't say that it's been a sort of a shortage on M&A. I mean, at the end of the day, as you said, I mean, we unfortunately no one, as I said, predicted the market conditions, which unfolded since the beginning of last year. And that's really the key driver of the variance.

And very shortly after the 2019 Plan was announced, the deal with Novartis was announced, right now, it's a slightly different position. We've just in the last couple of months…the last few months announced the deal with [indiscernible] again, which is why, you know, I'd say it's very difficult to compare that sort of split in 2019 versus, you know what, maybe the sort of split now. I hope that makes sense.

On the R&D…

COMPANY REPRESENTATIVE: You know, Andrea. It was a balance of objectives on [indiscernible]. Joe, if I recall correctly, the other question was, do you want more insights on how we build, if I understood correctly, our M&A component or business development components in our numbers, our 2023 numbers between Rare Diseases….

JO WALTON: It's the balance between older products…tailored products, which are immediately accretive. And buying more specialty type products, which may take a little while longer. So as we're trying to think about how much money you're likely to need to spend to get to your objectives? And it's

relatively easy to work that out from the tail point of view. But I'm assuming that you're also keen to do more deals that will get you products at the beginning of their life cycle rather than at the end of their life cycle.

LUIGI LA CORTE: And I think if you've said it right, Jo, I think in terms of the way we thought about the target and the overlay, I mean, if you look at the last 5 years, we've done on average between €200 million and €250 million on BD. You know, that was not been a sort of consistent, I mean, some years we did north of €300 million, some years we did less. And we built our sort of targets around that, and the leverage is…assumption is consistent with this. And of course, within that, we're aiming to do both [indiscernible] deals and accretive.

ANDREA RECORDATI: But we gave ourselves an objective of, you know, additional, you know, obviously additional growth, but that we don't know this moment exactly where that growth is going to come, we clearly have ideas of where we want to go. We want to pursue growth in Rare Diseases with growth deals. But at the same time, we also want to keep, you know, sustaining and developing with accretive deals in Rare Diseases business I would say not only. So it's a mixture, so I think you need to take the number. You need to take our range of predicative EBITDA, kind of, let's say range. And obviously of the net of EBITDA to the net debt and calculate from there. I mean, but we don't want to give a further kind of insight into this. I mean, it's impossible to do.

COMPANY REPRESENTATIVE: And on the sort of…on your question around R&D, I mean, you're right. I mean, I don't think we have ever sort of pretended it to be otherwise, that relative we're not a sort of company, which has part of its business model, a significant investment in R&D and pipeline on a cash basis. As we set out on Slide 4, you know, we actually sort of look to take…make selective investments in R&D. And whilst as we said we are

open to opportunities, which are in late potential mid stage development in rare diseases. Now, rare disease is also an area where there's not a lot of difference between sort of mid stage and late stage. We're certainly open for that. And we do think we have the capabilities for that. But, if you just look historically our track record over the last 10 years, the growth has been both sort of on market and BD driven as opposed to product coming from our R&D pipeline. Hope that makes sense and answers your question.

JO WALTON: Thank you.

COMPANY REPRESENTATIVE: Next question, operator?

OPERATOR: Yes, the next question is from KC Arikatla of Goldman Sachs. Please go ahead.

KC ARIKATLA: Thank you, everyone. Thanks for taking my questions. I have a few please. The first one, if I look at your specialty division, you have now built a sales force CNS with Reagila and for urology through Urorec and Eligard. As you think about in licensing strategy for this division. Are you looking at assets where you already have a presence and want to build on the operating leverage or are you focused on also expanding into other therapeutic areas within specialty? That's the first one.

Second one, what is your view on incremental pricing pressure in Europe as economies come out of COVID? Is this something that you have incorporated in your Business Plan, please?

Third one on China opportunity for Isturisa, you make it very clear that that is an upside and not in your Business Plan. I am just wondering the driver behind that delay? Is this because you need to undertake additional

trials to be approved in China or are there any other commercial hurdles for Isturisa to launch in China?

And final one, if you could just provide an update on the clinical projects that you have undertaken historically be it retinopathy prematurity or maple syrup urine disease? When can we expect clinical updates here? And if you could confirm if there's any contribution from them in your Business Plan? Thank you.

COMPANY REPRESENTATIVE: First question. I'll answer the first question KC. So regarding the SPC, you know, obviously ideally, I mean, our objective is to reinforce and look for assets. Let it be you know, in license, growth assets or crucial ones going to fit with our current presence on the field. And which line or within our current areas of expertise goes without saying. So we're also looking at…we're looking at urology, we're looking at cardiovascular, we're looking to gas intestinal. And we're also obviously looking to CNS to some extent, because clearly, we've set up you know, structure to promote Reagila. And we would like to build more critical mass and synergy let's say on the promotional targets, with the addition of other products. However, let's always keep in mind that, you know, we are…we always give some degree of opportunistic approach in when we look at you know, different assets deal. So we also look at other stuff, but we tend to focus more on areas. The answer to the question is, we tend to focus more on therapeutical areas where we already have a strong presence both on the field and in our let's say know-how.

COMPANY REPRESENTATIVE: Maybe on pricing, KC, you know, we still at this stage do not see significant sort of more higher pricing pressure in Europe over the next few years. I mean historically over the last years on SPC, we've seen sort of price erosion of plus or minus 1% higher in years…slightly higher in years where we lost exclusivity. But we're on average for total group and

they've gone up to 2, and we don't see a wall of new price measures being taken. Don't forget you know, pricing, reimbursement, generic policies in Europe are still decided on a market by…or country-by-country basis, they're not decided at pan-European level. So it doesn't…we don't see sort of governments starting to act on that debt. So honestly, we don't…we're just not seeing, and I think I may have mentioned in some calls have noted in the past, we've seen one price reduction across the portfolio last year as a result of COVID being additional 10% discount in Spain on products which were going generic, which impacted pitavastatin. On the other hand, we've seen Italian authorities increase you know, the level of healthcare budget, and where pharmaceutical spend is sent as percentage of healthcare you know, that's allowed higher ceiling for total country pharmaceutical spend. Doesn't impact us significantly either way, but just as…just to say, we're not seeing significantly increasing pricing pressure over the next years.

COMPANY REPRESENTATIVE: The next question was I think on China right?

SCOTT PESCATORE: This is Scott, I will take the question and add some additional details on our expansion in China. And you're absolutely right, that's a key strategic priority for us moving into new territory. China offers a large opportunity for us outside of the planning period. Just to give you some additional insight into what we've been doing so far, we hired General Manager who started in Quarter 1 this year. And we also began…we approached an agency to begin discussing with the filing requirements for our products that we'll be launching there with the China FDA. So things are progressing there and we will continue to build out the organization, as we also have opened headquarters in Beijing. So it's more to do with regulatory timelines and interaction with authorities. And you know, the same applies to the FDA on the label expansion opportunity, which we've always said there's an upside to the guidance that we've given where the

FDA clearly has quite a backlog following COVID as we understand it. So again, it's more to do with regulatory timelines and building a data packet based on what we have and the evidence which we continue to accrue through the use of Isturisa in the market.

COMPANY REPRESENTATIVE: Okay, I think the last one was on some timelines around our pipeline development, right KC?

KC ARIKATLA: That's correct. You had announced back in [multiple speakers]?

ANDREA RECORDATI: You mentioned MSUD, the micro syrup and MTA. So like I mentioned for MTA, I mean, we're still in early phase. I mean, we're expecting a study, read out of the Phase 1, Phase 2 study is expected by Q2 2023. So it's towards obviously end of the plan period. And also when it comes to MSUD, we are expecting to file at the end of this year, but we're expecting an approval in the first half of 2023 approximately. Just to give you a bit more kind of [multiple speakers].

KC ARIKATLA: And on MTA, I mean, it's fair to say. I mean, it's true for all studies, but even more where patients are rare. I mean, obviously the pandemic is generating…has carried some delay in terms of patient enrollment.

ANDREA RECORDATI: We have to be honest. Yes, absolutely, recruitment of new patients for studies, you know, any clinical development study has obviously been impacted you know, quite negatively by the COVID pandemic, which is totally understandable clearly. So but there for a moment our study readout is still planned for the second quarter of 2023 then we will update you, it might be still feasible.

KC ARIKATLA: Thank you.

ANDREA RECORDATI: You're welcome KC.

OPERATOR: The next question is from Rajan Sharma of Deutsche Bank. Please go ahead.

RAJAN SHARMA: Hi, and thanks for the question. First one, you mentioned that you'd be comfortable going to kind of 3 times leverage for really high-quality opportunities. So just be interested if you could define what you see as a really high-quality opportunity perhaps profile of potential asset there? And then secondly, could you just provide your thoughts on CDC and long-term in a business, given that they've been involved for every year now. Can you just perhaps give us an update on how you see that progressing going forward? And then, thirdly just on the BD teams again, the types of deals that you've talked to potentially doing, particularly in the rare disease base are in high demand. So how confident are you personally in closing these deals and what advantages do you see the group having versus competitors in this regard? Thanks.

ANDREA RECORDATI: So maybe I'll start with the CDC one to get off the table. So I mean CDC has been together invest in the company for approximately 2 years now and honestly, they're committed to remain invested in the company for some years to come. I mean, they see a lot of potential you know, in the growth potential of the company, they're very happy with their investments, the collaboration is excellent, with the management of a company. So I think on that I can say…that's all I can say on that. So I wouldn't add anything else. We don't expect any substantial exits you know, shortly or stuff like that from what I can say and see.

COMPANY REPRESENTATIVE: Now Rajan. First of all, I look forward to connecting and thank you for starting to cover the stock. With regard to leverage, first of all just to be very clear, for those of you maybe newer to Recordati. I mean,

clearly the guidance that we provided in terms of EBITDA is not built on an expectation of 3 times, that's just to say that, well, we've set our sort of targets on the basis of an estimated leverage of 1.5 to 1.8. We just want to make sure it's clear that we would not be constraining ourselves through those level. If we find an opportunity which is compelling, a strong strategic fit and it generates a value for the business. So it's more to speak to the flexibility that as an organization we have on the back of the results that we deliver in terms of both profits and cash flow. So I think that's how to think about it.

And in terms of BD and you know, what being in high demand. Frankly, that's in our experience never…there's nothing new. I mean, good assets have always been in competition. We have a very strong and established infrastructure in Europe on the specialty primary care side, which is appealing for many. We're not a newcomer to rare diseases. We've been in rare diseases since 2007. We have established capabilities and you know, we've picked up as recently as 2019, 2 great assets from Novartis, so and I'm sure we'll continue to do so. So and again, good assets have always been in competition from our point of view, and the track record of the company, we'd like to think is fairly robust in terms of executing on M&A and BD. I hope that answers your question.

RAJAN SHARMA: Yes, thank you very much.

OPERATOR: The next question is from Katerina Tchakalski of BlackRock. Please go ahead.

KATERINA TCHAKALSKI: Hi, good afternoon. So you talked about your leverage target at the OpCo level. Do you have any information to the market about what your intentions are for the expensive bonds that are sitting at the Rossini level?

ANDREA RECORDATI: No, I'm sorry that we have nothing to do with the Rossini level, sort of financing, you'd have to ask that question to Rossini. I believe in the Q1, when they sort of gave their update at the end of the year, they said they have no current plans, but we honestly do not have any info or insights into that.

KATERINA TCHAKALSKI: Okay. Thanks.

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

ISACCO BRAMBILLA: Hi, good afternoon, everybody. Thanks for taking my questions. I have 3. The first one is a follow-up on the building block, of your expectations in terms of turnover growth. If we take the midpoint of your 2023 target, so roughly speaking €500 million related to [indiscernible], is it correct to assume that some 70% of this cumulative growth is related to products which are currently in your perimeter and just some 25%, 30% coming from future M&A.

Second question is on your target in terms of profitability. For a Group going increasingly towards a more profitable segment of Rare Diseases, it is somehow comforting too if you were to see EBITDA margin target in line with one of the past Business Plan, so can you provide more color on the assumption on your margin which is embedded in your 38% EBITDA margin target.

And the last question is on license. Can you provide more color on the amount of milestones which is included in your financial leverage target as of 2023?

LUIGI LA CORTE: Thank you for your question. Sorry, if I disappoint on the first one in terms of say, you know, a range is range and I will not try and take the midpoint of the range in terms of what, you know, assuming we achieve that, one of that would be from current portfolio versus BD.

You know, we have given a range which is consistent what sort of peers would do and we have given also quite a bit of color on what we think the current portfolio should be able to deliver. Of course, it is never A plus B equals C. You know, we are giving a range which is a composition of what we believe we will deliver to the organic portfolio and what we will deliver through BD continuing to invest at a level that is consistent with what we have done in the past and going for both growth and accretive deals and without wanting or being able to exactly second guess over the next 3 years which ones we will do and what time and so and so. I think you have to accept that that's the way we will leave that one.

With regards to profitability, I think we said consistently that margins over the course of 2020 and also now over the course of 2021 are enhanced by the impact that COVID has by putting pressure on the topline but at the same time reducing our level of activity spend and again, we want to make sure that and reflecting through this targets the intent to continue to invest behind the growth the business, particularly once market conditions will return to normal.

In terms of milestones, assume around €100 million, €110 million in each of 2021 and 2022. Of 2021 number, as I said, we have already paid close to €50 million of that in the first quarter being the milestone for Eligard and [indiscernible]. So hopefully, that addresses your question again. Apologies if I am sticking to the guidance on the range.

ISACCO BRAMBILLA: Okay. That's great. Thank you.

OPERATOR: As a reminder, if you wish to register for a question, please press "*" and "1" on your telephone. The next question is from Niccolo Storer of Kepler. Please go ahead.

NICCOLO STORER: Good afternoon, gentlemen. Thank you for taking my questions. 2, if I may. The first one, I would like to come back a bit on profitability and the assumptions on your Business Plan. I was wondering whether we can see during the plan period some operating leverage coming come Isturisa, meaning if you plan to have higher profitability in 2023 versus the one you have today on that specific product and how this fits into your guidance of the 38% margin.

The second shorter one on your net financial position target, how much buyback are you assuming in your 1.5, 1.8 time target? Thank you.

LUIGI LA CORTE: So Niccolo, we have never given sort of profitability by product and so firstly, we can't…we are not going to start doing that on Isturisa. I mean, you know, of course, and as we said, we did say, there will be some growth of Rare Disease percent to total, thanks to the growth of the Endo franchise over the period, but we are committed to invest and grow both businesses, but again, we don't provide sort of profitability by product.

In terms of net financial position, you should assume a level of buyback consistent with the average of what we have done over the last years, which was really to sort of, cater to the management long-term incentive plan. So we have not built into sort of those leverage targets any sort of buyback over and above that, if that makes sense.

NICCOLO STORER: Okay, cool. Thank you.

OPERATOR: Once again, if you wish to ask a question, please press "*" and "1" on your telephone. The next question is a follow-up from Isacco Brambilla of Mediobanca. Please go ahead.

ISACCO BRAMBILLA: Hi, just one from my side. For what concerns ARS license. Is there any kind of turnover from this product included in your 2023 target?

LUIGI FELICE: Only marginal to be honest, Niccolo [ph]. We have always said, this would of launch sort of mainly in 2022. And so, it has end up don't forget I mean in Europe obviously, you know, launching is one thing than you go through the imbursement process. So, no…yes…

ANDREA RECORDATI: There is marginal sales and there is still investments that you know, launch investments like its normal for a product under launch phase. So it's actually…and now it's actually a negative impact like it is normal [indiscernible] under launch which also applies clearly to Isturisa which is [indiscernible].

ISACCO BRAMBILLA: Okay. It is very clear. Thank you.

OPERATOR: Once again, if you wish to ask a question, please press "*" and "1" on your telephone. The next question is a follow-up from Jo Walton of Credit Suisse. Please go ahead.

JO WALTON: Thank you. Just a couple of questions about…again about your future investments, are there any other countries where you would like to move from stay distributor model to how your own footprint, and are any of those so geographic expansions included over the next couple of years. What countries might they be? And also, if you could tell us a little bit about your objectives in OTC rather than prescription, do you see a difference in that. Do you want to be more involved in products where the

patients pay themselves or more involved in government pay? And finally, because it's the market that's relatively important to you, but we don't hear much about from other people, I wonder if you could tell us a little bit about your view of the outlook for the Turkish market? Thank you.

ANDREA RECORDATI: So, for countries where we are planning to move from a distributor that's Turkey for sure for rare diseases, okay. Clearly, we are planning to enter during the course of plan in China. But, also that is going to be, you know, a partial, you know, it would be the start of the entry.

And on SPC, I don't recall now, we don't have any plans to kind of move from our distributor. I mean, as we said before in the presentation our plan is to remain, you know, present in the countries…already present as now, and be regional player for SPC.

Regarding the other question was…on the OTC portfolio, I mean it continues to be an integral part of the SPC portfolio I mean…

COMPANY REPRESENTATIVE: We like the diversification Jo. So we likely think that diversification within SPC, you know, between [indiscernible] OTX, OTCs, and we would keep on pursuing, you know, a mixture of you know, BD activities around reinforcing all those areas.

COMPANY REPRESENTATIVE: And on Turkey maybe I will let Alberto say, a little bit more in terms of sort of current dynamics in the field in Turkey. But, fundamental view on the market longer term remains positive, both in terms of volumes, and in terms of pricing. And of course, the currencies [technical difficulty] these days, and we suffer from that and Turkey is under some restrictions that is been on from a COVID perspective. Alberto, do you want comment on sort of the current environment there?

ALBERTO MARTINEZ: Yes, with pleasure. Turkey is being particularly these days affected with COVID restrictions, there is a current lockdown and somehow hindering the ability of our salesforce to access health care professionals, that is clearly distorting the activity but the growth in the market, the demand remains…our business remains very strong and our commitment to continuing to grow our business in Turkey, is intact is actually one of the large operations within SPC in the Recordati.

COMPANY REPRESENTATIVE: And regarding, you know, pricing around Turkey or better currency issues, obviously that we mentioned on Slide 38 that we have built a general minus 1.5% of FX headwinds which is clearly does not only applies to Turkey, applies to the whole group. But clearly whole point of that, is attributable to go to Turkey, but we are not going to give that full detail. But, you know, like Alberto said, I mean for us it remains a few markets, we still see a lot of potential in growth in the market, and we are happy with our…with our size. We are not planning to do any M&A deals, I think we already have a very good critical mass and it is working well for us.

JO WALTON: And could I finally ask you, I think you said your maple syrup urine disease. You would be able to file at the end of this year. But, you wouldn't get an approval to the first half of 2023? Is there any reason why it's such a long approval period or maybe I missed heard?

COMPANY REPRESENTATIVE: I'll let Corrado Castellucci answer this one.

CORRADO CASTELLUCCI: Hi, Jo. What we are going to do for maple syrup disease is built a package based on real world evidence. We will file with that package, but prior to that we are going to consult the EMA and check whether this is going to be enough, and we are not going to need more. So this is pending

on the impact to the positive opinion of EMA. We are seeking to have meeting with the agency before the end of the year, and hopefully be clear through and have the chance to file at that point in time. And then, the usual, you know, time lag for the approval through EMA.

COMPANY REPRESENTATIVE: So, there is a bit of healthy caution also in this time line, okay.

CORRADO CASTELLUCCI: Well, it depends on the package.

COMPANY REPRESENTATIVE: Well, but it depends on the package.

JO WALTON: Thank you.

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

ANDREA RECORDATI: So, thank you very much everybody for having joined our presentation today, and for your very interesting questions and have a good afternoon or evening depending where you are. Bye-bye.