Diasorin S.p.A

"Second Quarter 2024 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 Second Quarter 2024 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 to everybody and welcome to the Quarter 2 2024 results I'm going to make some introductory comments first at constant exchange rate, and then I'm going to leave Mr. Pedron, the CFO of the company, to go through the numbers in more detail.

So, let's start from the top-line, it was a strong quarter. The company ex-COVID grew 7%, and there is an acceleration in Quarter 2 compared to Quarter 1, when it comes to the COVID business, €5 million in the quarter, so far in line with our full year guidance of €30 million.

As said, it's a very strong quarter and it's a combination of immunoassay that is growing 11% with CLIA, which is the major component of this business, growing 13% in the quarter. And this is due to the fact that US and Europe, as we will see later, continue to provide strong results. China is not still impacted by VBP, even if in second quarter we had no growth.

Molecular, plus 5%, it would have been…as we did comment before, we lost a contract last year that has been impacting first half. Without the effect of this contract, our molecular franchise would have grown 8% and there is no impact of PLEX yet, but I'm going to comment on PLEX later.

LTG, in the quarter, minus 7% deceleration, although I think we need to be more analytical about this result. We see growth in consumable, we see growth in royalties, and we see…continue to see a strong decline in instrumentation as a result of the fact that in the life science sector, our partners are not placing systems. So, the performance of this business, I remind everybody, is fundamentally reflecting what the major biotech and medtech companies that are distributing our products are doing globally.

Now, let's dive into the different segments. So, let's start from immunodiagnostic. As said, immunodiagnostic ex-COVID, plus 11%. There is a very strong positive trend on CLIA. So on the LIAISON also in this quarter, which is the result of the performance of 2 main geographies, Europe and the US. When it comes to the US, as we have seen in the last few quarters, the hospital strategy is working well. We are keeping expanding our presence in the US hospitals and is very relevant also for our molecular business, and I will comment on this later.

We are well on track to deliver our 2027 plan with 600 hospitals. So far, we are over 300. Within H1, we closed 50 new accounts. I remind everybody that the target for 2024 was 100 hospitals and we are on track to deliver also the growth this year. Clearly, this has been possible, as I did comment before, on the increased commercial footprint. Thanks to the Luminex acquisition and to the…our menu, which is a combination of specialty products that well fit this segment of the market.

When it comes to Europe, very strong performance, it's around plus 12% in the quarter in spite of some headwind with some legacy products like Vitamin D. When it comes to Europe, the performance is supported by the fact that we continue to see growth in testing volumes

in all the main European geographies and we see no headwind in front of us when it comes to this volume contribution.

If we now move to China, if you remember Quarter 1, we had a positive result but they won the market that was because of an easy comparable to Q1 2023 when there was still low testing volume because of COVID. In Quarter 2, we, in China, experienced a high single-digit decrease that makes the H1 almost flat. We don't see the VBP effect yet, but we continue to see headwinds when it comes to the strong competition due to local suppliers and the fact that there is today, I would call it, moral suasion coming from the government to buy more and more Chinese-made products.

I remind everybody that China does represent today less than 3% of the overall business. So, there is not a significant impact on the company results. However, we continue to stay in China and working to the transformation of the business from Me2 [ph] product catalog, which is what we sell today to specialist or specialty business, which is what is going to be coming with the registration of the QuantiFERON product and the stool products that today are not distributed in China yet.

When it comes to other geographies, we are delivering very good results in all the geographies where we are working direct. Australia, notwithstanding, where we have a very high penetration, is growing almost 15% in the quarter, and high single-digit growth in more established market, Mexico and Brazil, where we have a solid business. The only area where we are suffering is the Middle East, and specifically in Iran, because we had a strong business and because of the local…the current situation, we have not been able to ship products in H1 of 2024. So, overall, immunodiagnostic is doing great.

When it comes to new products…I wanted to discuss MeMed and Lyme. Lyme is in line with the plan. We received…remember, we have submitted to the FDA, our initial clinical results, and we have

received from the agency comments and we are collecting data for a final resubmission in September. So, we believe we are on track to get our product approved by 2025, as per plan. We are also finishing up discussions with a large lab in the US that is going to help us to educate the market, because, as we understand, we need to make sure that we move the market from current testing [ph] to the adoption of the T-cell component.

MeMed, the Jupiter study is confirmed to be completed in Quarter 1 of next year, and in Quarter 3, Quarter 4, there is going to be an initial set of data has already made public by MeMed. It continues to be a door opener for us for discussions with hospitals in the US, and we continue the education campaign to ramp up demand of this test. So overall, our immunodiagnostic franchise is doing fantastic in all different geographies, and we are very comfortable with the sustainability and growth of this business in long term.

Now, let's move to molecular diagnostics. As said, ex-COVID, plus 5% in the quarter. Without the effect of the lost business, last year is 8% growth. And again, there is no contribution whatsoever on PLEX that we just launched 2 months ago. The legacy Diasorin molecular business, what we call the targeted business on multiplexing is growing double-digit. The Verigene business is holding pretty well, and I'm going to comment on the customer base of Verigene shortly.

We have sunset at ARIES as per plan, and we are transitioning the ARIES business to our MDX platform, and it is moving forward as expected. We continue to see growth in the respiratory, also high single-digit growth in Quarter 2. This has nothing to do with the respiratory season that, as you know, will start in…late in the Q3-Q4, but there is more to do with the fact that we do have a presence in this business and we have other infections happening outside the season that are making this business strong. And overall we have a very good performance both in Europe and in North America.

Now, let me make a couple of comments on PLEX and NES. When it comes to LIAISON PLEX, where we have a very good start with a strong interest for the PLEX concept, I remind everybody that as we discussed previously, the adoption of PLEX testing in the regular customer in the US would grant saving in the range of 30%-35% compared to what they are spending today, and certainly in the current environment in the US, this is very well appreciated.

We have a customer base in the US of over 800 customers that we have access to…these are existing Diasorin customers, 300 Verigene users, and then over 300 other hospitals that we serve with our immuno business, and they are not buying from Diasorin molecular and they represent relevant base to market the new platform. Today is an important day. We are here in Chicago in our manufacturing site and we are hosting an event for investor and analyst to review the strategy and explain the technology. And we are extremely positive about the launch of this platform.

LIAISON NES, we have conducted and almost wrapped-up preclinical study in Australia with the new assay, the flu, RSV, and COVID. So, the 4-PLEX assay that we have developed in the platform. We are very happy with the results. We have tested this platform in a clear wave environment, and we are ready to start clinical's in October, as we have discussed.

So, when it comes to molecular, very excited…and very excited because we have a strong business, and we have 2 very nice platforms, very innovative, that are hitting the market now and within the next couple of quarters.

Now, let's move to LTG. LTG, I remind everybody, our LTG franchise is a combination of diagnostic partners and life science partners. Diagnostic partners are doing very well, reflecting the fact

that the diagnostic market worldwide is experiencing strong growth. In the life science technology, we have partners that today are experiencing, as we all know from public information, single to double-digit decline.

Net-net, result is that we see an increase in consumable. We see an increase in royalties, which are the relevant part of this business, and clearly we see a strong decline in instrument placements, and because the market fundamentally is frozen due to the fact that there is CAPEX restriction in the R&D and university environment. So, we continue to monitor the market we…I believe some of the partners are highlighting the fact that they expect this…the life science component to bounce back in the second half. And...but as far as margin are concerned, clearly the fact that consumable and royalties have continued to increase is actually posing for Diasorin. So it's positive for the company.

Now, I'm going to pass the mic to Mr. Pedron, who is going to go through the numbers and then we're going to have the Q&A session. PG.

PIERGIORGIO PEDRON: Good afternoon, Carlo. Good morning, good afternoon everybody. Thank you for joining Diasorin H1 '24 earnings call and for the interest you are showing in our company. In the next few minutes, I'm going to walk you through the financial performance of Diasorin during the first half, and I will then turn the line to the operator for the usual Q&A session.

H1 '24 total revenues at €589 million are above last year by 2% or €13 million. Despite the expected decrease in COVID sales, down by €21 million, and the different perimeter of consolidation coming from the carve out of the Flow Cytometry business in Q1 '23.

Business ex-COVID is growing in H1 at constant exchange rate by 6%, 7% excluding the Flow business, therefore, in line with a higher range of the full-year guidance. H1 COVID sales in the quarter accounted for €40 million vis-à-vis €35 million in 2023, confirming our 2024 outlook, which is calling for nearly €30 million. The FX impact in the quarter is not material at all.

Q2 revenues ex-COVID constant exchange rate grew vis-à-vis 2023 by north of 7% of €20 million, thus recording an acceleration toward Q1, which grew 5%. This variance as we just heard, has been driven by a better performance of both the immune and the molecular franchises partially offset by the LTG business because of the generalized softness of the life science market and in particular to instrument sales.

H1 gross profit at €390 million or 66% of revenues is better than last year by €11 million or 3%. Q2 gross margin ratio at 66% of revenues as well is slightly better than last year, which closed at 65%. All the initiatives aimed at improving operation processes and containing costs alongside a more structured approach to pricing which we discussed in the past, allowed us to preserve margins and despite the inflationary pressure experienced in the last 18 months, now muted, and the manufacturing costs we are incurring into to set up our new plant in Shanghai which has not started production yet. I believe this to be a remarkable indicator of the success of the relentless efforts we put in place to safeguard our profitability.

H1 '24 adjusted operating expenses at €229 million, basically in line with 2023, with a ratio of revenues of 39% vis-à-vis 40% of last year. The fact that operating expenses have not increased despite the investment to support the MeMed acceleration program in the US, and the physiological yearly labor cost rise is a clear demonstration of our discipline in managing the cost base and the result of the synergies delivered after Luminex acquisition, and marks a clear path to

increasing profitability in line with the plan presented during the last Capital Market Day.

Adjusted H1 other operating expenses are higher than last year by €4 million. This increase is driven by many moving parts, amongst which I'd like to mention a new tax introduced in 2024 by the Italian Government on medical devices companies equal to 0.75% of sales made to laboratories covered under the Italian National Health System. The early impact of this new levy should be around €1 million. Please be aware that this is different and on top of the Italian payback mechanism, we have discussed many times in the past, and that I will cover in a few minutes because there are some news there.

As a result of what I just described, H1 '24 adjusted EBIT at €153 million, 26% of revenues, is higher than last year by €9 million or 6%, whereas the increase in Q2 is 14% or €10 million. Half year adjusted interest income at €2 million is in line with last year, and the same is true for the adjusted tax rate, which closed the first 6 months of the year at 23%.

Moving now to the year-to-date adjusted net result, we see €120 million or 20% of revenues, which is better than '23 by €7 million or 6%, whereas the increase in Q2 is 12%.

Lastly, H1 '24 adjusted EBITDA, just short of €200 million or 34% of revenues, is better than '23 by €8 million or 4%, whereas the increase in the second quarter accelerated to 10% with a profitability of 34% vis-à-vis 32% of Q2 '23.

Let me now move to the net financial position. We closed June '24 with a net debt of €781 million basically in line with the end of 2023. The free cash flow generated in H1 has been offset by the payment of dividends to our shareholders, some share buyback to support the

equity compensation plan for Diasorin employees, plus some minor moving parts.

Before discussing 2024 guidance and opening the Q&A session, let me update you on the so-called Italian payback, which, as I think you will all remember, is a request for companies to payback part of the regional budget over-spending on medical devices covered by the Italian National Health Service. A few days ago, and precisely on July the 22nd, the Italian Constitutional Court ruled in favor of the legitimacy of the law that introduced this mechanism back in 2015. At the same time, though stating the possibility for each company to settle the amounts due for the period 2015-2018 by paying 48% of the original ask.

Nevertheless, the payment is currently suspended, and only upon a new request made by their agents that must recalculate what originally due at the light of the ruling imposing the reduction to 48%, the amount should become payable.

On top of this, to make things even more complicated, the trial will continue before the Administrative Regional Court in Rome that will judge on the other objections, beside the constitutionality issue raised by the claimants last year. To confuse this saga even further, some operators are considering bringing this case before the European Court of Justice for the alleged violation of EU rules.

Now, let's move to what this means for us, for Diasorin. As you might remember, we have built over the last few years in our balance sheet a provision against this risk. Therefore, the latest legal developments are not going to have any impact to our P&L, whereas in the settlement scenario, we would have a net cash out of about €7 million.

We are assessing with our legal team and with the Association of the Italian Diagnostic Companies how to move forward, meaning if to

settle or keep on litigating, since many things are not clear and determined yet. And as usual, we will provide you with an update as things progress.

Let me now finish my remarks moving to the outlook. Considering the strong start of the year, we are increasing the 2024 guidance, aligning with the higher range of what previously reported, both for revenues and profitability. To be more specific, the new outlook is calling at pervious year exchange rate for revenues ex-COVID to grow between 6% and 7%, with COVID sales at about €30 million, that is not going to change, and an adjusted EBITDA margin at about 33%.

With that said, let me please turn the line to the operator to open the Q&A session. Thank you.

Q&A

OPERATOR: Thank you. 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 your phone when asking question. Anyone who has a question may press "*" and "1" at this time.

The first question is from Kavya Deshpande with UBS. Please go ahead.

KAVYA DESHPANDE: Hi, Carlo. Hi, PG. Thanks for taking my questions. I've got 2, please. So the first is just on the US hospital strategy. So, I know in past you flagged that there was only very little overlap between your hospital customers and Luminex's when you acquired it. And I was just curious if the new accounts that you've been adding, have those mainly been from the Luminex pool that you're now bringing over to the

immunoassay franchise or they are brand new accounts here as well that you're gaining traction with?

And then, my second question was around molecular. So, you called out MDX as one of the drivers of outperformance here. Was that mainly the respiratory portfolio in MDX, or was it more balanced between that and the specialty non-resp [ph] tests as well? Thank you.

CARLO ROSA: Hi, Kavya. Now, when it comes to the first question about the US hospitals, I would say that the vast majority of accounts are new accounts. And this is because the size of the hospitals served by Luminex was more mid/small. And therefore, when it comes to the…our current strategy on the LIAISON XL, we are going to meet high-volume accounts, which actually you see the effect on the revenue, the US CLIA business essentially growing almost 20%.

So, long story short, today we are really focusing on new accounts…completely new accounts. And as I did comment before, we see MeMed for the time being not as a strong contributor to revenues, but as a very relevant asset to initiate discussions with these hospitals.

Second, on the MDX, what we call the targeted is a combination of 2 businesses. As you remember, there is an ASR business, which continue to thrive as a combination of the fact that we keep launching new products in that segment. And in the last few years, there are really few players left in this space. And we actually inherited this business when we bought Focus from Quest, because it was the outfit that Quest was using to develop their full LDT business. So, it's a very, very nice business and it's growing double-digit for us.

The rest of the…the catalog on the MDX, you know, we have been focusing most of this business in the specialty, and actually this is paying off, clearly, because we don't have competition in the space and

we are really...we are extremely excited for Candida auris because it's been a de novo...it's a de novo 510(k). It's been a long clinical study. We are the only one in the US market to get this product approved is raising concern. And so, long story short, we really believe that turning the MDX into a specialty program strategically was a good decision and continue to support the growth of this business.

KAVYA DESHPANDE: Thank you very much.

OPERATOR: The next question is from Marianne Bulot with Bank of America. Please go ahead.

MARIANNE BULOT: Thank you very much, and thank you for taking my questions. I have 2 as well. So, the first one is, we've seen obviously very strong performance in North America driven by the hospital strategies. And so, I was wondering if you could give maybe a little bit more color in terms of profitability impacts from this strategy especially?

And the second question is more on your mid-year guidance and the phasing into this year. Obviously, you had a strong H1 that's 34%, which is above the upgraded range of 33%. So, if you could give a bit of color on the phasing for the rest of the year, and if there is anything that could be a slowdown into H2? Thank you.

PIERGIORGIO PEDRON: Hi, Marianne, this is PG speaking. Thanks for your questions. I will start with the guidance one. If you go back and look at the performance of our business over the last few years, what you would see is that typically in H2, OPEX, so H2 over H1 of every single year, OPEX are kind of increasing for 2 reasons that we see happening year-over-year. The first one is that we have our salary merit increase kicking off in July, right? And as you might remember, 60%, 65% of our OPEX is in reality labor cost, right? And we expect this impact to be give or take €5 million additional costs in H2 compared to H1. On top of that, if you look at the phasing of some discretionary spending,

we had some of those [technical difficulty] projects which are you know, gaining some speed of traction in H2. And my estimation is that from that we will have an additional €5 million give or take of additional OPEX, as I was telling you.

And it's interesting, if you go back and look at 2023 and you do the same exercise, once you would take out the fact that in H1 2023 we had the Flow Cytometry business, you would see a similar increase. So, long story short, so if you wish what we see in H2 is slightly more than 32% EBITDA margin with you know, similar gross margin, and one point let me say, give or take of profitability invested in OPEX, if I can use this word. So, we feel pretty comfortable with the 33% as usually you know, we like to deliver on what we commit. And this is, I believe, the story about guidance and phasing of the guidance for 2024.

In terms of profitability of the hospital business, usually we don't like, and we don't disclose profitability by customer segments, right? As you know, the immuno business is one of the businesses which for us carry one of the highest margins, so to say, definitely higher than the molecular one. So, you have obviously some kind of positive impact coming from that, but also, if you look at the margins of H1, we have a positive impact coming from the fact that we had lower...as Carlo was commenting, lower instrument sales in the LTG business, and the lower export sales, which usually come with a lower margin. So, once again, many moving parts. But you know, the general statement is that immuno business carry very good margins and hospitals pricing in the US allow us to, let me say, have margin rich assays.

MARIANNE BULOT: Okay, thank you very much.

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

ODYSSEAS MANESIOTIS: Hello, thanks for taking my questions. Sorry, the line is breaking a bit. It's not great here. But one on MeMed, please. Regarding the inclusion of MeMed in some US hospital guidelines, could you please talk about how exactly MeMed was included in the guidelines, as in…is it a first-line test for paediatric [ph] patients with respiratory infection? So I just want to clarify you know, how this was included there?

And secondly, could you give us where that might be, I might have not heard that because the line is not great. But could you give us a bit more color on the strength of immunoassay, as in the particular tests that did well in the second quarter?

And may I squeeze in one last one. So on the margins, you have previously said Carlo, that you're going after the molecular market for growth, not margin. So, also taking into account VBP and DRG becoming more of a problem in China in '25. Is it fair to assume that the '27 margin target should be very backend, as in not seeing much expansion next year? That's it. Thank you.

CARLO ROSA: Hi, Odysseus. So, the first question on MeMed was on guideline, not guidance, right? Guideline meaning clinical guideline?

ODYSSEAS MANESIOTIS: No, it was in clinical guidelines of hospitals as in for the ones that you have started doing that already, how is it...is it in first-line tests or for paediatric patients, or...?

CARLO ROSA: Yes, I think we did comment this before and I don't think that we have any specific update on that. And again, in short summary, the customers that we have up and running between us and MeMed this assay are all customers that have taken the time to implement the testing of MeMed of the algorithm B versus V, in a certain patient population that, as we discussed in the past, really depends from hospital-to-hospital. Some do decide to start with children, others do

open it up to different age groups. And what we see is a variability in the way that different hospitals are actually approaching the problem. But I believe that 2 things are very relevant.

The Jupiter study is important because it will remove potential issue of reimbursement. Although, today the assays are reimbursed by the insurance policies...the insurance companies using generic codes. We don't think...believe that this is sustainable long term, but today we don't see necessarily denials in that area. And including the fact that as we discussed few times, MeMed is covered under DRG, right? So, it's part of the lump sum that hospitals do get for outpatients. So, we're going to give, as we have discussed, more color on MeMed by year-end, because we will have one year experience in US and Italy. And I think it's going to be a very interesting discussion. What's noteworthy is that also by the end of the year MeMed is going to release a subset of data to the Jupiter study. And so, the market will have an indication on how things are actually doing clinically with that study.

The strength of the immunoassay, which I think was your second question, it goes back again to our specialty strategy. And it's stool, it's the QuantiFERON, that certainly are the #1, #2 products these days in terms of door-openers. But also the rest of the menu of the infectious disease we are experiencing as a result. We do have infectious disease in most of the European countries. We have market share, so 30%, 40%, and we were experiencing increase in testing volume. So, now we see the whole portfolio of products really kicking in. And as we discussed few times, China is...at this point, is minor damage in its damage control. And so, it does not really influence our CLIA, okay?

PIERGIORGIO PEDRON: There was one on the margin.

CARLO ROSA: One on margin, that I think that PG is going to take.

PIERGIORGIO PEDRON: Yes. Hey, Odysseas. So good to talk to you. I believe what we said during the Capital Market Day is that our increase in EBITDA margin is mainly an operating leverage play right. And I believe you can see it very clearly in Q2, whereby revenues increased by 5% and OPEX didn't increase at all. This meaning that we already have a setup when I think about our OPEX, which will allow to sustain the growth coming from all the new platforms which are going to hit the market. We asked ourselves, after Luminex acquisition, you know, what are we going to do? Do we want to keep on investing in the commercial organization, waiting for the new products to come? Do you want to pause? And eventually, we said it was more wise you know, to keep on investing on our commercial footprint, especially in the US, waiting for the products to come.

Now the products are coming, the PLEX hit the market. As Carlo said, NES is doing just great. And so, as soon as we will have those products in the market, you will see that, let me say, operating leverage play hitting our P&L. So, I would say that is a fair...obviously you know, there are many moving parts, the usual story, right? My disclaimer allows me some flexibility, but this is the story, which is also true if you wish. If you look at the guidance for the year, right, we started with the guidance which was 32% to 33%. And after the result of the first half, we felt comfortable enough to raise the guidance. I believe this is what I can you know, comment and share about margins and margin development.

ODYSSEAS MANESIOTIS: Very good. Thank you.

OPERATOR: The next question is from Shubhangi Gupta with HSBC. Please go ahead.

SHUBHANGI GUPTA: Hi, thanks for taking my question. So, I have one on PLEX, please. So, can you update the growth momentum in PLEX? What is the

feedback from customers? And how does it compare to the other instruments in syndromic testing that already exist?

CARLO ROSA: Okay. So, the audio was not great. So, I think you're asking for PLEX, and how does it compare with other existing systems. Is it correct?

SHUBHANGI GUPTA: Yeah.

CARLO ROSA: Okay. As we…I think, have discussed a few times in the past, and we're going to be covering today. Again, as I said, we are here in Chicago, we're very excited. We have a lot of analysts participating and a lot of US investors. So, when it comes to PLEX, the fundamental difference between us and competition has to do with ease of use in comparison with bioMérieux, with the BIOFIRE, because understandably so the BIOFIRE has been a very successful platform, but the technology is a little old, and so there is a lot of entrant time that more modern systems don't have.

But fundamentally, the distinctive offering of Diasorin is with the Flex. So, the ability to Flex, the panel depend optimizing, let me say, the panel with the population, the season tested by a lab. And I'm giving you a very simple example. During the respiratory season, if you look at the prevalence of the viruses. Well, first, the majority of the infections are virus-related and not bacteria-related.

And the second, if you look at the prevalence, you take the Top 7 viruses, which may vary depending on the population tested. So, there is a certain prevalence on kids that you don't see in adults. But with just 7 out of potential 19 targets, you cover 90% of the infections, okay. And this is giving you the power of flexing.

And if you apply these algorithms, that every hospital will be set free to the side, because we offer a basic 7 targets panel that can be...and

those targets are pretty much decided by each individual customer. If you just do the math, and you look at the prevalence, and you look at what customers are paying today for the full panel of 19 versus Flex, you're talking about saving a significant amount of money, 30%, 35%, 40% to what you're paying today.

And the second data point, which I think is very interesting, is that if you look at the respiratory market…just respiratory market in the US, that does represent 70% of the total syndromic business. And you look at what an average hospital system is actually spending in respiratory syndromic, you're talking about $350,000 to $400,000. So, you understand that savings are significant. You're not talking about tens of thousands, you're talking about $100,000, $150,000, which certainly is attracting the interest of many stakeholders in the hospital system.

If you now go behind respiratory and you go to blood, for example, because there is another concept which I think is very important for everybody to understand, flexing is not only relevant for respiratory, flexing is relevant for all different applications. If you look at blood, which is going to be the second panel that we are going to launch, we just got the Yeast approved, and we are on track to file by September the other 2 blood panel for approval in the US. Right there, you can actually use the panels according to the current guidelines without forcing customers to use a full panel gram-neg or gram-positive patient, which is what they are forced to do today.

So...and if you go now to GI, which is the last bucket, that is even more relevant, because when it comes to GI infection, you have seasons, you have geographical differences, you have people that are actually traveling in exotic locations are coming back, and therefore, you're not forced to do all and everything that is on mother earth [ph], but you can tailor-made these panels, so depending on geographies.

So, it's a very powerful positioning for the company. And we just launched it 2 months ago. We have a respiratory as we speak. And we have a lot of traction coming from customers because of what we discussed. So there is a financial incentive certainly to look into this technology. We have closed the first account, so we have real-time users of the technology, and we have a good funnel.

And the last element, which I think I did provide during my opening remark. We have in the US where we launched the system, by the way, everybody understand that we just did a US launch for the time being. We have an installed base of roughly 800 customers that are Diasorin customers, either immuno or Verigene or molecular...doing molecular, not doing multiplexing that we can address and present this new technology. Vast majority of this would be certainly hospitals, which are either hospitals managed by the very large labs or independent hospitals. And as you know, when it comes to hospitals managed by very…by the very large labs, we do have a relationship in this...with the large lab that is allowing us to discuss overarching contracts.

Last but not least, the opportunity in this space for Diasorin clearly is in the conversion, right? As said, we have a sizable Verigene business that certainly we will have to convert, but every time there is a conversion, there is a price increase because of the positioning of the Verigene I. So, all-in-all, clearly the jury is out, the system is on the market, and I think we're going to provide more color coming the next few quarters.

SHUBHANGI GUPTA: Thank you. Just a quick follow-up. Do you have a number on the installed base for Verigene?

CARLO ROSA: Yes, we do. But as you can appreciate, we don't disclose. What we have said is that roughly in the US, we have 300 customers using the Verigene I panels, blood, respiratory and GI. The majority of these

customers are non-respiratory, and simply because the respiratory business, which makes the lion's share of the market, requires the handling of volumes, and clearly the Verigene I that is more on hands-on technology did not fit that market. But...and therefore, our Verigene customer base is primarily GI and blood.

SHUBHANGI GUPTA: Thank you.

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

AISYAH NOOR: Hi. Good afternoon or I guess, good morning to both of you. Thanks for taking my question. My first one is on the immuno growth. I mean, you've had a few quarters of very strong growth already. And I think you know, you mentioned in the press release its 22% growth in the North America immuno business, which is pretty strong. How sustainable do you think this is as you look out into the second half of the year and even 2025? And if you could disclose what the pricing levels are in this business…in the immuno business, relative to historical levels, that will be super helpful.

And then, the second question is on the LIAISON PLEX. What do you think is the...well, actually, you mentioned at the beginning of the launch you were hoping to replace or upgrade as much as possible your installed base of Verigene I. How far along are you in that replacement phase now? And where are you hoping to be by the flu season in Q4?

CARLO ROSA: I don't remember saying that we want to replace the existing installed base, I said that we are going to be balancing new customers with the existing installed base. And clearly, I'm not going to provide any data in what we are doing today when it comes to the mix between the Verigene I accounts and what we do with the PLEX.

On the immunoassay, to be honest with you, I don't understand the question, because you're asking if I think this is sustainable long term. I think that we provided the answer in the past few times, because we said that we have 2,200 customers that have been mapped and they constitute a base that we can work on, primarily US hospitals. And today, we are really the beginning of the runway. So, I believe that this strategy is clearly sound. Now, we have been pushing in this segment for almost 3 years and we continue to see the strong success.

Pricing, as you can imagine, I'm not going to comment on pricing. It is though very well known that because of the size of the accounts, the hospital market is a richer market than the traditional commercial segment.

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

HUGO SOLVET: Hi. Hello. Thanks for taking my questions. I have a few, please. First on LIAISON PLEX, you guys had the approval of a blood panel last month. Just want to clarify the commercial rollout for blood panels here. Will you be gradually rolling out this one, or wait for the 2 next ones to be approved before to maximize the commercial opportunity?

Just to follow-up on that, maybe with 6 months into the year, 7 now actually, you can help us understand what's baked into the guidance in terms of LIAISON PLEX sales, as you likely have some strong leads now that you started to engage with US customers?

And lastly, Piergiorgio, you mentioned some operating leverage with new platform. Just a quick clarification. Would you expect that as soon as you launch the new platforms, or will you need to reach scale for operating leverage to be triggered? Thank you.

CARLO ROSA: I will take the first question. Clearly, we need full panel. So, Yeast was the first product that we went through. It did have strategic value for us, because we have negotiated with the FDA how to present the data. And actually, this panel went through, as you noticed, very smoothly. So, now we have a framework for gram-pos, gram-neg, but certainly, we are not...as we speak, we are focusing on respiratory and we are not working on blood, because we need the completion of the panel.

Then, I leave the other 2 questions to PG.

PIERGIORGIO PEDRON: Yes, I will start with the operating leverage. I believe what I was trying to convey is that you know, basically in our projection, the top-line is going to grow faster…much faster than operating expenses. And you already saw it in Q2, and this is what is going to drive and increase in our EBITDA margins. And when I talked about the launch of new platforms, what I meant is that since we will expand our offerings, thanks to the fact that PLEX just reached the market, we're going to expand the menu. We're going to obviously, launch the product. The NES is going to come, Lyme, MeMed, you know, all of those programs that we discussed about during our Capital Market Day are going to be very nice contributor to our already existing solid top-line growth. As a combination of those you know, new products' platform hitting the market, building on the existing revenue growth and on a management...tight management of our cost that is what is going to deliver increase in margins.

In terms of...if I got your second question right, you know, I believe you asked guidance on PLEX sales. We're not going to give any guidance on PLEX sales. I mean, obviously this is a sensitive topic from a competition perspective. You will see our PLEX sales you know, reported in our total molecular sales. We will give some color,

we will try to explain you guys you know, how the things are going, but don't expect from us a very specific number.

HUGO SOLVET: Thank you.

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

MAJA STEPHANIE PATAKI: Hi, good afternoon. Thanks for taking my questions. I would have 3, please. Carlo, you have been commenting on strong European volume growth now for a couple of quarters. Can you maybe provide a bit more insight what you think is driving the increased volume growth in Europe, and how long is that sustainable from a market perspective?

My second question relates to your commentary around the 7 pathogens covering 90% of all reasons for the infection. Is it any 7 pathogens that are covering 90%? And are you basically defining the first 7 pathogens that need to be tested or how do I think about that?

And then lastly, just to confirm, the flexibility is not only going to be on respi and gastro, but it's also going to be on blood culture and later on, on the meningitis encephalitis? Thank you.

CARLO ROSA: Hi, Maja. Look, when it comes to the European growth, it's very difficult for me to dissect this number, because is…first, we play fundamentally in infectious disease, right? We are not in oncology, thyroid, I mean, the more mainstream. So, I really don't know first if this is an overall volume increase or not. I assume, looking at...for example, I saw Roche reporting and they play in that segment, and they had an outstanding result in their immuno franchise. So, I assume that we also see a volume increase overall in these more Me2 panels.

When it comes to infectious disease, it is across the line and across the board. So, you see prenatal, you see hepatitis, you see all these essays going up, and when we talk to customers, and these across geographies by the way. So, it's not just one. It's pretty much everywhere, including countries where...like Germany, where typically it's...testing is very well controlled from reimbursement point of view. And customers are saying that as a result of the COVID, there is a resurgence or more attention to overall infectious disease testing, okay. This is as much as I can tell you.

Is this sustainable? I don't know. I think that we are talking about...just to put in perspective, we are talking about a volume growth of probably 3%, 4% versus what traditionally was more into the 1%, because you always see volume increase, but not to this level. By the same token, I believe that PG made a good point. We do have now a process in place to control pricing much better than before. And we were able...we now see also the effect of this price increase that we negotiated across different geographies with customers because everybody recognizing that there has been…there is an inflationary effect on the market.

Now, if I move to Flex, yes, Flex is going to be across the different panels, and I'm going to make a comment about it later. But when it comes to the 7 targets, I'm not deciding the 7 targets, the customer is deciding the 7 targets. And what we are presenting today here in Chicago is the fact that the 7 targets, which are primarily viral targets, really depends on the mix of population that in the season, okay. For example, in the RSV season, it makes sense to include RSV, in the non-RSV season, or you know, RSV is particularly widespread between kids and elderlies. And so, when you test someone that is more my age, I don't consider myself an old guy yet, it will not make sense to run RSV, for example, if I show up with symptoms, at least as a primary screening.

So...but again, just to make it clear, we are not deciding which are the targets. We are just saying pick 7. And the hospitals clearly have the ability to do what they want. One last comment on flexibility. I believe flexibility is very relevant for the existing panels, but is super-relevant also for the future panels, because if you think, for example, the tick-borne is an area where we are present. We are very strong. We are present with Lyme. Today, where we dominate the market, we are investing with Qiagen in this area. And certainly there is a need of a molecular component to it, not to Lyme specifically, but to all the other tick-borne's where we are present with our ASR.

And in that case, again, tick-borne, you have ticks diffusion in different geographies, so it would not make sense to have a fixed panel for that. But custom should be able to adopt depending on season, depending on geography, and depending where actually the patient is coming from, okay So, to me, flexibility...in this environment, I believe that not offering flexibility is a nonsense...is a medical nonsense, and I think financially also is a great incentive for customers. This is the feedback I'm getting so far from the launch of PLEX.

MAJA STEPHANIE PATAKI: Okay, thank you very much.

OPERATOR: The next question is from Ana Bain with Barclays. Please go ahead.

ANA BAIN: Hi, there. Thanks. Congrats, guys. Yes, on the line on behalf of Gaurav Jain here. Just a quick one from me on PLEX, you mentioned, sort of, I think, over 300 US immuno customers as a potential to the cross-sell target market for PLEX. Just wanted to clarify, do you feel like these customers are existing molecular customers who are with a competitor, or is this blue ocean strategy addressing you know, new targets, the molecular market that can be tapped into as a result of your lower price point?

Related to that, just a question on your sales and marketing. I'm keen to understand the extent to which there's cross-selling within immuno to molecular. And I guess sort of based on that as well, I guess a couple of months into the launch of PLEX. Do you remain comfortable that your existing level of sales force is sufficient for the rollout of PLEX in line with your guidance? Thanks, guys.

CARLO ROSA: When it comes to the 300 existing hospitals, and it's over 300 by the way, these are hospitals that do...all of them clearly do molecular testing, because they are mid-large institutions, hospital systems. And so we see...and today, remember, when we go with our immunoassay platform, fundamentally, the menu is an infectious disease menu, because you have QuantiFERON, you have stool testing, which is also infectious disease, and then we have the traditional panels for all the prenatal infections. So, we are an infectious disease company and this is why molecular fits very well with our customer...existing customer base in the US and in Europe. Unfortunately, in Europe, we feel that the market for multiplexing is not so developed for many different reasons and we want to focus today just on the US market.

Sales and marketing, today, look if we look…if I look at the funnel moving forward for PLEX...initial funnel we just started, but there is already cross-selling happening. So, 10% of the funnel today are hospitals doing immuno and not doing molecular, okay? So, I see...this is why I was referring during the call to a potential installed base of 800 hospitals and commercial labs in the US that we can reach with our PLEX either because they are Verigene accounts or they are infectious disease, people, labs, they do know us and we can access with PLEX.

OPERATOR: The next question is from Giorgio Tavolini with Intermonte SIM. Please go ahead.

GIORGIO TAVOLINI: Hi, good evening or good morning, everyone. Regarding your revenue guidance, is it correct to assume that the improvement is sectionally linked to the growth of molecular diagnostic since after the 4% growth in H1 and 5% in the second quarter? So, I was wondering if the original target of a flattish molecular revenue growth should be now understood as flat to low single-digit, I don't know.

And the second question is on the QuantiFERON platform. We have seen the new US guidance recommending the use of the latent TB test in paediatric population. So, I was wondering if you're seeing any acceleration in the adoption of this test, and if you see any new developments from competition on the latent TB test. Thank you.

CARLO ROSA: Look, the new guideline just hit the strait when it comes to TB, and therefore, certainly there is an increase awareness of TB testing in the US. I think Qiagen has been doing a fantastic job in educating this market and we continue to see an uptick in volumes for this product line, okay?

And I'm leaving then PG to answer to your first question.

PIERGIORGIO PEDRON: So, Giorgio, on the guidance, you're right. I mean, I think you are looking at the Capital Market Day data where we said that in 2024, we would have expected a flattish molecular growth. In reality, what is happening is that both for the molecular franchise and the immuno franchise, we are seeing better numbers than what we originally budgeted for. And for molecular, I believe Carlo said very clearly that we are enjoying a very nice growth on the...not only on the legacy Diasorin business, if you wish, the specialty business with ASRs and you know, the products such as the HSV, vis-à-vis, all of those high specialty products, high price, but also you know, the legacy, if you wish, Luminex business, so the Verigene and what we call non-automated assays is doing slightly better than what we originally expected.

And that has been able to more than offset the softness that we are seeing on the LTG business, right, because of...we are not expecting the life science business to be in the LTG business, I mean eventually capable of offsetting the increase we saw in the diagnostic part of the business. So, long story short, is the answer is molecular. Both legacy and legacy Luminex and legacy Diasorin and immuno business, which grew to such an extent to more than offset the softness we are seeing on the LTG business.

GIORGIO TAVOLINI: Many thanks, Carlo and Piergiorgio.

PIERGIORGIO PEDRON: Thank you, Giorgio.

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

CARLO ROSA: Thank you, operator.