DiaSorin S.p.A

"First Half 2019 Results Conference Call"

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MODERATORS: CARLO ROSA, CHIEF EXECUTIVE OFFICER

PIERGIORGIO PEDRON, CHIEF FINANCIAL OFFICER

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome, and thank you for joining the DiaSorin First Half 2019 Results Conference Call. After the presentation there will be an opportunity to ask questions.

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

CARLO ROSA: Yes. Thank you, operator. Ladies and gentlemen, welcome to the quarter 2 conference call. As usual, I'm going to give you some general comments about what happened in quarter 2, and then our CFO, Mr. Pedron, will drive you through the numbers.

Again, as usual, I'm going to comment all the results in constant exchange rate, since as you know, there is a variation especially on the dollar side which has been clearly impacting, in this case on the positive side, the financial of the company. So everything I will comment on is going to be at constant exchange rate.

So let's start from the top line. It was a very good quarter. The growth at the group level was 6%, and what is very interesting to look at is that the underlying technologies which are the CLIA technology, ex Vitamin D and our molecular franchise grew particularly strong in this quarter. The CLIA scored 13%...over 13% increase over prior year and our molecular franchise, 26% increase over prior year. And we are going to go through geographies and you will understand where the growth is coming from.

So now, if we analyze our business from a geographical point of view, let's discuss Europe, U.S., and then Asia Pacific, with...that overall represents over 80% of the revenues.

So as far as Europe is concerned, quarter 2, 4% growth, where we had a very strong quarter again with Italy, where we launched the QuantiFERON on our installed base and the results are very good.

Strong growth in all geographies, I would like to comment specifically 2 geographies that didn't perform as expected. One is France, and France, in this quarter…and year-to-date is very weak, minus 3.3% versus last year. But this is a combination of 2 events that happened in quarter 1.

One is the fact that 2 codes have been eliminated from the reimbursement in France. These are 2 specific products that we sell in France, is about €1 million of revenues, which...the vast majority of which is going to go away. Some of it already happened in half 1 and some is going to happen in half 2.

These are super-specialty products that where we had...the usage in France was particularly elevated. And this...the cancellation of this code pretty much brings France where all the other geographies are. So we're going to take a hit when it comes to 2019 and then eventually, it's going to smooth out.

The good positive event about France is that the placement rate is doing very well, the number of instruments placed in the market. The consolidation of labs, clearly is helping us because the more they consolidate, the more we have specialties going to the labs, where DiaSorin is already operating.

And by the same token, I think that in France, we are going to have a lot of good positive effect on the business since in the second half, by the fact that a couple of very large labs have been actually closed when it comes to

QuantiFERON. And again, those sales will happen in the second part of the year.

The other market, which is delayed, compared to where we expect to be is actually Germany. Germany is a combination…Germany is growing 1%. And I remind you that Germany is one of the geographies where we have the most amount of Siemens business.

The conversion of the ELISA business…Siemens business from ELISA to LIAISON in Germany is taking longer than expected. This has to do with the fact that a lot of that business is in commercial labs and commercial labs these days are very busy as far as consolidation is concerned and also transitioning their core lab activities to high throughput platforms coming clearly from competitors. That doesn't affect us at all, but it does affect their ability to dedicate time in conversion of a business from one technology to the other.

So in that particular geography, the Siemens legacy is there. Clearly, that business is not growing, it's flat, but it's not converting as expected...as fast as expected to the LIAISON which means that pretty much leaves our LIAISON business in Germany growing around 6%. A stable, slightly declining ELISA business and overall leaves the country so far in H1 flat.

Good news about Germany, though again, is placement rate. We have placed, in Germany, 24XLs in H1. And just for your reference that is pretty much the number of sales that were placed in the country last year. So there's an acceleration of placements in Germany, which again gives us certainty of the fact that this geography as well is going to pick up in growth in the second part of the year. Also then, Europe is growing 4%, so which is in line with company expectations.

Now, let's go to the U.S. In the U.S., we have an acceleration of growth. In the quarter, we have a 10% increase of revenues which is phenomenal for the country and that's a combination of different events.

The first one is that, if you remember in Q1, we did comment on the fact that the flu season had heavily impacted quarter 1 results for the U.S. Again, the weakness of the season which was felt by us and all other competitors, but then the underlying business was doing fine. And this shows in quarter 2, because now the flu effect is behind us and that at that point, we have DiaSorin Molecular, so all our Molecular business growing 26% which is a very strong growth.

A combination of launch of products that happened last year, plus we just got approval of our VZV assay which fits very well with the current installed base. And then the fact that we did close a very large agreement when it comes with...when it comes to Molecular with one of the major labs, with which we have historical, traditional very good relationship. And this contract has been...is in execution, it is going to be fully executed by year-end. And clearly, it's impacting very positively our DiaSorin Molecular business in the U.S.

As far as the immunoassay business is concerned, we continue to see double-digit growth when it comes to our CLIA x-D business. But the good news is that contrary to some of our expectations and trends that we had seen in the previous quarters, our Vitamin D business has been, in this quarter relatively stable. As said, difficult to draw any conclusion for this trend. I think that we need to see what will happen in the future quarters as well, as far as a reduction in volume of Vitamin D usage which I remind you is fundamentally related to the policy of certain insurance companies that have...are actually promoting with the physician a different

use of Vitamin D, so not for screening, but it's suspected for certain clinical conditions.

By the same token, if you follow what the major lab…Quest Lab called Sonic said, I think that what is working in favor of the Vitamin D business is the fact that even if the insurance company does reject reimbursement for that particular Vitamin D prescription, then the lab have been authorized now to go after the patient and get the money and get the test reimbursed directly from the patient. And that clearly allows the labs to recover their money and volumes to continue to be stable as in the past. But again, as far as the Vitamin D is concerned, I don't want anybody to draw any long-term conclusion on where the volume will go. We need to wait and see what is going to happen in the second part of the year.

Again, remarkable about the U.S., is the success with the CLIA x-D and the placements in the commercial labs, and we start seeing placements in the hospital labs as well. If you remember, we got approval of all our stool line now. And we are waiting anxiously for the final assay to be approved, which is the TB assay, the QuantiFERON assay.

We have filed with the agency all documents and all amendments by the mid of this month. By the book, it should take 90-days for the agency to approve the assay. I think that is reasonable to expect that we should get approval some time by the end of August. So I would cautiously say that by the end of August, we should have the TB approved in the U.S., which is a couple of months delayed versus what we expected, but is...again, is a tremendous opportunity for the U.S., also because it is happening...this approval happens at the time when the volumes in the U.S., of TB testing and the conversion from the skin test to the blood test is accelerating, is a result of the fact that there has been a declared shortage that is going to

last until quarter 1 of next year of the antigen used by the companies to make the skin test.

So it's a very favorable time for conversion and volume growth. We see volume growing in all the major labs in the U.S. So again, anxiously waiting for the approval which is very...will happen soon, and then we'll start also our activity with TB in the U.S., market. Overall, again, U.S., plus 10%, it's a great result.

Now let's go to Asia Pacific, 7.4% growth. Overall, China, which is the lion's share of our business, is...grew 7% in the quarter. Again, I think we need to look through this number because that growth is a combination of double-digit growth of our CLIA x-D business. So the reagent business continues to grow as expected, whereas we have a negative, again effect on the instrument sales, and this is due to the fact that, as said, we continue to move to our policy where we tend to reagent rent rather than sell instruments.

As far as number of placements and you have seen from the total number of placements in the quarter, we continue to be on track. And we will end up…I think, we have 250 net placements year-to-date. We are on track to end up to have, at a group level, around 550 system placed worldwide.

In China…going back to China, China traditionally represents anything between 90 to 100 systems that we installed in the region. And in the first half, we are around 50 systems. So also as far as placement is concerned, again, China is fine. So to make a long story short, also in Asia Pacific, growth as expected, CLIA growing as expected. And in this region, the good news as well is the fact that in the last few days, we got approval of the QuantiFERON TB test that now is going to be launched in Australia in quarter 3.

The last things that I would like to comment on has to do with the fact that...is a renewal of major agreements. As you know, as we have discussed many times, 2019...2018 and '19 were 2 very relevant years for us because there were 3 agreements that were under renewal, 2 in the U.S…with 2 major labs in the U.S., and 1 with a major international laboratory chain. If you remember, we have signed already 1 of the 2 big labs in the U.S., December last year. So that has been renewed.

And I'm happy to report the fact that when it comes to the major international laboratory chain, now we came to terms and that agreement is going to be renewed as well which is fundamentally guaranteeing continuation...continuity of supply when it comes to all product portfolios, including Vitamin D. And we are going to add to that menu also more products as usual. When we have these renewals, you know, we have price concessions, but we've got benefit as far as the implementation of new assays on our installed base. So that's also very positive. One contract to go, that particular contract in the U.S., does expire end of the year. So we have time to work with this lab and you know, sign up as well this laboratory for renewal.

Finally, just one comment, we launched the LIAISON XS, our small mid-sized platform. It was actually CE Marked and presented in June...in May, June, and we are proceeding with soft launch. As said, we expect by year-end to have 20-30 units installed in Europe, but that is very typical. This is what we did with the LIAISON XL as well. It goes to opinion leaders, and it goes to reference accounts and then we expect then a full commercial launch in 2020.

So far, as far as, what we have committed to in the first 6 months, I believe that things are going as expected. And certainly, you see that all

these events that have been affecting positively our top line do result in profitability which is again in line with expectation, but I would like to underline profitability which is exceptional, as far as, our industry is concerned.

And again, the profitability and the high EBITDA level which we record in quarter 2, again is a result of different components. The first one is the fact that we continue to launch and develop products which are high priced, and therefore we have a mix...our revenue mix is continuously shifting from a base of products which include ME2 [ph] and specialty to a more specialty based product...base bag and that's very positive.

And the second effect is that we now see all the benefits coming from the industrial operations efficiencies that we've been conducting over the last 3 years that actually led us to streamline operation, consolidate operations and close Ireland last year. So we now enjoy the full benefit of the fact that cost base is not with us.

And we are committed to continue this trend in terms of efficiency and in terms of consolidation of manufacturing in order to guarantee that in a world where we have seen volumes...testing volume is certainly increasing, but price is always under scrutiny, we will continue to guarantee the level of profitability that we see today.

Now, I'm going to leave now the podium to Piergiogio, who is going to go through the numbers. Thank you.

PIERGIORGIO PEDRON: Thank you, Carlo. Good afternoon, everybody. In the next few minutes, I'm going to walk you through the financial performance of DiaSorin during the first half of 2019. And I would also make some remarks on the contribution of the second quarter.

As usual, I would like to start with what I believe are the main highlights of the period. So we closed half 1 with an increase in revenues at constant exchange rate of 3.7%. After a soft first quarter, mainly driven by a weak flu season as we saw, the second quarter has been strong recording a growth at constant exchange rate of 6%.

Q2 '19 gross margin confirmed the very good results achieved in Q1 '19, with a ratio of revenues of 69.4%, in line with what we recorded in Q2 last year. This brings H1 '19 gross margin ratio at 69.5% which is 100 basis points better than 2018. I will cover later on the main drivers behind this increase.

Half 1 '19 EBITDA at €139 million increased by 6% at constant exchange rate compared to the previous year. H1 EBITDA margin, again, at comparable FX rate is 39.6%, vis-à-vis 38.7% of 2018. Q2 EBITDA margin at 40% is confirming the very good performance achieved in Q1.

Lastly, we keep maintaining our ability to generate a very healthy free cash flow, €70 million in the first 6 months of the year. The net financial position, positive for €62 million, has been affected by the payment of ordinary dividends for €49 million in May.

Let's now go through the main items of the P&L. H1 revenues at €350 million grew by 5.8% or €19 million compared to last year. The growth at constant exchange rate is 3.7%. The strengthening of the U.S., dollar against the euro is the main reason behind this FX tailwind. Considering where the U.S., dollar is trending now compared to 2018, I believe it is fair to say that the positive FX impact should be less significant in the second part of the year.

Gross margin at €243 million, grew by 7.2% compared to last year, closing the first 6 months of 2019 with a ratio of revenues of 69.5%, which is 100 basis points better than 2018. Q2 '19 margin at 69.4% is in line with what recorded in Q1 '19. The increase in year-to-date gross margin is the result of following different moving parts.

The positive sales mix coming from lower instruments and export market revenues and higher specialty test sales that Carlo just commented, lower manufacturing and distribution expenses coming from the several cost reduction initiatives started in the last couple of years. And just to remind one of them, let me please mention the shutdown of the Irish manufacturing site.

And finally, lower royalties are coming mainly from the fact that at the end of 2018, some patents, some key raw materials of our molecular kits have expired. This royalty upside should stay in the second half of the year as a consequence of increasing latent tuberculosis sales.

Total operating expense is at €128 million or 36.6% of revenues have increased by 7.5% compared to last year. The growth at constant exchange rate is a touch above 5%.

OPEX ratio of revenues is 36.6% vis-à-vis 36% of 2018. And this somehow penalized by a revenue growth which as discussed in 2019 is expected to be skewed towards the second part of the year. Indeed Q2 '19 OPEX ratio is at 36% vis-à-vis 36.4% of Q2 '18.

H1 other operating income and expenses are in line with 2018 at €5 million or 1.4% of revenues, because of what just described, H1 '19 EBIT at €110 million or 31.5% of revenues has increased compared to 2018 by 7% or €7 million.

H1 net financial expenses are higher than 2018 by €2 million. This difference is entirely due to the revaluation at fair value of the participation in our Indian subsidiary booked in 2018 after the takeover of full control from the Indian partner. Excluding this positive one-off accounting revaluation booked in 2018, net financial expenses are in line with previous year. The tax rate at 23% is substantially consistent with 2018 which closed at 22.5%.

2019 net results at €84 million or 24% of revenues is higher than previous year by €3 million or 3.9%. This increase is the result of what's described so far and of higher net financial expenses of €2 million which I just talked about.

Lastly, H1 EBITDA at €139 million is better than 2018 by €11 million or 8.6%. The variance at constant exchange rate is positive for 6%. First half EBITDA ratio on revenues is 39.8% at current exchange rate and 39.6% at constant exchange rate vis-à-vis 38.7% of H1 2018.

Quarter 2, 2019 has confirmed the very good results of Q1 '19, closing at €72 million or 40% of revenues. H1 '19 improvement compared to last year is mainly driven by higher gross margin we just discussed about and by the application, starting from 2019 of IFRS16 which accounted for about €3 million in the first 6 months of the year. And I believe we already covered this point in the last quarter call.

Let me now move to the net financial position and the free cash flow. We closed the period with a positive net financial position of €62 million. After the introduction of the just mentioned IFRS16 which implied a booking of a financial liability of €30 million. Let me please remind you that in May, as I said, we paid €49 million ordinary dividends.

In H1, the group generated €70 million free cash flow vis-à-vis €69 million of 2018. I believe it is very important to note that Q2 '19 has been affected by the payment of a one-off exit tax for about €6 million deriving from the shutdown of our operations in Ireland and the following transfer of some intangible assets to our Italian legal entity. The value of the mentioned intangible assets will be depreciated over the next few years in the relevant Italian legal entity, therefore neutralizing the cumulative cash impact to the group coming from the Irish exit tax.

Lastly, we confirm 2019 guidance, which foresees an increase in revenues between 5% and 8% and an EBITDA margin at the same level of 2018. Actually, since we closed 2018 at 38.2%, considering the impact of IFRS16 as we discussed a quarter ago, should be more closer to the 39%. Please let me remind you that the guidance is, like always, at constant exchange rate.

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

Q&A

OPERATOR: Excuse me; this is the Chorus Call conference operator. We will now begin the question and answer session. The first question is from Catherine Tennyson with Bank of America Merrill Lynch. Please go ahead.

CATHERINE TENNYSON: Good afternoon and Thank you very much for taking my questions. I just have 2; my first one would be on the margin which looks to be tracking a little ahead of group guidance in Q2. So therefore do we see a chance of a bit of a guidance upgrade as we go into the second half

of the year or given the fact that you've just confirmed guidance there, what headwinds are you anticipating in H2 which would bring that margin down a little bit?

And then my second question would be on the Siemens ELISA business. You just commented that, there has been some delays in converting the customers over. Are we [indiscernible] a risk of losing these customers or what exactly are the dynamics at play there to cause this delay? Thank you.

CARLO ROSA: Yes. I'll take the second one, and then I think Mr. Pedron is going to address gross margin. On the gross margin, I'm just going to make a general comment, I don't think that today we are in a position to extrapolate anything, as far as, the year end results. But I think that PG is going to be more specific about it.

On the Siemens one, I don't see necessarily the risk of losing these customers. The reality is that this business which is a business which has been entrenched with these customers for 30 years, I remind you that this ELISA business was actually developed by Dade Behring which eventually was acquired by Siemens through acquisition. It was actually launched in 1980. So we are approaching 40 year shelf life of these products. And these customers have been very comfortable using this ELISA line. And today, especially in Europe and especially with these private labs, they are going through lots of transformations, as far as, efficiency is concerned.

And so, their major problem today is how they are going to automate more and more and more of their main core business in order to face a reduction in payments, and you know, everywhere in Europe, there is a reduction in health care reimbursements, which is primarily clearly affecting this lab.

So in this very complicated life, where they are trying to address the 80% core of their business, then there is this issue with ELISA, which they are fine with, and it's not necessarily a priority.

The problem is that the clock is ticking, and we keep telling them that by end of 2020, this business, as per the Siemens agreement, is going to be ceased. And either they move to us or they need to find another solution, which is not clear what the solution is, it's not standing up. So to make a long story short, I think that the issue is not losing, but what concerns me is the fact that if the conversion is stacked up toward the end of this year and beginning of next year, then it's going to become very complicated for us in terms of activities then to convert all these customers.

PIERGIORGIO PEDRON: Yes. So I will take the rest of the part of the question on the margin. So Carlo as he already said, it's really difficult to foresee by now exactly how the margins will end up at the end of the year. Certainly, we're very pleased to see the very good results in H1, but we also have to consider that there are several moving parts. H1 has been positively affected, as I said, by lower export and instrument sales, which by all means improved, helped our gross margin, and so our EBITDA margin. At the same time, we are expecting, in H2, our latent tuberculosis sales coming from the registration of the product in the U.S. And as we have discussed, those sales will bring some royalties with them. So very pleased with H1. Difficult to say exactly how we will end up the year considering H2.

CATHERINE TENNYSON: Thank you very much.

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

MAJA PATAKI: Yes, thanks for taking my question. Carlo, I was wondering if you could remind me quickly on where the quantity around TB tests have been rolled out in Europe already. I noticed that you both in Q1 and Q2 stated that TB and latent TB testing helped your sales in Italy. Is Italy the only market that's rolled out? I believe not so. And is there a difference in the different kind of European markets, why Italy would be doing significantly better than other markets in Europe? And lastly, you're probably not going to answer that, but could you quantify how much revenues you generated with the latent TB test in Italy in H1?

CARLO ROSA: Maja, good afternoon. Listen, as you know, this is a project...program that we share with QIAGEN. And so we...as part of the agreement we have with them, we don't disclose numbers, okay. So I will not be able to comment on specifically revenues generated by this.

What I'm saying is CLIA; we will report this under CLIA x-D. You see that our CLIA x-D business is doing well. And by the same token, I'm saying that from a...let me comment geographically. From a geographical point of view, I see that there are...there is uptake very favorable in those geographies where the business is concentrated in large labs, because these large labs is exactly where, today ELISA is representing an issue, because high volume with poor automation provided for ELISA really pushed these labs to find an alternative solution.

And these labs typically, as you know, are in Germany, are in France. And so as far as these 2 geographies are concerned, the uptake is going...following expectations. And in France, there is going to be an acceleration in quarter...in half 2, because some of the large chains were actually signed up lately with implementation, because we need to install dedicated XLs in quarter 3. So France is going to pick up as far as TB is concerned second half.

As far as Italy is concerned, it's a domestic country. We have almost 900 systems installed in the country. And so we have a very large installed base here, and the uptake is going well, but naturally going well, because we control this market. So this is as much as I can say.

As far as the opportunity, okay, let's not comment about the U.S., because it's so obvious to everybody. I think also Australia is very interesting for a very simple reason. In Australia, again, the business is very much concentrated in the hands of a couple of very large private labs. One is Sonic. Then there is another one. And again, these labs are the ones that do suffer from the lack of automation. And this why I'm expecting that this approval for TB in Australia was very relevant for us, because the...these big labs, I feel, will convert. We're going to be very open to converting soon. Okay?

MAJA PATAKI: Thank you. And a question...a second question, if I may. We've seen an approval...an FDA approval for a Lyme test by Zeus Scientific, for Lyme disease. I was wondering, is that test competing with your current offering that you have for Lyme disease? And how does the competitive landscape in Lyme's disease develop currently?

CARLO ROSA: Listen, that kit...allow me to be a little bit technical here. So today, there is an algorithm that has been used for 20 years, which requires the doc...the labs to test with one immunoassay. And then to reflect positives with a different technology, which is called Western blot, which is extremely awkward, very, extremely labor intensive, non-automated, it's a pain. And what very recently this panel of experts have recommended is to move to a different algorithm, which is called 2 tiers, where you fundamentally screen with 1 immunoassay and reflects on a different immunoassay. That doesn't add anything to the fact that there is a

dramatic problem in terms of sensitivity and specificity of current technologies. So there is a strong need to introduce a complete different technology in order to support the early Lyme detection, which we strongly believe is going to be offered by the T-cell response.

So to make a long story short, this Zeus product in this algorithm is...I see it as a transition phase, but again, it doesn't really address the problem. And the problem is early detection, which can only be resolved with the introduction of new different technology.

Let me just remind you that usually, these...technology is PCR. So in other situations where you want to get early diagnosis, PCR is the technology to go. Unfortunately, when it comes to Lyme, PCR is not applicable, because the bacteria clears very rapidly from circulation. So detection by PCR is not...is useless. And this is why, our industry for 30 years have not really been able to...with traditional immunoassay address the problem. Again, I am a strong believer of the fact that this QuantiFERON technology of QIAGEN can be revolutionary when it comes to Lyme disease.

MAJA PATAKI: Got it. Thank you very much.

OPERATOR: The next question is from Michael Ruzic with Berenberg. Please go ahead.

MICHAEL RUZIC: Yes, thank you for taking my questions. I just wonder about the large contract renewal, given that guidance was set before that was actually settled. Now that you guys have settled that, how much more confident are you that guidance will be achieved? And furthermore, should we start thinking more towards the mid or upper end of guidance now that you've settled that as well as added some new tests to that negotiation process?

And then the second one from me is just...you might have answered this earlier, but can you give us a percentage of the Siemens business that is converted on this stage? Thanks.

CARLO ROSA: Okay. On...let's talk about the contract guidance and all the rest. This...okay, we have 3 contracts to be renewed, 2 in the U.S., and 1 was actually global. We renewed 1 U.S., lab and we renewed...and now we are pretty much renewing the global agreement with the other lab. Now our concern and I think everybody else's concern, has nothing to do necessarily with what is going to happen in 2019 with this. Yes, there is an effect and there is an effect, because for some of these contracts, we are giving rebates, by the way, or it depends on the structure.

But the real concern was that, that business fundamentally was a good chunk of our Vitamin D business and everybody was actually was...some people were thinking about doomsday scenario where the time came when Vitamin D fundamentally would disappear from our business, which didn't happen. And so I'm saying now, 2 of the 3 have been renewed. And in total, 3 cases, Vitamin D is there with us for the foreseeable future. Certainly, there has been a trade-off in price. It always happens. But as we have done in the past, the trade-off in price comes with a positive effect on more products that are brought in line from these labs.

So to make a long story short, I think that strategically, it's very important for DiaSorin that we renew this contract, because we remain on the map of very large labs that will, like it or not, continue to buy everybody out and continue to increase their market share in the major markets, namely U.S. when it comes to Quest and LabCorp, and Germany and with Europe and Australia when it comes to Sonic.

Now as far as this effect on the guidance, some of this was included in the guidance. I'm not going to comment now how much this is going to impact on the guidance versus what the expectation is. My point is that where we are today, we know one thing for sure from what we have stated in terms of negative effect, the flu season has been a disaster, as for everybody else. And that clearly has affected our ability to reach the upper end of the guidance. Everything else, I believe, it's too early to say where in that range we are sitting.

MICHAEL RUZIC: Thanks. And just on the Siemens business conversion percentage?

CARLO ROSA: Okay. Let me say that...let me give you a more specific comment. In all the major geographies, with the exception of Germany, we have converted 80% of the business. When it comes to Germany, if today we have converted 40%, I would say, 30%, 40%, you need to excuse me if we cannot be that precise, because I have in mind the number of labs converted versus the amount of business converted when it comes to Germany. But I would say that, again, the...what's remaining to be converted is fundamentally Germany and some of the larger sites, commercial sites.

MICHAEL RUZIC: Okay, thanks.

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

MAJA PATAKI: Yes, thanks. Just 2 minor questions. One, Carlo, you mentioned that the expected approval for the TB test in the U.S. is now end of August, and you talked about a bit of a delay. Could you remind me what your initial expectation was for the approval? And then the second question, you also mentioned that you have now introduced Molecular with a larger

customer. And you also mentioned €1 million amount this quarter, whether that was the €1 million in a quarter that was accounted for coming from that contract? Or whether that is €1 million for this year that you're expecting? Could you clarify that, please?

CARLO ROSA: Maja, I'm a little confused, because I don't understand where the €1 million is coming from. So let me just answer to the TB one in the U.S., which is simpler. Our expectation was June, okay? And the reason why we did not get approval in June is because we received a request for an amendment. And that...and this has to do, unfortunately, with the fact that between the time we submitted and the time they started reviewing, the FDA changed the analytical guidelines, which fundamentally means that all the internal data, so nothing to do with the clinical result, but internal data that we were...we have done as far as the kit's stability, the precision and so forth had to be all recalculated because of the guideline change in between. And that has caused fundamentally the need to go back and issue and submit an amendment.

Now the amendment, as said, has been submitted. Now by the time the amendment is submitted and now there are no other comments from the FDA, they have, by the book, 90 days to issue approval. Now I don't think that it's going to take 90 days, because they pretty much...the review is pretty much completed. And therefore, I am guessing that considering that also the Americans go on vacation and the FDA goes on vacation in June...in July, I assume that by the end of August, we're going to get this cleared. Now going back to the €1 million, help me out with this. Where is the €1 million coming from?

MAJA PATAKI: I thought that you said...you talked about the Molecular business that you signed a large contract in U.S. with Molecular? And I saw the figure €1 million [indiscernible]. Can you anyway quantify how material or kind of

give us an indication of how material you think that Molecular business would be for the new client?

CARLO ROSA: Listen, Maja, as usual...however, it's not €1 million. It's way more than that. So this is why I got confused about the €1 million. It's a very significant contract. And again, it goes back to 2 considerations. The first one is that, don't forget, this business was owned by Quest. And therefore, Quest being a competitor of all the other commercial labs, by definition, they were not selling much to all the commercial labs. So most of the business we bought was actually hospital-based business, because hospitals did not see Quest as a competitor. Now that the business is off their hands and really in the hands of DiaSorin now for 2 years and because of the relationship we have this commercially, as we open up the business, all the channels of the commercial labs, we're starting to reap the benefit. The amount...but again, it's not a €I million, its way more than that.

MAJA PATAKI: Okay, guys. Thanks very much.

CARLO ROSA: Thank you.

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

CARLO ROSA: Okay. Thank you, operator. Take care. Bye-bye.