DiaSorin S.p.A.

"Full Year 2022 Results Conference Call" Monday, March 27, 2023, 15:00 CET

MODERATORS: CARLO ROSA, CHIEF EXECUTIVE OFFICER PIERGIORGIO PEDRON, CHIEF FINANCIAL OFFICER OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the DiaSorin Full Year 2022 Results 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 Mr. Carlo Rosa, CEO of DiaSorin. Please go ahead, sir.

CARLO ROSA: Yes, thank you operator. Ladies and gentlemen, good afternoon. Welcome to the year-end 2022 results call. As usual, I'm going to make some remarks about the business and then I will leave the microphone to the CFO to go through the actual numbers and guidance for next year.

So let's start to discuss 2022. As usual, I'm making comments at constant exchange rate to understand how the business did progress in last year. As you know, we have...we are now used to represent the business looking at 3 different legs of the company, the immuno franchise, which is roughly €700 million business, the molecular business and the LTG business.

The immuno franchise last year grew 3% with different results depending on the different geographies. We have North America that grew doubledigits over 10% as a result of the hospital strategy that I think we have discussed over the last calls. The initial strategy was initiated in end of 2019 and the idea was to add resources to support deployment of systems in the hospital setting in the U.S.. We achieved by the end of 2022 the target we had which was to add 150 new hospitals. And the program has been so successful that we decided to continue to invest in this segment. We hired 20 more reps in Q4 last year and we gave our self the target to now add to the customer that we have in that segment over 250 hospitals in the next 3 years, as discussed many times this strategy is fundamentally centered around certain specialty products that we have today available in the U.S. and we are adding in the next 3 years as part of the immunoassay menu development effort.

Clearly, we are talking about products like MeMed, like the Lyme disease, like new products we have in mind for gastro-enteric, so we are talking about higher reward specialty products very differentiating that clearly will generate revenues at high margin, but at the same time do require investment in terms of resources to be allocated for the promotion and education, especially the education of some of the end-users of these products which are not the labs but are the clinicians.

When it comes to Europe, Europe grew 4% last year which is in line with what we historically achieved in this geography, remember this blend of Europe and Italy where we are clearly overly penetrated in the main regions as discussed many times, Europe for us is a geography where we expect steady growth, where we have an installed base in hospitals of over 2,000 systems that do benefit by an add-on strategy.

Clearly, the difficulty of Europe is that when it comes to the introduction of new products and new product meaning those products, we are...you need to educate the clinicians. You need an effort that goes country-bycountry and not necessarily is directed to a single larger geography like the U.S. So we need to be extremely choosy when it comes to in the market that are worth investing in, because it's the effort quite often that does not commensurate to the market opportunity. Anyway Europe continues to be for the soaring of flagship territory with...and we believe that 3%, 4% per year is fundamentally what we need to continue to guarantee and we will continue to achieve with our immuno franchise.

Now, let's go outside the rest of the world, the rest of the word actually declined 4%, and that's actually a combination of 2 different groups of countries, countries that are doing very well for us where we...today we work directly and namely as Brazil, which grew high single-digit, is India that grew double-digit and Mexico double-digit growth, and Australia, high single-digit because we are highly penetrated. And a different group of countries where the business did suffer last year, primarily in China, where our business declined 14% year-on-year as a consequence of declining volumes, the COVID situation and the kick-start of some of the program that are driving prices of certain process and products down by 30% compared to previous years.

We also suffered in other secondary geographies like Iran and clearly Russia, where we had business, certainly in Iran was not marginal. That because of what happened in the last few months clearly got to a stop in the second part of the year. Overall, although the immuno franchise I think is solid in terms of growth, in terms of success although in those geographies where the company has invested, and in terms of prospective growth funded by the new products that we have discussed and we are bringing to the different markets.

Now, let's go to Molecular. Molecular is a little bit more complicated because there is a change of perimeter that took place in 2021 with the acquisition of Luminex. So if I can make a general comment on Molecular, which is for us over \$200 million or euros of business, the business is stable, notwithstanding the fact that as we know in the multiplexing side, we are offering products which are getting old and will be replaced by the LIAISON Plex that I'm going to comment after this.

The business is stable and certainly with an acceleration in Q4 where the business grew actually 18%, but that has been driven by the very strong respiratory flu season that as I think you've seen for all the companies that have been working in this space was extremely strong in Q4. But by the same token, the flu peak was pretty much done and over with by December. So in Q1 of 2023, we expect a slow start in respiratory.

Anyway, as said the business is a combination of the DiaSorin single plex business, which continues fundamentally it's path of single-digit growth, very profitable, and the Luminex business, which is fundamentally multiplexing, which again, is stable depending on the respiratory as we discussed. And then we have some legacy Luminex business, like the ARIES, which is lingering. And as we've been discussing, we are evaluating options moving forward to consolidating some of these platforms into existing DiaSorin platforms.

Let's move to LTG. The LTG again, difficult to give year-on-year comparison, again because of change of perimeter in 2021. However, we've always stated that the LTG is a business that is very profitable and where we expect a growth of 7%, 8% per year, so a single-digit. We had slowdown of the business in Q4 on the instrument side. I think as we have discussed, because of supply chain issues with parts and electronic components. So if we dissect the LTG, we had 7%, 8% growth on the royalty side and on the bid business following the trajectory of our partners that continue clearly to sell their products in the research market. And we had in the second half, we had a decline on instruments, and not because we are missing orders, but because we were missing parts. I believe that comes H1 in 2023 this situation should be addressed and resolved and we should then see our LTG overall franchise continuing to grow at historical rates.

Now, let me move to the 2023, and we decided in order to make the numbers comprehensible to discuss the numbers of the projection ex-COVID. So, and I'm going to make a comment on COVID and exrespiratory, because when it comes to respiratory, there is...clearly there is a strong seasonal impact, and we made an assumption on respiratory, but truly we need to understand to see what will happen in Quarter 4, then to understand the business impact, positive or negative, versus what we forecast.

So if we look at the business, ex-COVID, ex-respiratory, we expect a growth of 4% to 6% where we see the immunoassay franchise to continue to grow mid-single-digit with a strong impact on from North America, again, Europe in the low single-digit numbers, and we expect China starting from H2 to recover, so not to be a drag compared to last year. And also you know, the effect of Russia and where we have sold in 2021 and not sold in 2022 is going to be now washed away in 2023 in terms of comparison. And so we also expect the rest of the world business overall to contribute to the growth of the business.

When it comes to the LTG, as said we believe that the supply chain issue should be addressed by the end of H1, and therefore we expect high single-digit growth in line with past expectations. Let me also add a comment here. As part of our attempt to recover from the increase of cost due to inflationary pressure, we have, starting from...beginning of 2023 we have increased prices of instruments and components to our partners following the pricing policy that partners applied to their end-user customers. And so we expect that there is going to be a low single-digit positive impact starting from Q2 and Q3 to the revenues that we get in LTG selling, again, instruments and components to partners. So we believe that fundamentally the LTG will continue its trajectory and a

margin contribution improvement compared to 2022 due to the fact that we'll be able now to overcome certain cost increase we had especially on spare parts and instruments.

When it comes to Molecular, we expect the business to continue to be stable notwithstanding the fact that as we will discuss, we're not going to see a contribution from Plex and NES in 2023, although there is an element of this business that we need to remark, and that has to do with the fact that Luminex already prior to the acquisition had lost a significant contract with one of the major reference labs in the U.S. where Luminex was a supplying tests for cystic fibrosis. It was a significant business, a \$12 million business, that...after the acquisition, we were able to continue to supply because of the, let me say, existing relationship between DiaSorin and this very large lab, although the lab has provided to us a final notification, they are switching to a homemade different technology, and therefore, starting from the second quarter of 2023, we are going to take a net loss of \$10 million in this segment. And this is going to be important, and we're going to be moving forward in the next quarters. We will continue to point this out, because it clearly dilutes growth in molecular and it is because of the size is...again it's important that you understand that this component is a one-off component that is actually going away in 2023.

Now let's talk about COVID. I believe that in 2022 we got 220 some million dollars, euros of COVID revenues. We already saw starting from Q4 last in 2022, that there has been a sharp decline in this business pretty much across all geographies, and I would say it is more relevant in Europe than in the U.S. Although starting from Quarter 1 of this year, we saw a dramatic decrease of this business, and therefore we expect that I think as for everybody else in this segment operating in COVID diagnostic we expect that our COVID revenues will be down 80% compared to what

they were in 2022, and so we believe it's going to be around €60 million of COVID revenues in 2023.

Now, let me make a couple of comments on the 2 strategic programs, one is MeMed and the other one is the LIAISON Plex and NES. And so let me start with MeMed, as I think everybody has seen MeMed decided to give another license to another partner. We got some questions about this. It is very clear that for us it was not a surprise at all, because it was embedded in the contractual agreement that we have with MeMed. We believe that because of the fact that we have the product and the product has been already approved in the U.S., we have a couple of years of advantage compared to the partner, although I have to say that I see the fact that there is another player or more players in this business, I see it as positive and not negative for a very simple reason. The opportunity is vast, but the opportunity also comes with the fact that clinical marketing is to be activated in order to promote in the...among the ID specialists. The adoption of this algorithm, the fact that the clinical guidelines do include this algorithm, and MeMed is a very, very small company, and they clearly decided to spend their economic resources in promoting the tests with payers. But they don't have the footprint in the U.S. to go and promote the clinical content to physicians.

DiaSorin made an investment, and we are making more investments in adding reps in this area, because we see that today the success of this product comes...will come from the adoption and not from a clinical value, it's just a matter of explaining to people that this product exists. But we are limited, limited in size. We are a great company, but certainly we don't have the footprint that by ourself we can cover the U.S. and the addition of a good player like Beckman. You know that we do have a relationship with Beckman in many different fields. We believe that having Beckman also taking the token of...and commitment to promote will certainly help the growth of adoption of this product. So I don't see this as a competitive threat. I see this as actually an advantage to make sure that this assay is adopted in the U.S.

Now, let me make a final comment on the LIAISON Plex and the LIAISON NES, and I'll go one-by-one. When it comes to the LIAISON Plex, we are as we speak in clinic...conducting the clinical study in the U.S., during the respiratory season. That will be concluded around May when the season is completely over. As you know, companies in respiratory are required actually to go through the full season, because of the fact that certain strains only appear toward the end of the season, and then we'll submit. And at that point we'll expect, we are expecting to have the product approved by the beginning of next year. Results so far are very good and the product is...the system per se is performing as expected. And so, now we are working on the second set of products that will follow suit, which is the blood panel, the 3 assays from the blood panel.

When it comes to the LIAISON NES, the initial product is as you know COVID, flu A and flu B. We had a delay on this product for a completely different reason, and this has to do with supply chain issues with us and the partner that is actually been awarded with the contract to manufacture the system. We are, as we speak, working with the partner to make available the first 100 units that will be necessary to start the clinical study. We are thinking that the clinical study on respiratory will start in Australia first in order to anticipate the season and then end up in the U.S. and the western world when the flu is going to cross over and come to us. So again, we expect to submit this...the LIAISON NES COVID flu by the beginning of next year and have it approved in 2024.

At this point, I'm going to leave the microphone to Mr. Pedron, who is going to take you through the numbers, and then we are going to take questions. PG.

PIERGIORGIO PEDRON: Thank you, Carlos. Good morning and good afternoon everybody. In the next few minutes, I'm going to walk you through the financial performance of DiaSorin in 2022. And I will also make some remarks on the contribution of the fourth quarter. Again, let me please remind you that consistently with what we did over the last quarters, in order to better understand the performance of the business, I will refer to adjusted P&L items, therefore sterilizing the impact of the Luminex deal related elements.

> In the press release available on our website, we are providing a line-byline bridge between adjusted and IFRS item. Please also remind that we completed Luminex acquisition in July 2021. So starting from Q3 2022, the perimeter of consolidation is comparable.

> So with that I would like to start with what I believe are the main highlights of the period. 2022 total revenues at constant exchange rate [indiscernible] by 2.4%, vis-à-vis 2021 as a combination of a decreasing COVID sales by 40% more than offset by an increase in the ex-COVID business by 21%. This performance is in line with 2022 guidance.

The Molecular Diagnostic franchise ex-COVID at comparable effects grew in the year by 3.3%, driven by an increase in clear sales by 5% partially offset by a negative performance in the Chinese market as we just heard. The Molecular business ex-COVID growth is mostly driven by the different perimeter of consolidation and by a very good performance in H2 plus 13% at constant exchange rate fueled by a strong respiratory season.

The licensed technology franchise growth year-over-year is due to the different perimeter of consolidation, whereas H2 soft performance minus 2% comparable FX rate is mainly due to COVID-driven supply chain issues on electronic components which affected our instrument sales. Q4 2022 total revenues at constant exchange rate decreased by 14% as a result of the anticipated decrease in COVID sales, 61% or €62 million partially offset by an increase of the ex-COVID franchise by 4%.

Before moving to EBITDA, we need to spend a couple of minutes on the so-called payback system for medical devices. This measure originally introduced in 2015 by the Italian government and never implemented since then, has been eventually reactivated in September 2022. With the goal of rationalizing public healthcare spending, this scheme requires company to payback any sum exceeding the budget allocated to the Italian regions by the government. Specifically the law obliges returning to the regions about 50% of the turnover exceeding the medical devices cap fixed for the period 2015-2018.

Please note that even if the September 2022 load [indiscernible] covers only 4 years, as said 2015-2018, the payback could be potentially extended to subsequent periods. More than 1,000 companies in Italy, including DiaSorin, have filed legal appeals set to administrative regional authorities to challenge the decree. The payment due date originally set for January, 2023 has recently being postponed by the government to the end of April.

The administrative regional court in Rome has scheduled a hearing on January...on June 2023 that will reveal its intention with respect to all the pending lawsuits. In the case the administrative court rejects the claim DiaSorin and very likely most of the 1,000 companies that already filed a

recourse will appeal the decision in front of the State Council, which is the administrative court of appeal.

Before September 2022, reactivation of the payback mechanism DiaSorin had already built in its balance sheet a provision based on the information available back then, and it's a relative risk assessment. Because of the news introduced by the September 2022 law decree, the provision has been increased during Q4 by about €4 million to €5 million. In case of a negative outcome in both the administrative court and the administrative court of appeal, starting from 2023 onwards, the payback will have to be accounted for as a reduction in revenues.

So having clarified the meaning of this payback mechanism in Italy, let me please move back to the financials. 2022 adjusted EBITDA at \notin 514 million or 38% of revenues is in line with the full year guidance in spite of the payback provision we just mentioned, which was not originally factored into our projection. The decrease compared to last year, \notin 29 million 5% is the result of the combination of diluted gross profit, mostly driven by different product mix and the lower operating leverage, driven by the inclusion of Luminex in the perimeter of consolidation and lower COVID sales.

Q4 adjusted EBITDA margin at 35% of sales or $\in 123$ million records a decrease toward Q4 2021 of $\in 39$ million or 24%. This variance is mostly driven by lower COVID sales, $\in 60$ million in the quarter to be precise and by the payback provision that we just discussed. Lastly, we keep confirming our ability to generate a very healthy free cash flow, $\in 316$ million in 2022 with an increase compared to 2021 of 5%.

Moving now to the P&L. 2022 total reported revenues at $\in 1.3$ billion grew by 10% or $\in 123$ million compared to last year. Luminex products

revenue in the period amount to $\notin 386$ million vis-à-vis $\notin 185$ million in 2021, in line with our budget, as a result of lower instrument sales for the Licensed Technologies franchise, which have been offset by higher Molecular of sales.

2022 adjusted gross profit at €904 million grew by 9% compared to last year with the ratio of the revenues of 66% compared to 67% of 2021. The full year contribution of Luminex on the different product mix are mostly driving these very light dilution. Q4 2022 gross profit ratio is in line with Q4 2021 at 66%. I believe it is important to underline that in spite of the inflationary pressure we discussed about in previous quarters, we have been able to put in place cost containment measures and the initiatives that have allowed us to safeguard margins.

Full year, adjusted operating expenses at €472 million grew by 32% compared to 2021 with the ratio of the revenues of 35% vis-à-vis 29% of last year. This increase in line with our expectation is mainly driven by the different perimeter of consolidation and higher COVID sales booked in 2021, that generated back then a very material operating leverage.

A negative FX effects, higher travel costs, and higher inflation mainly drive Q4 2022 adjusted operating expenses increase toward previous year of \notin 12 million or 11%. It is important to underline that the increase at comparable exchange rate is just short of 4%. Year-to-date adjusted other operating expenses increase toward 2021 as said, is mostly driven by the payback provision.

As a result of what we just discussed, 2022 adjusted EBIT at \notin 417 million or 31% of revenues has decreased compared to 2021 by 10%. Interest expenses at \notin 3 million are lower than last year by almost 40%, mainly because of better yield on our cash investment, whereas the adjusted tax

rate at 23% is basically in line with 2021. Year-to-date, so full year adjusted net result at \in 319 million or 23% of revenues is lower than previous year by \in 38 million or 11%.

Let me now move to the free cash flow and the net debt position. During 2022, DiaSorin generated €316 million free cash flow, as we said, vis-à-vis €301 million in 2021. At the end of 2022, the net debt was negative for €907 million vis-à-vis negative €986 million at the end of 2021. This improvement has been driven by a strong generation of operating cash, which has been partially offset by the following items. Share buyback for about €160 million, €57 million dividend to our shareholders and about €40 million of negative translation FX effect, mainly due to the U.S. denominated term loan that we put in place to finance the Luminex acquisition.

Lastly, let me move to 2023 guidance as usual, expressed at previous year exchange rate, total revenues minus 14%. Total revenues at constant perimeter of consolidation, which means without the Flow Cytometry business, which was sold at the end of February, minus 11% of which COVID at about €60 million, molecular respiratory business minus 20%, and the base business ex-COVID and molecular respiratory plus 4%...plus 6%. Adjusted EBITDA margin at around 34%.

Please note that we have built in our assumption an average respiratory season. Beside, we believe that 2023 base business growth will be skewed towards the second part of the year since we deem like many other peers that China will recover from H2. Moreover, please consider that 2023 guidance does not include any possible impacts on the payback mechanism in Italy since we have no visibility, neither on its potential implementation nor on its materiality. We deem that in the worst case

scenario, we could have a negative effect of $\in 6$ million to both our top line and EBITDA.

Before concluding, please remember that DiaSorin financials are highly exposed to the U.S. dollar, and even more so now than sales denominated in the USD. represents about 50% of our total group sales. Therefore, as a rule of thumb, please consider that for every 1 cent movement of the dollar against the euro, DiaSorin revenues moved by about $\notin 6$ million on an yearly basis.

Now let me please turn the line to the operator to open the Q&A session. Thank you.

Q&A

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

The first question is from Odysseas Manesiotis from Berenberg. Please go ahead.

ODYSSEAS MANESIOTIS: Hi there. Thanks for taking my questions. So I just had one question with several parts. I wanted some more color behind the reiteration of your immunoassay midterm growth trajectory. So could you touch on your thoughts around MeMed second partner a bit more than you initially did so, as well as the implications of the QuantiFERON exclusivity expiry, and recent launches in the low to mid throughput space

now by some of your bigger peers? My point is, have none of these affected your confidence in achieving this 7% CAGR? Thank you.

CARLO ROSA: When it comes to the QuantiFERON, I'm going to make a general comment. We have a contract which is valid and in place. We have provisioned on that contract that protects 2 partners, and we have a relationship more than a contractual relations. We have a business relation with QIAGEN that has been developed over the years that goes behind QuantiFERON. Lyme disease is also involved and we discussed, I think, last year that we are working on another application together. So I do not have a concern about the exclusivity provision or the relationship with QIAGEN. But again, these are confidential information that I am not allowed, and I will not share with third parties.

When it comes to other players launching in mid space is not a problem for DiaSorin, because again, we sell a fairly unique menu. So our differentiating factor has nothing to do with the box, but has to do with the menu and I don't see the other players actually getting into our space when it comes to menu and content.

When it comes to MeMed, I think that, I don't know what else I can add. I just, as stated, we have today, if we look at the 2,000 hospitals, at least in mid and large institutions in the U.S. that could run this assay, we have 15% market share, I think, so we serve 15% of this hospital base. So there is plenty of space for other partners to chip in and support the adoption of this assay. I think that we all came to the realization that MeMed is small. MeMed has been dedicating their effort, I think, in a very good way to obtain coverage. Now, they're working on coverage by private insurance companies, but this is what they can do in the U.S. And therefore, there is a heavy lift when it comes to education and the more players; they would

come to this market, I believe the better it's going to be for the different players.

I know that some of you raised a concern about pricing. I don't have a concern about pricing at all, to be honest with you. I think that today companies, especially when it comes to this new kind of products, we are maximizing clinical value and we are maximizing economical value for the specialties. Typically, the price work comes when you have too many players on me-too products and certainly this is not a me-too assay per se.

When it comes again to geographies, I think I gave my view. I think U.S. all times up. I think Europe, modest growth, but is in line with what the European market does. And when it comes to China, my expectation is that coming from second half, there's going to be a recovery driven by volume and driven by the fact that we put in place certain strategies, including some reorganization to the geography to allow China for us to unleash the opportunity with our product. I think in the last and during COVID times, has been for several reasons lost.

ODYSSEAS MANESIOTIS: Thank you for the detail.

OPERATOR: The next question is from Maja Pataki from Kepler. Please go ahead.

MAJA PATAKI: Yes. Hi, good afternoon. I have 3 questions. I'll take them one-by-one. I think it's easier. Carlo, with regards to the 2023 guidance, you were talking about flat Molecular sales in 2023. Is that including the headwinds that we're seeing from the respiratory? That's the first question?

The second question to that is, could you just give us a ballpark how big respiratory is within Molecular, because it is really helpful to have an understanding of how the rest of the business in Molecular is doing? That's question 1...1 and 2?

CARLO ROSA: Maja, are you done, because you said you have 3 questions.

- MAJA PATAKI: Yes, I can take them all 3 of them. Then the second question would really be with regards to the wording around the 2025 Strategic Plan. You are reiterating the trajectory for the immunoassay and the Licensed Technology, of course, adjusted growth rates for you know, 2025, you've talked to the fact that there are delays in Molecular. And so, is it fair to say that the €1.5 billion target that you've put out back then is no longer valid, and we should not basically also not take the Molecular growth rate of more than 23% that you've put in the Strategic Business Plan as a given for now?
- CARLO ROSA: Okay. Maja, let me go through Question #1. Respiratory, just to understand 2023. Well, overall our respiratory is a third of the business, Molecular, okay? So there are 3 components to the Molecular business. Respiratory, where in our guidance, we have embedded respiratory season, which is in line with previous years, okay? That means that we foresee a decline in the business due to the fact that Q1 2023 is extremely slow, because everything was actually done in Q4 last year, okay? Now, if you have in 2023, Q4 again, very strong, or better off, you could have a complete different number. But in the projection we gave we assume because of the way that the peak was shaped in 2022 versus 2023, the respiratory overall business will be less than what we had in 2022. Got it?

MAJA PATAKI: Got it. Thank you.

CARLO ROSA: Okay. Now when it comes to the second element is that you need to take a \$10 million hit on the business, which has to do with one assay, one contract that is gone, okay? The rest of the business is actually, we expect it to continue to be flat with growth that is coming actually from the single plex more DiaSorin products and a small decline coming from multiplexing, although we didn't see it in 2022. But again, it's a projection we are making for the 2023. So overall, the combination of the base business, ex-respiratory, ex-contract is flattish.

- MAJA PATAKI: Okay, got it.
- CARLO ROSA: Got it? Okay. Second comment about the 2025 plan, look I think we...all the trajectories when it comes to the business and the fundamental of the business are all there, because when it comes to a different program, the platforms and what we need to shoot for in the content and MeMed everything is there. So we are today reiterating our guidance and we are looking at 2025 overall in line with what we've presented in the LTP. I believe that comes, the end of 2023 when we are going to have the proof of the approval of the respiratory panel and much better visibility on the confirmation of the launch of the NES next year when next year is going to happen because it's crucial that it happens before...the 2024 respiratory season. And last but not least, on the MeMed side, the adoption, because they were investing ton of money and time in promoting the adoption, and we need to understand the adoption rate of that...of this product how it goes. But as I speak today, in Q1 2023, I'm reiterating the 2025 guidance.
- MAJA PATAKI: Okay. Thank you. And then my last question, Carlo, I think on one of the calls last year, you were talking about VERIGENE I at your customers, and you mentioned that the gastrointestinal test is one that is most used. Total respiratory prior to last year's flu season wasn't the main test. So when you have the LIAISON Plex, do we have to think that the replacement of the existing VERIGENE I platform in the market really

depends also on the gastrointestinal or do you think that doesn't really matter?

- CARLO ROSA: Maja, I think that what we stated is the following; we said that 30% of the business is respiratory. So to the contrary, in multiplexing, to the contrary of what we see from [indiscernible] for example, which is heavily skewed to our respiratory, in multiplexing, we have less respiratory, okay? The rest of the business is fundamentally blood, the blood panel and the gastro. The blood panel is the one that is highly adopted in the U.S., because it was the first assay that was actually made available to the U.S. market by VERIGENE on the VERIGENE I. It's ... let me say, let me call it a business which has been where the adoption of these technologies versus traditional culture has been now on the market for a long time. So let me call it the most boring part of the business in terms of innovation or gastro to the contrary where we do have a presence both with Nextech [ph] manual and with VERIGENE I is the one where we see the most potential, okay. So long story short, I believe that respiratory is growth, because we do sell much respiratory in relative terms. Blood is defend and grow a business that today doesn't grow that much, and gastro is growth, growth because the market itself is growing significantly.
- MAJA PATAKI: Great. Thank you very much.
- CARLO ROSA: Thank you, Maja.
- OPERATOR: The next question is from Aisyah Noor from Morgan Stanley. Please go ahead.
- AISYAH NOOR: Good afternoon and thank you for taking my questions. My first one is on...also on the midterm guidance, but on your margin targets, given that you are expecting to make 38% EBITDA margin by 2025 and your

guidance for this year is 20...sorry, 34%. It implies you have a lot of heavy lifting to get to 200 basis point expansion per year to 2025. Could you talk about some of the drivers of you getting there? And may be perhaps this is also an opportunity to update us on where you are with respect to your cost synergy program?

And the second question is just on the MeMed partnership. Do you have a better assessment now of how close you are to achieving this MeMed testing in clinical guidelines or what hurdles do you need to overcome, what KPIs are you tracking to achieve this? Just some color on the clinical adoption or reception you've received so far.

CARLO ROSA: Okay. I'll take the second part of the question, and then I think PG will cover the margin. Look, it's very difficult to say where we are at, because we just started, okay? And you will understand that in order to have here an assay into a clinical guideline, it takes years, okay? So...and I'm not banking on the same necessarily that this will go right away on a clinical guideline. And this is because the assay if you think about it, it's not so complicated. So in a way this was a new way of to diagnose pancreatic cancer, clinical guideline would be of key importance. In this very specific case, the assay...the product actually goes to answer a relatively simple and understandable clinical question like fever without source. And so to me, what is more relevant...and the data are extremely supportive. The clinical data have been generated by MeMed, not by us, I think, at a good start today there is a clinical study that is ongoing is actually starting, where us and MeMed together are going to fund 1 year plus clinical study to generate data for the private payers, okay? That goes to the payers. But when it comes to the physicians/clinicians, is not a matter of clinical guidance, it's a matter of just reaching them, because you're talking about 1,000's of doctors that need to understand the availability of this assay.

So it's foot on the floor, in terms of having clinical specialists, its digital campaign and marketing because these days, these doctors are actually using the tool, especially the specialists to be updated on what's new in the field, and so it's a matter of investment, but not necessarily on a clinical When it comes to reimbursement, which is another key guideline. element, the discussion, I believe, MeMed did great in setting the foot on a \$280 reimbursement when it comes to Medicare, Medicaid, but that's the beginning of a story, because now you'll need to go to the payers. And when you go to the payers, you need to have to achieve good results. The first is in the clinical having the insurance to recognize very specific code reimbursement for the assay. The second one is the unbundling, meaning that today, each hospital has negotiated with insurer bundling payment for somebody showing up in emergency room with these symptoms, and what MeMed is to achieve now is that they unbundle from this some money, a specific portion of this, which is dedicated to pay for the assay itself, and this will require time.

I don't think that today the lack of reimbursement is an issue necessarily because we recognize clinical value, then it goes into the budget of DRG of the hospital. And again, we're talking about the U.S. now of the hospital itself. Again, I see that today the effort is to go door-to-door and initiate these doctors to the concept of using this product. But again, clinical guidance, in my opinion, is not necessarily a must here. It will come. It will take time, but it's not a must. PG, on the margin?

PIERGIORGIO PEDRON: Yes. Hi, Aisyah, so let me take the one on the margin. Let me start saying that the 34% EBITDA margin we guided for in 2023 is not far. It's actually pretty close to the number we have in our plan, which is the plan we use for our 2025 midterm guidance. Obviously, you know, a few things have changed. We have the payback, which could be going against, and as I said, it's not included, it's not embedded in our projection. At the same time, back then, we were not factoring the sale of the Flow Cytometry business, which being mainly an instruments business is and was actually better dilutive to our EBITDA margin, and that is working in our favor, obviously, right? At the same time, it is true that back then when we did our plan, we knew nothing about a big inflationary headwind we had to face, which back of an envelope calculation, we think is going to be around you know, $\notin 25$ million. But at the same time, we put in place several measures to contain costs, which, as I think the gross margin in 2022 and in Q4 are kind of paying out. We kicked out these price increase initiatives. We have already started in our B2B business. So the Licensed Technologies business, and we...and that was not factored in our model. We started a program with an external advisor to extend this price increase also to our Immune and Molecular franchise. And those were not included in our projection as well.

So I would say really many moving parts, but as always, right, I mean margin are derivatives of top line growth. Since we said we confirm that we're still surly [ph] for the 2025 top line with the only exception that you have to take out the Flow Cytometry business, which is not there anymore now, right? So I believe that the 38-ish percent EBITDA margin is still a value we are assuring for exactly as the top line, exclusion of Flow Cytometry once again, but being this 3 years projection, as I said, back in 2021, we all need to build in some flexibility around these numbers.

AISYAH NOOR: That's very clear. Thank you so much.

OPERATOR: The next question is from Shubhangi Gupta from HSBC. Please go ahead. Mr. Gupta, your line is open. Please go ahead.

- SHUBHANGI GUPTA: Hi, thanks for taking my questions. So regarding your 2025 margin guidance of 38%, so this margin improvement depends on product mix, so does that include only MeMed or are there other products in the pipeline? Can you shed some light on that?
- CARLO ROSA: Hi, so if you are referring to 2025 guidance, it includes all of our products in our main site. So it is...it will be a combination of our 3 franchises, the Immunodiagnostic one and MeMed is for sure belonging to the franchise as it in line, for example, the LTG franchise and the Molecular Diagnostic franchise. So it will be a combination of all of the 3 different franchises.

SHUBHANGI GUPTA: Thank you.

- OPERATOR: The next question is from Hugo Solvet from BNP Paribas. Please go ahead.
- HUGO SOLVET: Thank you for taking my question. I have just one for clarification. Carlo, you mentioned that at the end of the year, you will have more visibility on traction for MeMed on the launch time line for LIAISON Plex. So should we expect you to either confirm or adjust the long-term targets by the end of the year?
- CARLO ROSA: I think that we are going to have this discussion at the end of the year.
- HUGO SOLVET: Thank you.
- OPERATOR: The next question is from Emanuele Gallazzi from Equita. Please go ahead.
- EMANUELE GALLAZZI: Yes, good afternoon everybody. 2 questions from my side. The first one is on the LIAISON XS, if you can just provide more details on

the rollout in the U.S.? And my second one is on the current trading. If you can provide us an update on what you have seen in the first quarter to understand how the year has started? Thank you.

CARLO ROSA: Sorry, can you just repeat your second question, it's not clear to me what you are saying?

- EMANUELE GALLAZZI: If you can just provide some color on the performance of the business in the first quarter of 2023, as we are at the end of March?
- Not really. I cannot provide colors on a quarter that is not over. So I think CARLO ROSA: you need to wait until early May for the Q1 call. When it comes to the LIAISON XS, as you have seen in this platform, I remind everybody, it was designed for China and the cluster hospitals in the U.S. when it comes to the hospital strategy, clearly, and then tactically in Europe, and in some of the developing countries. So far, we have placed around 150 systems, and we just started the program in the U.S., because we were waiting for the approval of the TB assay, which came last year. China has been completely put on hold for obvious reasons. So we'll think about China and the XS starting from 2024 and other, keep in mind that when it comes to China now that there has been a strong push to move manufacturing instrument to China, and so most likely, our priority is going to be to move the XL first and when we think about the XS. So the LIAISON XS today is tactically placed in Europe and in the rest of the world and strategically to continue to feed our hospital strategy in the U.S. So it's very, very relevant for us.

EMANUELE GALLAZZI: Thank you very much.

OPERATOR: The next question is a follow-up from Maja Pataki from Kepler. Please go ahead.

- MAJA PATAKI: Yes. Carlo, just a question on the respiratory testing. Last year, you were discussing or sharing with us that there could be a bit of a change in respiratory testing more towards the low plex respiratory testing, given the fact that there was you know, flu and COVID and everything. What have you observed in the market? Have we seen a shift away from the single flu tests to a bit more like the low plex tests or has that not happened yet?
- CARLO ROSA: Look, Maja, I believe that the comments that were made by [indiscernible], we're actually very right. So I believe the following, I believe that when it comes to respiratory, there is a business...a business opportunity moving forward in the...not in the existing market, but in the POL market and in the pharmacy market. So decentralization of Plexing respiratory, I believe, is going to be there. And I also agree to the fact that the level of multiplexing that you need in that space is not the complicated 30 some assays the targets we provide today, but it's more on the 5 or up to 10, depending on the different customer setting. I also believe that we saw a low plex, meaning really, we saw an uptake starting from the end of the COVID season because of now the need of differential diagnosis until COVID was all over the place, they were testing COVID first because 80% of the time was COVID. Now that the curse of COVID is not there any longer, now you see more adoption of differential COVID, flu A, flu B and eventually for kids the RSV, okay.

I believe that fundamentally, this market will continue as is and driven by fundamentally reimbursement in the U.S. when it comes to large panels in the medical institutions. I believe that the low plex will take place, especially in decentralized setting. And this is why as DiaSorin, we have 2 different platforms to go to different segments, one, the existing one, which has stayed very interesting, dominated by one player. And I believe that it requires today, there is let me call it, an abuse of customers, meaning that the customers have been forced to use a very high multiplexing that I don't think makes financial sense or it will make less financial sense due to the constraints of reimbursement. And this is why we believe that flexibility in testing is key to continue to flourish in that market. And by the same token, as discussed, you need to invest in decentralization.

Last but not least, because of decentralization is driven by reimbursement and availability of players to actually work in decentralized setting, I believe that it's fundamentally a U.S. play. The rest of the world still is half pregnant in a way, didn't make a decision to reimburse or develop decentralized testing through decentralized testing and therefore, for respiratory in my opinion, the market to play in the U.S.

- MAJA PATAKI: Okay, thank you very much.
- CARLO ROSA: Thank you, Maja.

OPERATOR: Mr. Rosa, there are no more questions registered at this time.

CARLO ROSA: Thank you, operator.