Diasorin S.p.A.

"Nine Months 2025 Results Conference Call"

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MODERATORS: CARLO ROSA, CHIEF EXECUTIVE OFFICER

PIERGIORGIO PEDRON, CHIEF FINANCIAL OFFICER

OPERATOR: Good evening. This is the Chorus Call conference operator. Welcome, and thank you for joining the Diasorin Nine Months 2025 Results Conference Call. As a reminder, all participants are in listen-only mode. After the presentation, there will be an opportunity to ask questions. Should anyone need assistance during the conference call, they may signal an operator by pressing "*" and "0" on their telephone.

At this time, I would like to turn the conference over to Mr. Carlo Rosa, CEO of Diasorin. Please go ahead, sir.

CARLO ROSA: Thank you, operator. Ladies and gentleman, good afternoon, and welcome to the Quarter 3 Diasorin conference call. As usual, I will make some qualitative and quantitative comments on the quarter and then I will turn to our CFO Mr. Pedron for the financials…comments on the financial results.

Let me start with, some, general notes and on the 2 main businesses that we have immunodiagnostic and molecular diagnostic. With the immunodiagnostic, the strategy continues also in Q3, as we've been discussing now for a few quarters, and I would say in the last 2 years. So, we have a development strategy in the US, as we know, enlarging our footprint in the hospitals, and as it happened last year, we foresee from the results that we have seen in the first 9 months including Q3, that we will hit our target of roughly 90 new hospitals. And we confirm our ambition to reach 600 new hospitals by 2027.

Meanwhile, we continue to develop content on the Liaison platform. We have developed a new version of the QuantiFERON essay for TB is called high throughput that we are ready to launch in Europe and we have submitted to the FDA for approval and this is to continue to offer better and improved solution to high volume accounts around the globe again together with our partner Qiagen. We have launched a new assay, a specialty assay,

which is the TSH receptor assay, and this is in continuation with our strategy of continuing to enrich the catalog of the LIAISON XL with new and specialty products.

I mean it, there's been new evidence which has been presented at the ASID meeting in 2025 and so we continue to, I mean it continues to deliver on its on its promise to fund clinical study that prove the clinical use of the algorithm for differential diagnosis between bacteria and viral infection. And so, we continue to believe in this program and we continue to support MeMed deployment in the US and key markets using the LIAISON XL and also the key system of MeMed that we have in distribution in the key markets.

From, cost point of view, we have announced that we're going to consolidate our manufacturing in Europe. Closing our German plant and consolidating all our volumes into the Italian and UK plant and the project is ongoing as expected and will be concluded as expected.

If we now turn into molecular diagnostic, where we have 3 platforms, and I will comment more on the sale result of the 3 platforms. Although, when it comes to menu activities and major achievement for the LIAISON MDX, as you have seen the press release, we got finally approval of our FLU A/B & RSV and COVID-assay, which we were missing from our arsenal, and this should give us the opportunity to stabilize our MDX respiratory franchise that has been suffering, as we will see later, both from increased competition with the 4-Plex, but also clearly decreasing volume due to the very late start of the respiratory season. On the LIAISON MDX, we continue to develop strategically new assays and the Candida auris, which has been very successfully launched in the US, now has also been made available in Europe through CEE marking.

If you move to the LIAISON PLEX, we have launched the blood panel, gram-positive, gram-negative and yeast. We have been completed the clinical study for GI that we plan to submit by the end of this month, assuming that the FDA will open up, because today the FDA is working on current applications but not on new filings. So as soon as they reopen, we are ready to file the gastroenteric, and we expect clearance by H1 next year, and this will complete the fundamental stream of products needed to be competitive on PLEX.

On the LIAISON PLEX, as we have previously, we signed a major agreement with Quest. Quest is a very trustworthy partner of Diasorin, and we have initiated deployment of PLEX for the RSP panel in all the Quest labs. This is going to be completed and validated year end, and we will start to generate revenue starting from Q1 of next year.

We have launched fully customized base panels as part of our flexing strategy in the US, and I will comment later on the success of PLEX, but we see adoption of the flex algorithm in half of the installations that we achieved in the US.

Now, when it comes to LIAISON NES, which is our third strategic platform, we submitted in July for the 4-Plex respiratory panel. The interaction with the agency is continuing without hiccup or anything unexpected, and we expect to get clearance by year end of early 2026.

So, let me just now move to discussing the Quarter 3 revenue, as usual, at constant exchange rate. So, in Quarter 3, our business ex-COVID grew by 3%, driven primarily by immuno, which delivered a 6% growth, with molecular diagnostic, where the overall molecular diagnostic franchise declined by 1%, and LTG declined by 6%. I'm going to comment later on each of these elements. This means that 9 months into the year, ex-COVID,

Diasorin grew 6%, with immuno leading at 7%, and molecular at 3%, and LTG at 4%. To fully understand the Quarter 3 results, we will provide more data and deeper segmentation across the 3 business lines. So, I'm going to talk about immuno, molecular, and LTG.

So, let's start from immuno. In immuno, let me remind you that in H1 '25, so in the first 6 months, the franchise grew 8%. If you look at this growth, taking out for one second China and the outbreaks event, which we did comment before, growth has been 11% in H1. With North America growing 16%, the rest of the world, including Europe, ex-China, growing by 9%, and China declining by almost 20%. What happened in Quarter 3? In Quarter 3, total immuno grew by 6%. If you look at the total immuno without China, the outbreak effect in Quarter 3 has been very minimalistic. So, the base business without China grew 9%, so strong growth.

If we now look at the major geographies, US continues to grow very strongly at 14% in the quarter. The rest of the world, including Europe, had mid-single-digit growth 6%, and there is a very specific element that did impact Europe, and I'm going to comment later. In China, because of the implementation of the VBP2 [ph] that now is covering all the oncology products, took a hit…very severe hit in the quarter, minus 30%.

Now, let's look at what happened in the main geographies. Let's not discuss North America, because North America continues to deliver. Hospitals are in line with expectations, and growth in the quarter has been 14%, so let's take that off the table.

When it comes to Europe, we see immunodiagnostic testing volumes decelerated in Quarter 3 versus H1, and this specifically has been reported in 2 main markets for Diasorin. One is Germany, and one is Italy. So again, we saw a deceleration of testing volumes in these 2 markets. In Germany,

this is explainable by the fact that there has been a new reform that has been implemented, and now we feel it's taking effect in Germany, where the denial rate in commercial labs is a result of the recent healthcare reform is increasing.

What does it mean? It means that the government is controlling diagnostic volume growth in 2 ways. One, which is historical, providing to general doctors, general practitioners, a budget for diagnostics. But now, assigning also to the hospital and the laboratory the responsibility over the budget, which fundamentally means that over a certain budget, private labs and hospitals are denied by the government, by the different states of the reimbursement. And this is, again, to control a volume growth that has been explosive in Germany in the post-COVID time.

Italy is not subject to any specific reform, but we saw the Italian volume becoming seasonal again. What does it mean? Historically pre-COVID, we always have experienced that volumes were growing in H1 and seasonally declining in H2. That didn't happen in the last 5 years, and this is to do with the fact that there was a continued testing volume increase, has been interpreted like a post-COVID catch-up.

We saw that 2025 is going back to historical seasonality, which in my opinion means that in Italy we are going back. There has been a complete catch-up in testing, and we're going back to what it used to be. So, you expect to be more front-loaded in H1 than in the second part of the year.

China, we did comment, so it's minus 25% in the quarter, but it's due to the effect of VBP2. We expect that starting from next quarter, this effect in China will start to smooth out.

Now, let's talk about molecular. I'm going to comment on molecular looking at the 3 different platforms that today Diasorin is serving to the market, the MDX, the multiplex franchise, and then I'm going to make some specific comments on the NES. When it comes to the MDX franchise, let me remind everybody that the MDX is the platform that we sell to hospitals, and we provide it does have a limited multiplexing capability up to 4, and it is the Diasorin platform for specialty products.

The revenue…total annualized revenue of the MDX franchise is roughly €100 million, and it is split in 3 segments. We have 15% of these revenues, so roughly €15 million, which are respiratory. So, it's extremely seasonal, and it is actually a market that Diasorin has not been able to hold post-COVID because of the fact that we were lacking as a combination of 2 things. The market was actually shifted by CFA [ph] to a 4-Plex, and we didn't have the 4-Plex. We had the 3-Plex. The 4-Plex was just approved last week.

The second thing is that this platform was never intended to be a platform for respiratory. It has always been, again, intended, even at the beginning, as a platform for specialty. So now, we have the respiratory, which is, again, as I said, roughly 15% of total revenue for the MDX. That has been declining severely in the last quarter and in the current quarter.

Second cluster of products is the targeted, and this is where this platform becomes strategic for Diasorin is roughly 40% of total MDX franchise, so roughly €40 million. And on this franchise, we've been experiencing in Q1, Q2, and Q3, growth of 35% to 40% per quarter. This is driven by all the specialty, the congenital CMV, the C. auris, and the HSV testing for meningitis, which continue to be very successful and drive placement in the US market of this platform. So, this is the future of the franchise. And this is actually the reason why Diasorin has developed also the follow-up

platform, which is going to be the MDX Plus that will actually continue to give life to this strategy.

And then we have the third bucket, which, again, is roughly €40 million that runs on the MDX, and is the ASR. The ASR business is a very profitable business that Diasorin has inherited by with the focus acquisition from Quest. It's clearly a business that does not provide strong growth, because it has to do with the fact that hospitals…certain hospitals in the US market are developing NTDs on this platform for certain applications. Let me say the more difficult application, those that companies don't take through the FDA. And typically, you would expect from this franchise to provide low single-digit growth, which in fact this has been doing every quarter in the last few years.

Again, this is not a strategic portion of our portfolio, but a very profitable portfolio, and is one that we continue to keep and nurture with the development of NTD. And this also is giving us the opportunity sometimes to launch certain products, see the uptake, and then decide to move them from an LDT to a fully validated 510-K product, as it happened with the CRS. So, the total franchise for MDX in H1 grew 9%. In Quarter 3 grew 4%, primarily driven by the seasonality effect of influenza. And in the 9 months it grew by 7%.

Now, let's now move to the multiplexing franchise. Our multiplexing franchise, we look at this business in 2 buckets. What we call the non-automated multiplexing, which is an old technology that fits very well certain markets, actually is adopted more in Europe than in the US. It is a franchise that continues to decline, clearly, because labs have been moving to more automated solutions. It is still relevant for Diasorin, around €35 million annually, and extremely profitable, so we continue to keep it. We use it opportunistically in Europe in certain markets, but certainly it's not,

and it cannot be a strategic franchise for the company. Although it does represent roughly 35% of the total multiplexing franchise. So, the total multiplexing franchise, it's around €110 million for the company. Of these, as I said, around 35% would be non-automated. The rest is a combination of Verigene I and LIAISON PLEX.

I'm going to comment specifically on the Verigene I and the LIAISON PLEX. So, it's very clear that the Verigene I represents a very interesting install base, sitting roughly on 200 or 300 customers in the US of different size between commercial labs and hospitals. It does have part of this business of the Verigene I is still respiratory, although a good chunk of this business actually is more blood and sepsis, because this is how this technology was launched by Luminex at the time. It does offer for Diasorin also clearly an opportunity strategically to replace this Verigene I with the LIAISON PLEX. We have not announced and we don't have any intention to announce in the near future that we're going to stop making the Verigene I, but certainly we make an effort to transition some of these accounts to the LIAISON PLEX. You will see later that every time we transition these accounts from one technology to the other, that drives a price increase in the range of 20% to 25%.

Let's talk now on the LIAISON PLEX. First, let me remind everybody that we launched the LIAISON PLEX just in the US. Second, we have today closed approximately 100 customers in the US. Split by, if you look at these 100 users, 80% of these customers are hospitals and 20% are commercial labs. Although, if we look at the RSP revenue contribution, and again, I will not comment on blood because blood has been just launched, so it's not relevant when it comes to the quarter results.

So, if we look at the revenue contribution of this base of PLEX, 65% of revenues are coming from commercial labs and roughly 35% are coming

from hospital labs. What does it mean? It means by definition that the majority of the respiratory revenue that we get on the PLEX are outpatients, by definition, and not inpatient. And this is exposing our PLEX business more than other competitors to seasonality, right. So…because we don't have the inpatient component that it gives more stability across season to this business. And again, this explains why, since the season is late, we are particularly hit on our multiplexing revenues, again, because of this dependency.

If now, we look at the usage of these accounts between flex and fixed, so between offering the total panel versus using mini panels or credits, 60% of the customers adopted flex as a combination of mini panels and/or credits, and 40% adopted the fix, right? So, it's almost 50:50. Although, if we look at hospitals versus commercial labs, we clearly see more adoption of flex into hospitals than the commercial labs.

What does it mean? It means that this one of the customers, if we look at the contracted yearly business, so annualized business, clearly on an average season, right, because it is a lot of respiratory, is above $30 million, with half is brand-new business, half is conversion from Verigene I to PLEX with an average price increase of, as I said before, 20% to 25%. So, if I look at the overall PLEX launch, I believe it has been very successful. I believe that more than what we discussed before and by some of the competitors, the market is veering toward flexing as a combination of mini panel adoption, where, again, the difference between our positioning and competitor position of mini panel is that we allow the customer to fully customize their mini panels, whereas competitors offer fix mini panels. And we believe that there is a competitive advantage in offering full flexibility versus fix mini panels.

Now, let me just conclude with the LIAISON NES. As said before, we submitted, Clear the LIAISON NES is intended to serve hospitals and POLs, so at launch we will offer this platform in hospitals and POLs in the US. Submission is gone as expected, and as said, we expect clearance by year-end or beginning of 2026.

As far as commercial readiness is concerned, we are hiring, as we speak, a dedicated commercial team that will be in place by Q1 2026, assuring readiness for a successful US launch. And we are also working on the selection of a distributor or a couple of distributors which will complement our direct salesforce, and we expect this distribution network to be in place by H1 2026.

Let me now comment briefly on our LTG. If you remember, in H1, LTG provided growth which was double-digit. We clearly explained that we could not expect, due to the situation with the life science market, we could not expect that growth certainly to continue year-end. We were driving the market to low-single-digit year-end growth. And, in fact, in Quarter 3, and this is because of the seasonality of this business, you know we actually supply and…our end-user customers are actually the major life science companies that then package our reagents and instruments into their own offering. So, if you look at Quarter 3 results, minus 6% is very much expected in order to drive year-end results, again, at around low single-digit growth.

Although, if you remember, this business is actually a business that is by half of it, roughly, is directed toward companies that use the technology to develop diagnostic tests, and half of it is actually we are supplying companies that develop products for research, academia, and biopharma. And it's very interesting that if now we look at how this business is performed, right, and, again, we need to look at the seasonalization here is

driven, not necessarily by an end-user seasonalization, but, again, by how the supply chain is scheduling, ordering, and inventory.

We continue to see, even in Quarter 3, that the diagnostic business continues to grow low single-digit, although life science, we continue to see a steep decline. So minus 15% of the life science business in the quarter, indicating that this life science market stabilization is not in sight yet. If we look inside this decline or this instability of life science, what we really see is that the instrument component of this is almost completely frozen, whereas the reagent side continues a modest growth or a single-digit…low single-digit decline, indicating that the issue today in this segment of the market is that academia and researchers clearly do not have CAPEX availability to buy instruments, but they continue to buy reagents to feed the current installed base of systems that they have.

Now, before turning to the CFO, 2 comments, one on PAMA and the Result Act. We continue to get questions from analysts and investors about PAMA, and how this will affect the business, and just summarizing where we are. The Congress now is pushing the adoption for PAMA, but the timing is very uncertain. And today the government is trying to understand through a better survey than the one that was originally done in 2015, better understand what is today the differential in reimbursement or price reimbursement, actually between what private payers reimburse for certain tests versus what the Medicare does. And the reason is a result of a discussion between the different stakeholders. The Results Act has been issued, and now the CMS is collecting new data to really understand, to define this differential between private payers and Medicare.

So, long story short, there is an effort ongoing. We believe that PAMA will eventually be on a hit. The diagnostic players is very difficult for anybody to predict when and to which extent, right? So, this is what, at best, this is

what we can tell, but certainly is not a 2025, and we are not sure if it's going to be a 2026 event, but I believe all the players are going to keep the investors updated on what's happening.

Last comment I want to make is on tariff. Mr. Pedron is going to comment on tariff better, but from a business perspective, I believe the majority of the industry has decided that in the US, for the time being tariffs are not going to be pushed through the channel to the customers. And so, everybody has been keeping tariffs in their balance sheet. For a series of different reasons. And same thing has happened for Diasorin. So, today we anticipate, when it comes to 2025, roughly a 5 million, negative contribution on tariffs that on a full year basis will impact our profitability by roughly €11 million, so nothing astronomical, but to the contrary of what we were thinking before, we don't believe that in 2025 or 2026, we will be able to push this to our customers.

So now Mr. Pedron is going to drive you through the numbers.

PIERGIORGIO PEDRON: Yes, Carlo, good day everyone. Thank you for attending the Q3 2025 earnings call. During the next few minutes, I will provide an overview of Diasorin financial performance for the first 9 months of the year. Following my remarks, as usual, we will proceed with the Q&A session.

So year-to-date revenues for 2025 reached €900 million reflecting a 3% increase of €23 million growth compared to the same period last year. This performance was achieved notwithstanding an €11 million reduction in COVID sales and a €19 million negative impact on foreign exchange. Primarily due to the depreciation of the US dollar against the euro as previously discussed during our last earnings call.

To this note, let me please remind you that on a full year basis each €0.01 movement in the US/Euro dollar exchange rate. Usually affects Diasorin revenues by about €6 million to €8 million and adjusted EBITDA by €2 million to €3 million considering that the average USD/Euro exchange rate in Q4 of last year was around 1.07, we anticipate a continued foreign exchange headwinds into the latter part of 2025. Excluding COVID impact and the constant exchange rate, our core businesses achieved a 6% year-to-date growth. Carlo has already covered all the different elements.

In the third quarter, revenues at current exchange rate declined by 2%, representing a reduction of €7 million compared to 2024. In contrast, the performance, excluding COVID effects and the constant exchange rate as we just showed was plus 3% with a negative effect in the quarter of €12 million. So out of the €19 million, €20 million, I was discussing about for the full 9 months of the year €12 million were in Q3.

Gross profit for the first 9 months of 2025 totaled €587 million accounting for 65% of revenues broadly consistent with 2024. This represents an increase of €9 million or 2% compared to the same period in the previous year, but withstanding a tariff impact of about €2 million as we just discussed. For the third quarter, the gross profit margin remain stable at 65% of revenues aligning with the Q3, 2024 and continuing the trend we saw over the past previous quarters. Despite the negative tariff effect that we've just mentioned.

Year-to-date adjusted operating expenses at €346 million represented a 1% increase compared to the prior year or about a 3% at constant exchange rate. Adjusted OPEX as a percentage of revenues declined to 38%, down from 39% in 2024. The increase in absolute value and operating expenses relative to 2024, was mainly driven by higher labor costs from the annual salary review cycle, as well as, an increased depreciation related to the

recent product and platform launches previously in the development phase, such as the LIAISON PLEX.

Excluding the impact of this increased depreciation, I think it's interesting to notice that adjusted operating expenses at constant exchange rate would have risen by only 1%, indicating a very disciplined management of our cost base. Adjusted other operating expenses for the first 9 months of 2025 were negative by €8 million. €1 million better than the same period in 2024. As a result of the dynamics, we just described September year-to-date adjusted EBIT, reached €233 million representing 26% of revenues, confirming the profitability we had in 2024.

Adjusted interest expenses for the first 3 quarters were just under €1 million compared to an income of €3 million in the same period of 2024. The primary factor behind this variance was a reduction in our cash balance and investment yields, reflecting the reduction of our debt and the decline in interest rates.

The adjusted tax rate increased from 23% to 25%, mainly due to the termination of the patent box regime for our Italian legal entity, as we discussed in H1. Year-to-date adjusted net income amounted to €174 million accounting for 19% of revenues. In the first 9 months of the year, adjusted EBITDA reached €302 million marking an increase of €10 million or 3% over the same period last year at current exchange rate and 7% at constant exchange rate. The EBITDA margin was at 34% both at current and constant exchange rate. An improvement on the 33%, we had in 2024. At constant exchange rate the Q3 EBITDA margin stood at 32%, remaining broadly consistent with the same period in 2024.

Turning now to our net financial position, we closed Q3, 2025 with a net debt amounting to €617 million. In line with the position at the end of 2024,

this reflects a solid free cash flow of €161 million compensated by cash outflows, including €97 million in payments to shareholders exercising withdrawal rights after the recent implementation of the enhanced voting rights mechanism, as well as €63 million distributed as dividends to our shareholders.

Let me now close with our revised outlook for the full year 2025. Taking into account the factors mentioned by Carlo that are affecting our overall top-line. Our guidance has been revised as follows. Revenue ex-COVID to grow by about 5%, with COVID related revenues projected at around €10 million, adjusted EBITDA margin at about 33%. As always, these figures are at constant exchange rate, assuming the USD/Euro rate of 1.08, which was 2024 as a reference.

I would like to emphasize that despite the headwind affecting our revenue and impact of tariffs, we have managed to review the adjusted EBITDA margin by only 100 basis points. I believe this outcome reflects, as I was saying before, the very disciplined approach we have applied to managing our cost base.

With that, I will now turn the line over to the operator to begin 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." Please pick up the receiver when asking questions. Anyone who has a question may press "*" and "1" at this time.

First question is from Anchal Verma, JP Morgan.

ANCHAL VERMA: Hi, good afternoon. I have 2 questions, please. The first one, can you provide us an update with the divisional guidance for FY '25. And given the revised guidance for the group. Are you still comfortable with 8% for immuno and on the molecular side above 8% seems quite challenging, so what would be a realistic guide. And just trying to understand how you see the recovery in the top-line, and while it's still early, are you able to provide any comments around the trajectory into FY '26?

And then the second question is, just looking at the last couple of years of performance and to raise your revised guidance, the path to midterm targets, how confident are you in those in the high single-digit to low double-digit CAGR for the top-line and 36% to 37% EBITDA margins by 2027. Could you potentially hold a Capital Market Day next year and revisit the midterm targets?

PIERGIORGIO PEDRON: Hey, Anchal. Hi, this is PG speaking. I would try to take all of your questions. So, we are not providing guidance for 2026 yet, right. But I would like to underline that, a few, I would say most of the things that Carlo discussed about that affected the last quarter…that will be affected in the last quarter of 2025 and we saw already in Q3 of 2023, so a lot of those headwinds will not be there in 2026. And so, we do still feel comfortable with the 2027 guidance we put out there at the end of 2023, which was calling, as you just rightly said, for a growth of the top-line of high single or low double. Obviously considering what has happened, we believe that the high single-digit growth for the top-line is, I would say, more likely.

And yes, we will be reviewing in a dedicated event in 2026, I believe, towards the end of Q2, we will be renewing…reviewing our plan because,

you know, the previous plan was coming due in 2027. So, we felt like it was the right time to go in front of investors and the market, Q2 next year to tell the market how we see the business developing from 2027 onwards.

Let me please remind you that when we put in front of the market the guidance for…long-term guidance for 2027, it was back in December 2023. And we had not launched yet, you know the LIAISON PLEX and the LIAISON NES platforms, which by the next Capital Market Day, will have been brought to the market. So, it will be also let me see…we will have more real-life data to project the future.

For 2026, as I was telling you, you know, the guidance for 2026 is going to be released when we will be discussing about year-end results for 2025, but building again on what Carlo was saying, I would say that it wouldn't be unreasonable to think about a number which in 2026 vis-à-vis 2025 will show a top-line increase of high single-digit. Again, the precise number will be given March 2026. But these high single-digit, I believe, is very reasonable number.

ANCHAL VERMA: That's helpful. Just kind of follow-up on the divisional guide for '25, please.

PIERGIORGIO PEDRON: When you say divisional guidance, exactly what do you mean because, you know, we have not issued for 2025 the divisional guidance, we have issued the guidance for the overall top-line of Diasorin. Then if you are referring to the documents we put in front of investors back in 2025, where we told investors, how we saw the progression of the 3 main technologies we have immuno, molecular and LTG, you know, that is not a guidance that we gave in 2024, not in 2025, right? But the main trajectories stand, meaning that the immuno franchise should expect to see a growth of, let me say, mid to high single-digit and the molecular franchise is going to show a growth of let me say mid to high teens, let me put it in that way, coming from once

again, you know, the full effect of the LIAISON PLEX. Now, you're going to see the gastrointestinal panel being available on the market plus all the, let me say the full effects of the 100 customers Carlo was mentioning, was discussing about plus once again the NES, for which I believe Carlo shared a few details in terms of sales organization and contract with distributors. But again in 2025, we did not issue a specific guidance as such for the 3 different franchises.

CARLO ROSA: Okay, I just would like to make a comment on a need of a new…of a new view. If you think about it, in the last 12 months…12 to 18 months, the world changed dramatically, right, with consequences to the business. Think about…all the discussion about life science, where is it going and the funding and the fact that certain projects will be funded, others will not going to be funded the effect on vaccines, funding, which by the way, does impact our business. And by the same token, the Chinese situation is very much new, right? So, if you really look at the business that was the business model and all the assumptions that we developed in 2023, project in 2027 and forward all these assumptions I believe are changed one way or another, some are positives, some are negatives.

For example, in our plan, there was a small component of the LIAISON NES. Today, the LIAISON NES is almost a product, I am crossing fingers. It's going to be a product approved in the US very soon. We have done…we have developed a 5 years' view for the LIAISON NES; we now have an understanding of the potential of that market with the segmentation. And so, we really feel the need that to go back to first ourself investors and I put myself as an investor to the board and to the other stakeholders and explaining this new environment of the companies see growth and the opportunity, and this is why PG is saying we will anticipate our revised LTP into 2026 rather than waiting for the full year '26 and then do it in 2027.

ANCHAL VERMA: Thanks Carlo, that's very helpful. Thanks, PG that was very helpful as well. The only division guide I was referring to was the soft comments you had made around immuno being around the 8% initial guide and molecular being above that, but I'm happy to jump back in the queue. That was really helpful. Thank you.

OPERATOR: Next question is from Odysseas Manesiotis, BNP Paribas.

ODYSSEAS MANESIOTIS: Hi. Thanks for taking my questions and Carlo, thanks a lot for your color today. That has been very helpful to get our heads around the current dynamics. I had one on the point you made about PAMAs. Could you give us some color on your exposure on the routine testing targets for your immunoassay franchise, just for us to get a sense of how this risk may be quantified for you?

CARLO ROSA: Hi, Odysseas. Look, it's very difficult for me, but let me make a couple of comments. Back then, 2016…2015, when all this really initiated, we had a very significant exposure to this, primarily with Vitamin D, because back then, Vitamin D was a big portion of the US revenues. And we actually knew that, clearly, Vitamin D reimbursement, that Medicare versus private was different magnitude. I mean, in today's environment, our US business completely shifted away from that, more into specialty, right? And therefore, if typically, in a laboratory, and I think [indiscernible] did comment on that, and Medicare does represent 30% of their revenue, give or take.

Today, our revenues, our portfolio, I think that is way less than that when it comes to the Medicare contribution versus others. For example, if you take TB, which is certainly relevant for Diasorin in the US, primarily, that business is driven by routine testing of healthcare workers, which has nothing to do with Medicare, right? So, didn't do a very specific analysis

and happy to give more flavor when we are going to do the LTP. But let me say, compared to what we were back then at PAMA, I believe that PAMA today will have a much, not necessarily a big effect on our revenue. And I keep saying that at the end of the story, even if I look at the Vitamin D story, what is changing dramatically, the environment is competition more than government cutting reimbursement, right? And again, if you look at Vitamin D the availability of more than one player drove the price from $8 to $0.80, which is the reality of today. But said that, so take it with a grain of salt, but I honestly believe that our exposure is not going to be dramatic.

ODYSSEAS MANESIOTIS: Thank you. That's very helpful. And a follow-up maybe on your…on the points made around the new reforms in Germany. Am I right to understand that this may be one of the factors, let's say, that also becomes a pressure into next year? And could you help us quantify your exposure into the country and how bad can it get, simply just to get our heads around how much of a pressure that can be?

CARLO ROSA: No, don't read too much into it. This has nothing to do with the exposure in the country. Actually, funny enough, most of the progress manufacturing in Germany were directed toward the Chinese market, right? Because we're…in Germany, we were making me-too products for oncology and thyroid that we don't sell…much of which we don't sell much in Europe. It is more for export market and China, right?

As far as the exposure, our exposure in Germany, if you don't mind, can comment on it because this is really…it would be good for competitors to know. But just for information, it is the second largest market for us after Italy, right?

ODYSSEAS MANESIOTIS: Got it. Sorry to clarify. I meant on the reforms that had an impact on testing volumes in Q3 that you mentioned, whether we should expect that as a pressure that may accelerate or become more since 2026? Sorry if I was not clear.

CARLO ROSA: To me, just to give you an order of magnitude, if in 2023, testing volume in Germany was…overall, was growing, high single-digit, right, and that was the effect of the post-COVID catch up. What we are seeing today later in H2…so in Quarter 3, so second part of the year is going more close to low single-digit, so 2%-2.5%. So that's the magnitude of the effect. So, we don't see a decline in volume. We see much less growth. This is important to understand. It is not that volume is declining, it's not growing as much as it used to grow.

ODYSSEAS MANESIOTIS: Got it. Thank you.

OPERATOR: Next question is from Dylan van Haaften, Stifel.

DYLAN VAN HAAFTEN: Hey guys, good, evening. So, just a couple of clarifications from my side. So, maybe firstly, just on the molecular business, if we kind of look into next year, can we just kind of reflect on what will happen with the composition of the low-PLEX respiratory…we also kind of think about what could happen with ASR and also how the flex side will look once the GI panel is there, and let's say if we do the same exercise you guys did on the slides, if we kind of look into next year, how would that look because so for instance I understand that with flex in the hospital side, the lack of a gastrointestinal panel kind of hurts you guys right now, that might look different next year. Also, Roche will be in the market then with the GI panel, maybe just a mental exercise if we could do that?

My second question would just be on NES, and if you guys have decided on a distributor if there's also going to be a direct component to the marketing?

And then thirdly, is there any update on the LymeDetect assay, and if you know if you've seen any change in the interaction with the FDA? Thank you.

CARLO ROSA: Okay. So, let me…because there are 3 different questions. So, when it comes to NES, as I said before, we are hiring as we speak, our own salesforce, and around 20-25 people that are going to be dedicated to serve some of the direct customers in the segment, so the larger POLs, whereas by the same token driving the distributor and again this is nothing new is what typically you do in this sector with the sales regional rep, that is more business development and a sales rep right because utilizing different channels.

No, the answer is no. We've not selected the distributor yet. We're working to…we're talking to the distributors to understand which one makes sense for Diasorin in light of the fact that one of them is already fully engaged with a competitor. And so, we are looking at other possibilities, right? And as I said, our objective is to have in place the distribution network by H1 of next year.

Now, when it talks to…about LymeDetect, we are reflecting, as I said, with Qiagen and talking to a major lab to understand if in the…we can introduce this product to the market as an LDT. Meanwhile, we are understanding how to get a clear path for clearance with the FDA.

Now, when it comes to 2026, look, I'm going to leave it to PG, but please take in consideration that we do not have a budget for 2026 discussed or

approved with the board. So, it is very difficult for us to make any specific comment on 2026. PG?

PIERGIORGIO PEDRON: Yes, I will try…hey Dylan, I will try to take it from a qualitative perspective, right? And all the trends I believe are very similar to what Carlo described in his initial remarks. So, for the respiratory, I believe it's fair to say that you shouldn't expect a negative, let me say an headwind, as we did in this year. Obviously, it all depends on the flu season, but the remainer of business that we have is smaller, as Carlo said. And now we have, we press released the fact that we have the 4-Plex, which will allow us to fortify and to better defend the remaining business we have, which is not a strategic business. But I would say it's fair to say, from a qualitative perspective, a directional perspective, that you should not expect an headwind as strong as the one we saw this year.

The molecular-targeted assays, on the contrary, should keep growing at a very nice clip. We have a few assays for which we are the only game in town Candida auris, as you know, is the only assay which is FDA-approved. We have congenital CMV. We have HSV with the cerebrospinal application…cerebrospinal fluid application. So, we have a very nice position in there. So, I would say, again, directionally expecting a double-digit growth next year is fair.

ASR, again, Carlo spoke about ASRs a few minutes ago. He said you should expect, in his remarks, he said, low to mid-single-digit growth on the ASR business. That's what this business usually provides to us. You are not going to have, obviously, the negative headwind from Auris. Auris, in the first 9 months of the year, was minus €5 million, and that is going to go away, simply because it's a different perimeter of consolidation. For the non-automated multiplex, he said that is not a strategic business. It's a business which is more material in Europe than in the US, but there you

should expect single-digit…low mid-single-digit decline. Again, directionally, this is not a budget.

Eventually, discussing about multiplex automated, so the LIAISON PLEX and the Verigene I, I go back to what I said previously to Anchal, right? So, this is one of the engines of our growth. Obviously, we said that we closed business for €30 million, and we still have months to go before the end of the year. You will see the full effect of that business next year, plus the contribution of GI and the blood panel…the 3 blood panels. So, all combined, obviously, this brings you to a double-digit growth for this franchise. And this is as much as I can say now, since, as Carlo just reminded everybody, we still need to go to our board approval for the budget. But directionally, I believe you have a good indication of where the business should go.

DYLAN VAN HAAFTEN: Thanks, Carlo. Thanks PG.

OPERATOR: Next question is from Aisyah Noor, Morgan Stanley.

AISYAH NOOR: Hi. Good evening. Thanks for taking my question. My first one is on molecular, so would love to unpack a little bit, Carlo, the numbers you've disclosed today on the LIAISON PLEX business. Apologies for the naivety of this question, but of the 100 customers you talked about, does Quest count as one customer or 8 labs or 24 systems? And of those, you know, we'd just like to understand whether or not you think you are taking market share in the quarter?

My second question is on immuno, so between China, Germany, and Italy, which are, I think, the 3 regions you called out as the weaker regions, which did you least expect to impact you in the third quarter from a growth perspective, because I think our thinking this whole year, Carlo, was that

China was VBP minus €5 million or so. And so, this seems like it's gotten worse than you perhaps anticipated. So, I just would like to know, a), you know, the ranking of, you know, the headwinds; and b), maybe how long you expect of these 3 regions, how long these headwinds are expected to persist. Thank you.

CARLO ROSA: First, obviously…and sorry for the naivety of my answer. But Quest is one, not 24, otherwise I would not share. Quest is one account, right? Then, as you have seen from the press release, we are placing different systems in different labs because they are decentralized testing within their facilities.

Now, talking now about the different regions, look, China, the problem is that the full year effect of China is going to be, I don't know, €7 million, €8 million, whatever it is. But €3 million was just Q4…Q3, right? So Q3 fundamentally was being one, we got it in one quarter, the same way we got it in H1, right? This is why it's more skewed toward Q3. Q4, is it going to be stabilized? Not yet, but I think most of the damage actually has been done in the first 9 months, and my expectation is that moving into 2026, we're not going to see 30% decline in China any longer.

Are we going to see a flat China, which would be a great result? I don't know, but probably we're going to see a more reasonable low single-digit decline, which again, in these days in China means stabilization, right? As said, and as we will discuss moving forward, the problem for us in China is that we had a business which 75% was me-too, and as a me-too I'd say we were hit by competition VBP, full blown.

Moving forward, the residual business is still partially me-too, but now the full hit has been taken, but then we have the specialty component, which now is more relevant. And again, I think as we discussed already, specialty for us in the future has to do with 2 products, TB, which is not registered

yet in China, and we expect, we filed the clinicals around the discussion, and we expect to get it approved next year. So, TB will be available in China.

And the second product is more calprotectining and inflammatory, where we are starting registration, clinicals, and it's going to be at 2027, but that will move fundamentally our business away from me-too VBP kind of business.

Now, Germany and Italy, I think it's very different. Certainly, Italy is double the size of Germany, so any effect you have in Italy is bigger than Germany. But by the same token, if I look at Italy, the overall performance, right, so the full year performance, is not that far from what we expected in the budget. The problem is that we had a tremendous H1, because the volumes…volume growth was very significant, and now we see that, what I call seasonalization, I see now that H2 is going to be lighter, which still provides for Italy low single-digit growth, okay, so it's not a declining market. It's simply you don't have that effect of volume growth that was pushing that market from a low single-digit to a high single-digit.

Germany is a completely different story, and I believe it's more difficult to predict. Again, in Germany, you don't have declining volume. You have a volume that is…volume growth that is stabilizing back to what it used to be prior to the COVID time, and all this turmoil that really happened over the last 5 years. For your reference, if you look at the EDMA data, and you look at the market…so the total market growth in immunoassay in Europe, major markets, is 2%, right? So, if I do have in Germany a volume that is growing around low single-digit, we are going back to pre-COVID times. This is what I'm saying. So, the true damage, if you call it as a damage, is that the H1 was skewed by the fact that all these effects hit, are going to hit H2 more than H1. That's it.

And was it foreseeable? Not really. This is the problem. And I think we've been commenting several times about the fact that in Europe, for now, several quarters, our industry has been enjoying an extra volume push, which was difficult to quantify. It was very difficult actually to forecast how long this has lasted. And I didn't follow actually reporting by other companies, and I really want to understand in Q3 and Q4 how other companies that are very much dependent on me-too's and in this market how they are going to comment the performance of Europe.

AISYAH NOOR: Okay, thanks so much. And just to follow-up on a comment you made earlier on the molecular markets, you mentioned a market shift to 4-PLEX testing against 3-PLEX testing. I'm just curious how you know that this shift happened if you didn't sell the 4-PLEX test before. Is it because you actively had customers requesting the 4-PLEX, or did you actually see customers deactivate the 3-PLEX usage with you? Just some color there on this comment?

CARLO ROSA: Listen, I am simply reading the press release of Danaher and Cepheid. If you remember the story, Cepheid was the first one actually to launch on the platform the 4-PLEX. And actually, they forced, during COVID times, at the end of the COVID time, right? They forced all their customers to move away from the COVID only to the 4-PLEX, right?

So, they launched it, and they forced that market to move. And it has been a very smart and winning move because it moved the market away from COVID or COVID flu into the 4-PLEX, which was…and they were the only company to really supply it. This business for Diasorin has always been, forget the COVID component, which was huge, obviously, but the flu COVID has been a good franchise for Diasorin. It has been declining over time because we lost some of it, again because of COVID per se.

Now we are back into the regular use of 4-PLEX in the market, which is the new reality. In fact, if you look at the LIAISON NES, the LIAISON NES is a 4-PLEX assay.

And if you go back to what we were discussing about why we delayed the LIAISON NES, it was because we had developed and ready to go to clinical with flu A, flu B, and COVID, and we realized very rapidly that the market actually moved away from that into the 4-PLEX. So, we actually did clinicals with the new product, and now we are launching the right product. But it's history, and it's driven by what Cepheid has been very acutely able to do in this market.

AISYAH NOOR: Understood. Thanks so much for your comments.

OPERATOR: Next question is from Kavya Deshpande, USB.

KAVYA DESHPANDE: Hi, Carlo. Hi, PG. Thank you for taking my questions. PG, I think you said that earlier, most of the headwinds impacting Q4 this year won't continue into 2026. Would you be able to break down in a bit more detail which ones continue and which ones don't? And then for the ones that do continue, so what is the quantum that they…are they kind of unwinding, or are they accelerating?

And then just another quick question on the sort of outlet for the multiplexing franchise as a whole. Carlo, I think previously you talked about €200 million as a target for sales by 2028.

I mean, in terms of the PLEX respiratory revenue exposure, perhaps making it lean more towards outpatient and making those revenues a bit more

sensitive to flu fluctuations, had you baked that into the €200 million revenue sort of outlet? And does that still hold? Thank you.

PIERGIORGIO PEDRON: Hey, Kavya, I will try to take the first one and I guess also the second one, and maybe Carlo can chime in if I'm not…if I would be missing anything. So, it's not yet. I understand why you guys want to have an understanding of 2026, but you need to be patient because we need to go through the board approval and then the 2026 guidance is going to be released next year. But I will try once again from a qualitative perspective to help you out to kind of understand the main moving pieces. I believe Carlo said a few seconds ago we are not expecting headwind from China or a very limited headwind from China in 2026. So, that is not going to be there.

And this €5 million-€6 million headwind is not going to be there in 2026 and onwards, obviously. This headwind we experienced is on the MDX platform, it's not going to be there for two reasons. One, the business now is very limited in size and so it's not material. And second, because of the availability of the new product, we think we will be able to better defend the remaining business, which is once again not material. The outbreak, we've not discussed a ton about the outbreak, but at the end of the day, by the end of the year, the outbreak impact that we had in 2024 is going to be 6 million, which is not going to be there. And if you just take China and the outbreak together, you have a 1 percentage point of our total sales, which are not going to be there.

If we move over to LTG, you guys have not made a ton of questions about LTG, but LTG, as Carlo said during his remarks is playing against us because of…it's a B2B business. We see a very nice growth on the diagnostic part of the business, but on the life science part, what our customers and it's the big names of the life science, telling us is that, you know, they're struggling as well to sell instruments. Instruments represent

one third, give or take of our life science franchise, in the LTG business and we had a material headwind, which we think is not going to go away in Q4. What's going to happen next year, very difficult to tell you. It depends on, it's a business we don't control, it's a business to business, depends on the NIH, it depends on you know funding. And then we will, see there what our customers will, will tell us.

Going to the molecular part of the business, I believe I've already covered that when discussing with Dylan, and those are the, let me say, drivers that you should expect in 2026 and onwards. Then discussing about the PLEX, the fact that most of the PLEX business now is in a reference lab, so it's outpatient, it's because of, it's driven by the fact that we have up until a few, few weeks ago one panel available, which is the respiratory panel.

And so, that limitation is going to go away completely when we will have the GI, but let me say, a very strategic part of our offering and strategy is to go to hospitals, that is where we want to play and we also see possibilities of cross selling to our immuno customers molecular products. So, the short answer to your question is yes. In the number that we gave for 2028, we already included the fact that a part of that number is going to be respiratory disease, but the majority of that number we believe is going to come from the gastro and from the blood as it is for the Verigene I offering as we speak.

KAVYA DESHPANDE: Understood. Thank you, very much.

OPERATOR: Next question is from Jan Koch, Deutsche Bank.

JAN KOCH: Good evening. Thanks for taking my two quick questions. The first one is on your new guidance. Does your new guidance assume any meaningful impact from the government shutdown in the US in Q4? And then secondly,

on your supply chain, do you face any negative impact from the supply chain issues that one of your key suppliers has currently?

CARLO ROSA: I'd take the second question because I'm not sure I understood the first. When it comes to the second question, the answer is no. So whatever strata issued for magnets, I don't know what you are talking about, but certainly it's not to do with anything that has to do with the supply of the LIAISON X. First question...

PIERGIORGIO PEDRON: I'm not sure I got it. If you can please clarify your question, the one on the guidance, thanks.

JAN KOCH: Yes, on your guidance, essentially for LTG, do you expect any kind of incremental, yes, negative impact in Q4, yes, on the back of the government shutdown in the US?

CARLO ROSA: No, I don't think the government shutdown per se is creating an issue with…any issue with the instrument, the real issue again has been the lack of funding or redirection of funding or the freeze of funding to academia that has frozen completely the instrument market in…so far. What is going to happen in quarter 4 and again I am…I really…in order to understand how we will do this business, please listen to what Thermo Fisher and the other, players are saying about the space. Because whatever they say about that space is going to be reflected on the way our life science business will perform because Thermo Millipore [[ph], Biotechnique, I mean these are the companies that are buying system and distributing systems for us in that segment, right? So, I did not even follow their latest reports. Please refer to that and you would have a better understanding of what…that business for you.

PIERGIORGIO PEDRON: If I can add a comment here on the LTG just again, but it's just reasoning it out with available data, right? If you look at the 9 months data we provided for you, obviously, what Carlo said about the life science part of the LTG business stands, but if you look at the diagnostic part of the business in the first 9 months of the year, you see a plus 20%, right, which is unusual, right. Because it means that our customers, diagnostic customers would have been growing their business by 20%. So there remember as we always said, there are…there is a phasing of these big orders, bulk orders that we got from diagnostic customers, meaning that you should expect a Q4 for the diagnostic part of our LTG business, which eventually will deliver full year for a diagnostic growth, which is usually, let me say mid to high single-digit. But it is just what we always said, so it's just looking into the numbers and information that we have already disclosed.

JAN KOCH: Understood, thank you.

OPERATOR: Next question is from Natalia Webster, RBC.

NATALIA WEBSTER: Hi there, thanks for taking my questions. First, a confirmatory question on PLEX. You mentioned that you now have 100 users in the US. Do you still see your previous target of 150 active users by the year end as achievable? And then secondly, in terms of that mix, you mentioned that the GI panel could help you increase your mix of inpatients. I was just wondering if you are expecting that GI panel introduction to also increase the number of customers that are using the flex versus the fix option.

And then thirdly a question on NES. You mentioned that you are looking for clearance towards year end or early 2026 and an agreement for distribution by H1. So, is it reasonable to assume revenue contribution from Q3, Q4 2026 and also just trying to understand how you plan to differentiate

yourself here given the market has become increasingly competitive? Thank you.

CARLO ROSA: Okay, let me…let me start from the last. So, yes, we expected to see contribution from H2 from this, okay, but if you don't mind, we are going to give more color on NES, certainly when we talk about 2026 budget, but very much so during Capital Market Day that we are going to do by the next…by 2026 summer, okay?

When it comes to Flex, my…I believe that what PG said is as follows. The more we complete the menu, the more the market will develop into the hospital because commercial labs have enough volume to justify multiple placements of systems with one parameter. But when you need to penetrate the hospital market, clearly you need more than one. Even if hospitals…quite often these hospitals have multiple platforms, right? You need to be able at least to take away one, which typically runs on one or two panels.

So, my take is that moving forward with Flex, blood with respiratory, blood, and GI, we're going to penetrate the hospital market also because, by the way, GI is a hospital market panel. And more than that, a comment I would like to make is that, as we discussed I think previously, GI is almost the perfect example for the mini panel because at that point, the combination of mini panels that a hospital can make is very large. You can go seasonal. You can go depending on where the patient is coming from. You can go by outbreak. You can go in many different ways. And so, I expect that, as said, today 50% or 60% of our customers are using already Flex with respiratory. With GI, that number will increase significantly, again, because of the nature of the disease.

When it comes to the first question, you said 150 accounts. We are at 100 today. I believe we're going to get close to 150. I see the funnel. I see the number of accounts we have there in the funnel, but I believe that again counting requests as one, we are going to get close to that number.

NATALIA WEBSTER: Great. Thank you.

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

CARLO ROSA: Thank you, Operator. Good night.