DiaSorin S.p.A

"First Half, 2023 Results Conference Call"

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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 First Half 2023 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.

CARLO ROSA: Thank you operator. Good morning, good afternoon and welcome to the DiaSorin H1 conference call. As usual, I am going to go through some comments about the business, and then I will allow the CFO, Mr. Pedron to go through the numbers. As usual, I'm going to comment all the numbers at constant exchange rate.

So we had very good quarter, a quarter we had an acceleration of revenues compared to Quarter 1, in fact the quarter closed at plus 5% versus Q1 at plus 3%, that is clearly excluding COVID, and I am going to now briefly comment the 3 legs, so the way we look at the business, immunodiagnostic, molecular and the LTG.

Let's start from the immunodiagnostic, the immunodiagnostic franchise ex-COVID closed in H1 at plus 7% with a very strong Quarter 2 with growth over 8%. There has been a very strong performance of our CLIA franchise that net of Vitamin D in the first half has grown over 13%.

So if we look at the different geographies starting from Europe, Europe Quarter 2 was plus 6%, ex-Vitamin D CLIA was plus 11% and fundamentally in Europe what we continue to see is an increase in volume most likely due to rebounding of testing after COVID. We saw this positive effect in Q1 and we continue to see this effect in Quarter 2 in all the different European geographies.

When it comes to North America, very strong result in H1 13% up. If we exclude Vitamin D is 19% up in the Quarter 2 specifically 15% over last year, and if we exclude Vitamin D is plus 22%. As you all know, in North America, the program has been mainly focused on the hospital segment in 2022 we heavily invested in doubling our salesforce, we completed the hiring end of last year, so effective Q1 we now have a very complete salesforce that is serving the market segment of the hospitals.

We are on an ambition to close in the next 3 years, over 250 hospitals doubling our hospital presence in the U.S., and as we have discussed many times, we are very successful, as a combination of the 2 systems we have, the LIASON XL and recently the LIASON XS and the products.

Mainly, I would like to mention clearly that QuantiFERON together with our stool franchise, these products together are actually driving interest of customers that typically in this segment have been sending out products and with a viability of this products and the systems we provide, they can insource and making clearly this testing a profit center for the hospital, so it is working very well.

When we look outside of Europe and North America and the rest of the world, I believe that the good news is that China that has been a real drag in Quarter 1 did actually stabilize in Quarter 2 for the first time we've seen a modest growth in CLIA, and this is certainly very positive. I think that we continue to be very cautious about near term opportunities in China because of the current very rapidly shifting policy toward China made product that we continue to become more and more popular in our customer base.

Although it is certainly true that we have invested significantly in turning our commercial sale force with new leadership and changing

our distribution network in China, and I think we start to see in the first positive effects.

The other element which I believe is very important is that now that we are close to opening our manufacturing site, it's very clear to the customer the direction that DiaSorin is taking this challenge to become China based, and this I believe is certainly helping the business. Again I'm very cautious about the future because as we did comment few times, Chinese is unpredictable in the short term.

So let's see how it goes, but certainly good a news. In all the other geographies where we are direct, Brazil, Mexico and Australia, we are enjoying strong growth of the immuno…in immunoassay franchise and clearly related mainly to our traditional infectious disease product line.

The other thing that I think is I think very relevant to discuss is the fact that for the first time in post-COVID era, we've been launching new products, and specifically in Quarter 2 we launched 2 new products on the LIASON XL and XL the new Legionella test and pro-Adrenomedullin a very interesting product that has been developed together with Thermo Fisher with a license coming from Thermo Fisher.

And so, I think finally, after the COVID, the 2 very difficult years of COVID has consumed our R&D resources in '20 and '21. Now starting from 2022, we restarted product development and now you see how slow new products that are hitting the market taking us back to where we were prior to the COVID pandemic time. So this is, I think, great.

The other thing I would like to mention is that will specifically relate to the U.S., we really start to see the effect of the critical mass that we were able to build as a consequence of the Luminex acquisition. As I think we have discussed strategically, DiaSorin wants to improve the footprint in the U.S., and sees itself as a U.S., company when it comes

to the future, and is very clear that Luminex acquisition give us the brand, the visibility, the footprint and the resources which are now very useful in launching of the new products that they will bring into the market. So is intangible or tangible value from the acquisition critical mass clearly is paying out.

Last but not least, when it comes to MeMed, as we've discussed I think in the last conference call, we decided to increase our spending in marketing and providing commercial coverage. For the launch of the product we have hired the dedicated clinical reps that are needed to go and solicit demand with the clinicians. Let's say the dedicated MeMed salesforce now with staff has been trained and starting from Quarter 3 will start to hit the market together with other tools like the digital campaign in order to create demand for this very interesting product.

Now, if we move to Molecular Diagnostic, ex-COVID the franchise in the first half is relatively flat, it's a combination of low growth in respiratory, and we have a very good performance in the syndromic panel with Verigene 1 which is partially offset by the flu only test that we carry only on the ex. I remind you that this is an effect of the last flu season that was extremely strongly in Quarter 1 and therefore relatively weak…relatively strong in Quarter 4 and so relatively weak in Quarter 1.

In the non-respiratory, we have a decline of roughly 5% but this is primarily due to the fact that as we have discussed we lost a contract with a very large lab for CF and now in the second quarter we start to feel almost a full loss of the revenue related to this product ex-cystic fibrosis, the growth is low single-digit. So considering the fact that our molecular…our molecular business today when it comes to the syndromic still relies on technologies which are very solid but certainly they are showing sign of time to put it that way. And this business is extremely resilient.

And certainly, we are waiting for the Plex now to invert from stable business, and go back to growth. When it comes to the Plex, we have completed the clinical studies for the respiratory panel, and we expect the filing in Q4 and approval by next year respiratory season.

When it comes to the LIAISON NES, same thing. Clinical study started in Australia because now, as you know, if the flu season, will continue in the U.S. and we expect filing in the U.S. of the ABC. So the flu and COVID product at the end of the coming respiratory season.

Now, last but not least is our licensed technology business. And I think we all need to remind ourselves the fact that Quarter 1 was very weak. And we did comment last time that Q1 was weak because we had a significant back order still of instruments, due to the supply chain issues that we still encounter till the end of last year.

Well, Quarter 2 is completely different. As you have seen, we have double-digit growth at 10%, but this is primarily due to the fact that we were able to close our gap, and now we have availability of spare parts. We were able to make systems, and we shipped all the instruments that were in back order.

I believe that as you have seen from other competitors, when it comes to the Life Science business, we see initial signs of slowdown. Therefore, I just want to caution that the double-digit growth in Quarter 2 should not be intended to be what we believe this business can continue to perform in Q3 and Q4. And we really need to understand…I remind everybody, this is a B2B business.

So, we actually sell a relatively small portion of these revenues come from direct sales to customers. Most of the revenues in this business come from B2B with some of the largest life science companies. In the U.S., we are waiting to see the way that they're going to be

forecasting Q3-Q4, then to provide an expectation to what we believe is going to be yearend and beginning of next year. So, just be cautious, don't take the plus 10% of Q2…of Quarter 2 as a true running rate.

Couple of comments. Very good news. We actually received from the FDA the closing of the warning letter. This was a significant effort by the company and a couple of years of solid work by our quality assurance team and regulatory brought us to…again, brought the FDA to close the warning letter. So, we are going back to the regular business. We made significant investments in the quality system of Luminex to resemble the DiaSorin quality system. And therefore, we are confident that moving forward, we are going to be able to work in an FDA environment also at Luminex according to the most recent standards.

Last but not least, when it comes to the synergy and integration plan, glad to report that we are on time, and we expect by 2023 a running rate between €50 million and €55 million in cost synergies, as provided in our long-term plan.

At this point, I'm going to turn the microphone to Mr. Pedron, and then I'll take your questions after. Please, go ahead.

PIERGIORGIO PEDRON: Thank you, Carlo. Good morning, good afternoon, everybody. In the next few minutes, I'm going to walk you through the financial performance of the DiaSorin. During the first half of 2023, and I will make remarks on the contribution of the second quarter.

Let me please remind you all that consistently with what we did over the last earning calls, 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.

As we did over the last few quarters, I would like to start with what I believe are the main highlights of the period. H1 '23 total revenues at constant exchange rate decreased by 16%, whereas the reduction at constant perimeter of consolidation, which means without the contribution of the flow cytometry business that we carved out in February 2023, has been 14%. This result, which is in line with the full-year guidance, is a combination of the expected fall in COVID sales, the carve-out of the flow business, partially offset by a growth in the ex-COVID business of around 4%.

And to be more precise, ex-COVID revenues at constant exchange rate and perimeter of consolidation without the contribution of the molecular respiratory business grew by 4.2%, as a contribution of very good performance of the immuno franchise, plus 7% in Q2, which saw an acceleration compared to what we achieved in Q1. Moving from the 6% of the first quarter to 8% of the second. The recovery of the LTG business, which closed Q2 '23 with an increase of 10%, therefore, ending the half year with a growth of 2% compared to 2022.

And lastly, a slightly negative performance of the molecular franchise net of the respiratory business driven by the budgeted loss of the cystic fibrosis business that Carlo just mentioned.

Lastly, the molecular business, respiratory business recorded in the first 6 months of the year, a performance substantial in line with 2022, plus 2% to be precise, as a combination of an increase in the VERIGENE I respiratory panel, which offset the decrease in the flu and COVID [ph] only molecular testing for the reasons that Carlo just commented.

H1'23 Adjusted EBITDA at €190 million or 33% of revenues is substantially in line with the full-year guidance. The decrease compared to last year €79 million or 29% is mostly driven to the drop

in COVID sales, and therefore, to the corresponding worsening of operating leverage.

Lastly, we generated €104 million free cash flow in the first 6 months of 2023, down €34 million compared to last year. This variance, once again, is mainly driven by the fall in COVID sales, whereas the nonrecurring phasing events, which I talked about during Q1'23 earning calls have mostly been offset by the expected strong performance of Q2'23, which closed with a free cash flow generation of €76 million.

Now, before moving to the P&L, let me provide you an update on the so-called payback system for medical devices in Italy. As you might remember from the previous earning calls, 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 medical devices spending, this scheme requires companies to payback any sum exceeding the budget allocated by the central government to the Italian regions.

Specifically, the law obliges vendors to return 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 law decree covers only 4 years, as said 2015 to 2018, the payback could be potentially extended in the future to the subsequent years.

What has happened? So practically all the operators, including DiaSorin have filed legal appeals to the competent courts to challenge the decree covering the years 2015-2018. In particular, the administrative regional court in Rome has been charged with more than 1,800 recourses to suspend, and annul the payback regulations. The payment due date originally set for January 2023, after being postponed a few times, was set for the end of July. And based on the

most recent news, might be postponed even further till the end of October.

Moving from this very complex situation rich of legal controversies, the government recently issued a law introducing the faculty for each company to settle disputes relating to the period 2015-2018, by paying 48% of the total amount requested by the region, and by renouncing any pending legal litigation. We are assessing the possibility to adhere to this settlement, but no final decision has been taken yet.

Please note that, before September 2022, reactivation of the payback mechanism and DiaSorin had already built-in its balance sheet provision based on information available back then, and it's relative risk assessment. And therefore, the potential settlement we just discussed about would be covered with a provision booked in the past and would not have any impact to the P&L of this year.

Now, pending more clarity on the legal front for the years following 2019 and the amount already booked for in our balance sheet in the past, we have not changed our provision for the period 2019-2022, and we have not accrued anything for 2023. We will keep on monitoring the evolution of this very complex and daily changing situation and update you during the next quarter course.

Moving now to the P&L, H1'23 total revenues at €576 million, as we said, decreased by 16% or €109 million compared to last year. This variance completely due to lower COVID sales, which in the first half are down by €150 million or 77% compared to last year, and the disposal of the flow cytometry business. I think it is worth noticing that the second quarter recorded some €6 million FX headwind, mainly driven by the U.S. dollar depreciation compared to the euro. Considering the current exchange rates and what we had in H2'22, I believe it is fair to expect this negative FX impact to continue in the second part of the year.

First half adjusted gross profit at €379 million decreased by 16% compared to last year, with a ratio of revenues of 66%, in line with the same period of 2022. The carve out of the flow cytometry business alongside all the initiatives aimed at improving operations processes and containing costs, some of which part of our broader cost synergy plan, allowed us to preserve margins. Despite the reduction in COVID revenues and the tail of the inflationary pressure we talked about in 2022.

I believe this to be a remarkable indicator of the relentless efforts we put in place to safeguard profitability, which has been confirmed by Q2'23, which closed with a gross margin ratio over revenues of 65%. H1'23 adjusted operating expenses at €230 million grew by 2% compared to last year, with a ratio of revenues of 40% vis-à-vis 33% of 2022. The worsening of the operating leverage ratio is entirely due to the reduction in COVID sales.

Moving to Q2'23, adjusted OPEX decreased compared to last year by 1% or €1 million, with a ratio of revenues of 40% vis-à-vis 36% of last year. This OPEX reduction is the result of all the initiatives we implemented to control cost, the impact of the cost synergy plan that also Carlo just mentioned, and the disposal obviously of the flow cytometry business. Adjusted other operating expenses at negative €4 million are substantially in line in absolute value with 2022.

As a result of what we just described, H1'23 adjusted EBIT at €144 million, or 25% of revenues, has decreased compared to 2022 by 35%. Adjusted interest income at positive €2 million is better than last year by €6 million, mainly because of improved yield on our cash investment, whereas the adjusted tax rate at 23% is in line with 2022. Year-to-date adjusted net result at €113 million, or 20% of revenues, is lower than previous year by 33%.

Let me now move to the net debt position. At the end of June, the net debt was negative for €861 million vis-à-vis negative €907 million at the end of 2022. This improvement has been mostly driven by the operating cash generated in the first 6 months of the year, partially offset by the payment of just short of €60 million dividend to our shareholders in May 2023, and €23 million of treasury shares buyback. Lastly, we confirm 2023 guidance as usual expressed at previous year exchange rate.

Let me finally please remind you that we have built in our assumption an average respiratory season, and that 2023 guidance, as I just said, does not include any possible impact on the payback mechanism in Italy, since your situation is in flux, and the most recent news, which I personally deem positive and pointing in the right direction, has made even more difficult to make an reliable prediction on what is going to happen.

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." We kindly ask you to pick up the handset when asking questions. Anyone who has a question may press "*" and "1" at this time.

The first question is from Shubhangi Gupta from HSBC. Please go ahead.

SHUBHANGI GUPTA: Hi, thanks for taking my question. So are you seeing any impact from biotech funding cuts? Can you please shed some light on that?

Second, is it possible to give a margin according to the business, like how does molecular diagnostic margins compare to immunodiagnostics and licensed technologies?

And third, on MeMed maybe, are you seeing any resistance from physicians in adopting the test? And what is the workflow for that? Thank you.

CARLO ROSA: Piergiorgio, do you want to take the margin question first?

PIERGIORGIO PEDRON: I will, sure. So we don't disclose the exact number, you know, the different margins between the 3 business franchises that we are on, so immunodiagnostic, molecular diagnostic, and LTG. But a ballpark number, you should consider that immunodiagnostic and LTG have an higher margin compared to molecular diagnostics, and this is kind of a standard in the industry. So you can, let me say again, broadly consider a difference between those 2 franchises, immuno and LTG, very similar margins compared to molecular, which are slightly lower. But we don't disclose the exact margins by product line.

CARLO ROSA: Okay. With MeMed and the biotech, I think that it should be clear to you that we don't sell to the end-user customer. We sell, again, to the very large biotech company then serve that market. I think that if you listen to what Thermo has been saying yesterday…reporting yesterday, I believe it is going to give you part of the story. I think there is a slowdown in some of the segments. We don't see it yet, but we may see it in the following 2 quarters, and this is why we're cautious about projecting double-digit growth of our LTG franchise.

Another effect that we have seen is destocking. This is certainly true, because some of the partners, which traditionally have been relying on 6 to 9 months of inventory, are reducing inventory, and this has to do with clearly an increased cost of capital and need to manage the

working capital, right. Also then, you know, I believe the LTG will continue to be a solid business. I believe that sooner than later, all the funding that has been made available in the U.S. and in Europe through the new initiatives will support growth, especially in the academic environment. Again, I'm just cautious about Q3 and possible Q4.

When it comes to MeMed, I think it's a little early, meaning that so far we have seen that there is significant enthusiasm by the clinicians, because the data that MeMed has been supplying and has been used for the registration of the product also with the FDA, this data is extremely convincing and the value of the assaying [ph] ruling out the bacterial infections, I think is so far all the clinical studies done also by local hospitals have demonstrated that the value is there.

I believe next step especially in the U.S., is to find a budget because today, as you know, this test is not reimbursed by the payers and there was it would be part of the DRG funds that each hospital get for the emergency room visits. So, I believe the jury is out, but what I have seen and again is an initial effort is that physicians clearly see the value, okay? Now with the administration has to…2 things have to happen. The administration will have to accept the investment and there are ton of reasons to do so because you…there is a significant saving in the fact that if antibiotic treatment and also hospitalization of patients, and clearly now MeMed and DiaSorin are working heavily with peers in order to conclude a clinical study that isn't going to provide evidence then for the payer to provide dedicated reimbursement for the assay. That event, I think, if Met would unlock the full potential of this product.

SHUBHANGI GUPTA: Thank you.

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

MAJA PATAKI: Hi. Thanks for taking my question. Carlo, just to start maybe with your last comment around MeMed. As you said you believe that getting the reimbursement would unlock a significant potential. Do you have any feeling for a potential timeline? Are we looking at 6 months or is it 12 months from now, were you expect to have the reimbursement that could start to drive the growth there? My first question.

My second question is if we look at the full-year guidance on the margin side, you guide for adjusted EBITDA margin of around 34% and we were around 33% in the first half of the year. Is it the synergies that start to come through more and more, that are going to drive the margin profile in the second half of the year, or is there anything from a revenue mix that is going to start to drive margins up?

And then lastly, on the Italian payback system, and I am fully aware of the fact that there are a lot of unknowns there, but PG as you commented that there is this proposal that you could pay 48% of the current request…financial request. Would you…and therefore you would have to sign the 2…you step back from all claims, but would that also mean that you would in the future not be able to appeal against it or would that basically mean like every time something is introduced it's a fair new game and you could do whatever happens? Thank you.

CARLO ROSA: Should we make a non-technical comment on the payback and let's see if that would be enough. This payback story is a typical Italian soap opera because the government went back if I may, and being Italian, you know, I cannot be accused of not being chauvinistic but it's very confusing, and I think is an attempt to get resources well needed by the healthcare system, but it's the wrong way to do it. This 48% seem very palatable because was until few hours ago. Because it was a way to seal a deal, pay 48% and forget about it, right? But it would be

without a course so he would not be able to then go back and claim the money…and claw your money back.

I think what really changed the situation has been the ruling of this TAR of Lazio, which pretty much said without saying that there are doubts about the fact that this is even possible under the constitution. And I believe that if prior to few hours ago, I think the world was split in 2. Some of the large companies that were inclined to pay and clearly all the small companies that would have…would suffer from strong financial impact, not available really to pay or to agree to the 48%. This ruling I think moved pretty much everybody toward the wait and see, okay? And this is what most likely we are going to do our self. But I said is an Italian soap opera. We have seen this many times.

I believe that in the future, if well-conceived this is something that can be set in place. And we will have to understand how we…how to deal with it. To go back and claw back from the past, I think is unfair, but are very complicated, okay? So, I am relatively positive about this payback, but stay tuned because we need to understand how they are going to organize it moving forward.

Second thing is on MeMed. On the reimbursement, look Maja, you know and I know that in the U.S., to the contrary of the European model, it's…the system is profit-driven, okay? And I am not saying is only profit-driven but certainly coverage of reimbursement does help in a situation where most of the hospitals, as you know, are going back to the pre-COVID situation which means they are losing money.

So, we will…we with MeMed agreed to spend a significant amount of money in a clinical study intended to provide all the evidence to the payers and the study started and is going to take, I believe without being too optimistic or pessimistic, around 12 months to be completed.

Then you have the filing. So, I would say that no less than 18 months before you get a ruling from some of the main payers, okay.

So, for the next foreseeable future, we will need to leave with the clinical value and the fact that the hospital receives DRG reimbursement and they see value in bringing the test in. Clearly what I have seen Maja and it is counterintuitive, in a way, when you go to the very large institutions where you do have a very strong clinical group, the adoption rate is not as fast as you would think, because in these very large clinical institutions, they want to generate their own data, right?

So, yes the administration is weaker, but by the same token all these clinicians, they want to do their own studies and takes time. They also have plenty of technology for standard of care, okay. So, it's not that they are lacking tools. They have all the tools that are more expensive and they would see this clearly as a way to simplify their life. If you go in the periphery…if you go in smaller institutions where they do not have the technology, and they are not so sophisticated, this is…the adoption rate actually is way faster, okay.

So, today you are forced to go to some of the institutions to create scientific interest, but the real market is actually in the periphery. And again, driven by the fact that they need some cheap tools to serve these patients. So, I hope that you know, has been specific enough, but no less than 18 months just to get the money…to get the reimbursement.

MAJA PATAKI: Okay, great. Thanks a lot.

PIERGIORGIO PEDRON: So, I will…hey Maja this is PG speaking. I will take the one on margin. I guess I'll ask how you want to color it.

CARLO ROSA: No, please go ahead.

PIERGIORGIO PEDRON: So, we close the half with 33% adjusted EBITDA margin and Q2 with the 32% adjusted EBITDA margin. In the quarter though and the first part of the year to be more precise we had some extraordinary legal costs related to the whole legal issue with the Italian market authority that we discussed in the past. We believe we have done there at the light of the most recent news basically done. And there is going to be let me say, a tailwind in the second part of the year.

And then obviously, we have a few other elements that we need to consider starting on the assumption that nobody has a crystal ball, obviously, but at the same time, you know, the immunoassays franchise is going pretty well. And we have seen, as we commented a very nice growth in the U.S., where we are enjoying higher margins in a sense to…there are some uncertainty in China, as Carlo commented but you know, we might see some hopefully good news there as well. There are some assumptions on the flu season, we said that you know, in our guidance, we have regular flu season assumption. But that is going to be another factor which we're building into our projection for H2.

And eventually, last but not least, there is…there are also some…as Carlo commented some assumptions we are making on the license technology business, where we are seeing some indication which are telling us that potentially H2 is not going to go with or likely I would say at the same speed that we saw in Q2. So many moving elements but when we consider them all, I believe that shooting for 34% EBITDA margin for the year is still what you know, we have in our line of sight.

MAJA PATAKI: Right. Thanks a lot. That's super helpful. PG, just a quick question. Could you give me…could you provide us with the Q2 growth on the like-for-like basis ex-COVID if you were to adjust it for the contract that you lost in cystic fibrosis?

PIERGIORGIO PEDRON: You know, I'm not sure we can disclose the quanta [ph] that we lost the amount for cystic fibrosis.

MAJA PATAKI: Okay.

PIERGIORGIO PEDRON: I don't think I can do that.

MAJA PATAKI: Don't worry. Don't worry, this is fine. Thanks a lot.

OPERATOR: The next question is from Noor Aisyah from Morgan Stanley. Please go ahead.

NOOR AISYAH: Good afternoon, Carlo and PG, thanks for taking my question. My question is on China. There's been some very mixed feedback from your competitors this week around the trajectory of growth and some are saying it's worsened in the quarter. Can we talk a bit more about what you're seeing and why you're seeing some moderate growth already in Q2, is it because you're exposed to kind of specific pockets of growth or do you think you're gaining market share? And has this also compared versus your expectation about pricing and potential pricing declines in China from the VBP [ph] developments? That will be helpful.

The second question is on MeMed, and this is partly in response to the really nice clinical data you showed at the ACC [ph] this week, I believe you mentioned before about targeting 100 hospitals in the first wave of the program, just [indiscernible] how far along you are in…how many hospitals you've targeted versus 100 targets? And would there be scope to increase that once you start seeing more positive readouts from the hospitals in the coming months?

And then the third one, I guess is a more broader question about your midterm guidance and whether you have any new thoughts about when

you'd like to revisit that or perhaps revisit that with the investors in the Capital Markets in the coming 6 months? Thank you.

CARLO ROSA: Okay. We'll take the China, and MeMed and then I'll leave PG with the guidance. Look, as said, China is extremely volatile. So, it looks like that as far as we are concerned and in the immunoassay segment, we saw volumes in the provinces where we operate to bounce back. And that clearly did help in Quarter 2. It looks like from our own projections that we may have moderate, very moderate or no growth in Q3 and Q4, but without really seeing the level of losses that we have seen before, and this again because of the COVID volume…pre-COVID volume coming back. Everything else that everybody is discussing is still there.

So you have pricing going down 30% in the provisional tenders more Chinese preference to our Chinese products. This way I'm saying you know, good Quarter 2, Q3 and Q4 there is…there are not going to be a drag when it comes to next year I think we need to close the year and then we're going to see what happens in parallel though I am comfortable because I think we turn the corner and when it comes to the manufacturing site and perception of DiaSorin become more Chinese and that as you know, does really happen because we are starting to make first validation lot in our manufacturing sites in Shanghai. So this is very good.

When it comes to MeMed I think as you have…I believe you have discussed yesterday at the ACC the…and you have seen…well you've been at the event and you've seen the clinical data very impressive that we're presenting yesterday. Our…clearly our…the people that we hired are going to go and target customers, hospitals in different regions where we have an existing system because we do want to…we want to accelerate revenues and we don't want to actually have placements of new system dedicated you know, volumes of this test I…are relatively low. We are talking about between 2 to 7 tests per

days. So from a volume perspective is nothing, clearly with the pricing effect and it becomes a significant business. But as I think you may have discussed yesterday, we got over the installed base primarily on the East Coast and some very selected areas in California. PG.

PIERGIORGIO PEDRON: Yes, the question on the midterm guidance. I believe that as we previously discussed, we will be hosting an event where we will be updating the financial guidance…the midterm financial guidance said that all the strategic projects and trajectories that we discussed about at the end of 2021 all are valid impart considering the latest events the filing of the Platts, the filing of the Tenessa (49:40), the take up rate of MeMed what's going to happen in China the payback, you know, all of those elements for which is kind of more challenging making a projection, I believe that by year end some of those data points, some of those elements would be clear. And that will allow us to review refresh the financial midterm guidance. Once again said that all the strategic projects and trajectories are exactly the one that we discussed about at the end of 2021 during our Capital Market Day.

NOOR AISYAH: Thank you very much.

OPERATOR: The next question is from Hugo Solvet from BNP Paribas. Please go ahead.

HUGO SOLVET: Hi, hello. Thanks for taking the questions. I have a couple of follow-ups. First on latent TB testing. We have had some discussions about large European diagnostic players potentially entering the latent TB testing market sometime next year. Can you confirm that, and what's your volume price mix expectation within the long term guide?

Second on molecular diagnostics, I think you were about to complete some of the respiratory studies around now to file in Q3 or Q4 2023. Can you confirm the timeline here and any update on the gastrointestinal panel? Thank you.

CARLO ROSA: Look Hugo, I will not certainly comment about what other players are going to be doing with the LTB, it's a large market. We expect people to look at this market bioMérieux [ph] as you know already did it and they had to withdraw the product, the product so it's not a simple product to make. Also Qiagen develop the CD4, CD8 the 2 tubes which is certainly differentiating, Qiagen has been on this…in this market for 15 years gazillion publication supporting the product. That doesn't say that somebody will show up and try to make a run at this market, but I have no information whatsoever except for ton of gossips, and I am really sick and tired of gossips about who is coming to the market. So said that, wait and see and when the very famous large player is going to show up, let's see what they have.

When it comes to molecular diagnostic, you may've missed what I said before. Yes, we completed the Plex respiratory, clinical and yes, we are going to submit in Q4. GI, I am not available as we speak to give any date on GI or blood. Understandably, we believe that blood is going to be actually the panel that will follow suit realizing that with the VERIGENE 1 in the U.S. we have almost 30% market share in this segment. So is a segment we certainly know well.

Was there another question.

HUGO SOLVET: No.

CARLO ROSA: Anything else?

OPERATOR: The next question is from Louise Boyer from Stifel. Please go ahead.

LOUISE BOYER: Thank you for taking my question. I have a couple of follow-up if I may. On the financials first, I was looking at your adjusted EBITDA margin, you mentioned 32% in Q2. Could you run us through kind of a bridge, what do you think are the triggers to go up to 35% in order to

over Q3 and Q4 in order to achieve the 33%...or 34% objective sorry over the full year?

The second one on finance is about your payback issue. I was wondering you mentioned that the provision were in line with what you could have to pay for the 2015-2018 period. Could you give us a number there and maybe an estimation for 2023? I will stop there any maybe come back to my other…next question later.

PIERGIORGIO PEDRON: Hey Louise, this is PG speaking. So I am not going to provide you with specific bridge from Q2 which grows at 32% EBITDA margin as you said. To get to the 34% guidance, I believe few minutes ago I tried to explain, I think it was to Maja why I believe 34% for the full year is still in our line of sites. And that's why we are confirming our guidance. So I just referred to you, you know, to what I just said to Maja, because that's the reason why we see 34%.

In terms of payback, we have a provision in our book which we deem in line with the maximum…with the risk we might have coming from the payback, but please bear in mind the lowest quarter in the period 2015-2018, right. And that is the period for which we are kind of assessing the possibility to settle. That settlement, if we decided to do so, it's going to be just short of €10 million which was again had been fully provided for in our balance sheet. The low is completely silent for period after that 2015 to 2018 timeframe. The thing is that even if we decided to sell and it's a big if, as Carlo was saying, even if we decided to settle, we would still have the possibility that would not prevent us the possibility to fight back, to challenge legally any potential additional claim from the government for the period after 2018. So the decision we will take once again for the period 2015-2018 is not going to impact in any shape or form what we might want to do for the period after 2018. As said that, the situation is really in a flat. It's changing literally every day and unfortunately, I do agree with

Carlo this is an Italian supporter saga, but let's wait and see what's going to happen.

LOUISE BOYER: Okay. Thank you for those alignment [ph]. My other questions were about the strategic program. So you mentioned MeMed earlier in this call. Do you maybe have some more information than us on what they are doing to reach private insurance reimbursement, the unbundling [ph]…or do you talk about, you said maybe in a year. Do you have some data point we may miss on this one?

PIERGIORGIO PEDRON: Yes, I do but unfortunately, this is a confidential information to the company and therefore, I won't be able to disclose. The only think I can tell you is that in order to get the reimbursement of the payers there is…there has been a clinical study which has been negotiated with payers that is in process and as…when completed, it's going to be filed to the payers to support their decision or reimbursement, okay, but anymore of that, I can't disclose.

LOUISE BOYER: Okay. Thank you. And then maybe, just to finish…to confirmation of what you said earlier, you mentioned an update of your financial guidance during potential Capital Market Day or something by the end of the year. Could you remind us what you have now as an information that was not integrated into your formal guidance? And finally about the Plex, you mentioned that you finished the clinical test on the respiratory line and that you wanted to submit it in Q4. Could you just explain to us why not Q3?

CARLO ROSA: SO I am laughing, because I just had 2 days of reviews with the regulatory people, and I am trying to represent that interest. You need to understand that a clinical study for these kind of panels is like 19 clinical studies together, because the FDA is seeing each individual assay…as an assay. So it's like filing 19 510(k) and that takes a lot of time to compile all these 19 510(k) and filing with the FDA, and therefore the testing was completed at the end of the respiratory

season, and now, the team is working and compiling altogether. This is why I am saying I feel comfort with the fact that Q4 is the real timeline for the submission.

PIERGIORGIO PEDRON: Regarding the mid-term guidance, once again, you know, we have a mid-term guidance out there. I believe during Q4 call if I remember you know, we commented on that guidance, many moving elements which are the one that we just mentioned MeMed in China and the payback in the respiratory season and you name it. So that is the official guidance we have out there, but we have to build in some flexibility as again I said few quarters ago considering all the most recent news. And that's why we said we will revisit the financial guidance. So the numbers, not the programs in the project by year end.

LOUISE BOYER: Excluding the respiratory season, it's only bad news, right. MeMed, China and payback.

PIERGIORGIO PEDRON: Say it again, please.

LOUISE BOYER: I said like, excluding respiratory season, it's only on the negative side right, MeMed, delayed China we cannot expect it and payback that was obviously not included in your former guidance?

PIERGIORGIO PEDRON: No.

CARLO ROSA: No, we didn't…we didn't say it on the negative side.

PIERGIORGIO PEDRON: Absolutely.

CARLO ROSA: What we said is that we get better visibility with certain strategic programs and market conditions which you will need a crystal ball to really understand few quarters ago what would happen to China and this is the…MeMed and this is why we said we want to sit with investors and share with how we view with better clarity now, the next

2 to 3 years. But I don't understand why you're saying on the negative side?

LOUISE BOYER: Just because my understanding was that you had a delay on MeMed reimbursement that China was weaker than expected, and obviously the payback policy, you were not aware when you made the former guidance. So my understanding was that on those 3 topics you unfortunately only had negative incremental news since last guidance. But you're saying it's not the case.

CARLO ROSA: What I'm saying is that life is always a mix of things that go better than what you expect and things that are worse than you expect. And this is the time I think since there were many balls in the air, I believe that year end is the time to make a summary of the positive negative and give a view to the market.

LOUISE BOYER: Okay, but that's positive. That's a good news. Thank you very much for all your answers.

CARLO ROSA: Thank you.

OPERATOR: The next question is from Odysseas Manesiotis from Berenberg. Please go ahead.

ODYSSEAS MANESIOTIS: Hi there. Thanks for taking my questions. I got one of the CLIA ex-COVID growth this quarter and particularly the acceleration in Q2 over Q1? I understand QSP and Stu [ph] have been doing good. But could you give us some color on whether this is more of an issue of post-COVID testing environment [ph] recovery or more of new wins with hospitals here helped by your sales force?

And second one, please? Could you give us an update on pricing on your molecular and immunoassay divisions? I remember you're looking into this earlier this year? Would you have an expectation of

the magnitude of the price increases that you could take through in these 2? Thank you.

CARLO ROSA: Okay, I'll make a comment on your first question. I see honestly, 2 effect, I see that in the U.S. is all new business, because we are in an expansion mode in the U.S. getting more customers through the hospital program. We deploy the resources, we have platforms, we have systems, we have products. So U.S. is customer expansion and getting business…a combination of gaining business from competition and/or in sourcing versus stand outs, which is working very well.

When it comes to Europe, I think that there is an effect today of a very important factor of volume, which volume is going back in other different regions where it should be. And especially for some of the specialty products we have in infectious disease, I think we did comment over COVID that for pre-natal testing, we were severely hit during COVID. And now we see all that volume actually going back.

So short answer U.S. all new growth and when it comes to Europe, there is an effect of volume, which if I need to estimate is probably around 40% of the growth that you see. But don't necessarily quote me on that because I'm giving you my rule of thumb estimation.

PIERGIORGIO PEDRON: Yes, regarding the pricing. Odysseas hello, hi. I believe what you're referring to is the program we just started at the beginning of the year. We hired an advisor there to help us out to review the possibility for the group to our pricing strategy, if I can say it in that way, because, you know, we came from an environment without inflation whereby in the past we are very seldom and very few occasion very few geographies at an active policy of increasing prices year-over-year into customers. Then, you know, inflation came and we started that program aimed at being more, let me say, smart in a sense, considering the new market condition in the way in which we were managing our

pricing strategy and trying to eventually go back to customers and increase pricing on a recurring basis.

The exercise that we did is almost over. Now, our commercial organization is going into execution mode, we will start seeing something in the second part of the year. And the bigger impact will come over the following years. These initiatives does not cover only pricing, but we are also considering the possibility to ask customers as many peers are doing to contribute, for example, to shipping cost, distribution, and you name it. So this is one of the several initiatives, I was referring to when I said that you know, we are putting in place programs to keep on safeguard our margins. But so far in H1 you are really almost nothing, I would say nothing.

ODYSSEAS MANESIOTIS: Very clear. And I also have a follow-up. Thanks for your answer so far. So I mean I understand you might not be able to disclose that, but perhaps to try. So, on the clinical study with MeMed that you mentioned has been negotiated with payers. Could you broadly talk about the endpoints here? Are there your typical cost and specificity endpoints?

PIERGIORGIO PEDRON: No, I cannot, but just to make it clear, you said has been negotiated. The clinical…so the protocol has been negotiated. The clinical study is ongoing, and again confidential to the companies can disclose, especially in an environment with this test that is becoming more competitive, whereas you know there is another player today that got the license. So it can be more specific, sorry.

ODYSSEAS MANESIOTIS: Understood, that's fine. Thank you very much.

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

MAJA PATAKI: Hi, me again. I'm sorry, just a quick follow-up question. Carlo, you have been talking about this insourcing of stool testing, you know, driving solid growth in the immunoassay business, and of course there still is room from this to go. But like medium-term, long-term, what is the growth rate for the stool testing market? Are we looking at the similar like mid-single-digit growth or is it a market that you know, stands out with higher growth rate?

CARLO ROSA: Extremely higher.

MAJA PATAKI: Extremely higher?

CARLO ROSA: Yes, you're talking about around on average 25% growth today. And keep in mind we do have a full panel of products. It took years to set this in place and fundamentally you have 2 areas of interest. The first one is the H…you know, we have an H. pylori test, and so that's one growth, and the other one is the Calprotectin assay set, which is becoming extremely interesting because of irritable bowel disease. If you go to the U.S. and you just switch on your TV and you watch commercials, I mean you see how much Crohn disease, and all these new set of drugs, biological's that have been developed and now they hit the market in the U.S.

And what is very interesting, and I would like to tell you that it was all well planned and thought, but it was not. All these biological's actually require TB testing for eligibility, and the typical marker that is used for Crohn is Calprotectin in the last days. Right, so it's a very interesting position that the company puts together in this very much growing segment.

MAJA PATAKI: And can you, sorry that's obviously extending the follow-up question, but just could you provide some indication of how big the stool testing share is of your immunoassay franchise?

CARLO ROSA: No Maja, I cannot, because I realized that we are providing all these numbers, grow the appetite of competitors that are lurking around. So I can't.

MAJA PATAKI: Okay, fine.

CARLO ROSA: But there are 2 things that I think you should understand. Firstly, took years to develop because it's a complex matrix and overall the total panel is 6 products. The second thing is that when it comes to specifically Calprotectin, we have research…we've been researching to add more markers to Calprotectin to actually increase clinical specificity. And then…and I think we have some very, very interesting assays coming over. So, it's a franchise where DiaSorin has been investing over the last 10 years. And now, we are really reaping the benefit of the full menu and the product to come.

MAJA PATAKI: Understood. Thanks a lot.

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

CARLO ROSA: Okay. Thank you, Operator. Bye-bye.