DiaSorin SpA

"First Half 2018 Results Conference Call"

Thursday, August 2, 2018, 15:00 CET

MODERATORS: CARLO ROSA, CHIEF EXECUTIVE OFFICER

PIERGIORGIO PEDRON, CHIEF FINANCIAL OFFICER

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome, and thank you for joining the DiaSorin First Half 2018 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, good morning, and welcome to the quarter 2 conference call. Let me remind you that I will make initial comments at constant exchange rate, since as you have seen, the currency fluctuation has an impact on the business. And after my remarks, our CFO, Mr. Pedron is going to take you through the numbers. I will focus my comments on 3 points, which are key in my opinion to understand our business and the business in quarter 2. I will talk about top line, I will talk about margins, and I will talk about new product launches.

Now let's start from the top line. Let's start from Europe, which is simple. Strong growth and in line, we plan to incorporate with the Siemens' customer base, and then initiate the transfer of the business from the ELISA Technology to the LIAISON Technologies. We had good growth in all the different countries.

One point I want to make, which has to do with Germany because of the fact that in the last 2 months we hired a significant number of new commercial reps and engineers to support the Siemens business and also to facilitate the transition and installations we expect to come of new instruments, where we'll move from ELISA to LIAISON.

What we have seen in Q1 and in Q2 is a slowdown of the development of the new business. This is temporary for Germany, again because it has to do with the fact that lot of attention was actually dedicated to

incorporating the Siemens business, and we expect Q3 and Q4 the CLIA x-D business to start to grow again as a net result of the transition of the Siemens customers to our platforms. So Europe, I think, is self-explanatory and no concern and we move forward.

Now, let's go to APAC. And when it comes to APAC, it's certainly true that we need to discuss China, since China does represent the lion share of the revenues in this area. We see a strong...in China; we see a strong reagent growth, which is especially offset by the change of the instrument policy in China. What does it mean change of instrument policy? It means fundamentally 2 things.

First, as we said in the previous quarters, starting from late last year, we are refocusing our distribution network from the current one, which is okay, serving class 3 hospitals, which do represent the vast majority of our business today into a distribution network that is able to self-serve on the class 2, which as you know, as we have discussed, at times does represent the future growth opportunity for DiaSorin in preparation of the launch of the LIAISON XS.

Second element is that we changed our policy in China, whereby rather than favoring instrument sales, we are now favoring reagent rental, and the reason why we do that is that with the reagent rental, we can clearly better control where those instruments are actually going. So the net-net result is that you don't experience per se a decrease of placements, whereas what you see is a decrease on the revenue line, on the instrument line compared to 2017 because of this change in policy.

So when you look at China, China is doing well and China is growing the CLIA business as expected, double digit, and we expect to close the 2018 with double-digit growth. What you see in the top line, what seems a non-

growth top line...non-growing top line is a cosmetic effect because of this situation with the instruments.

Now let's talk about the U.S. And when we talk about the U.S., we need to talk about the elephant in the room, which as you know, for the U.S., for us, is Vitamin D, which in quarter 2 took a downturn versus the previous quarters. Now as said in the past, it is our expectation that Vitamin D decline at a worldwide level ranges between 3% to 5% per year. And that's a combination of decline in mature market, like the U.S., an upside in other countries where the adoption rate is still low.

What we saw in quarter 2, which we did not expect, is that there has been a volume decline steeper than in previous quarters. And volume decline means, utilization of existing customers...of some of existing the customers of the Vitamin D assay. And this is certainly a new compared to what we have been experiencing in previous years because the decline in previous years was mainly an effect of pricing, whereas the volume has always been flat or growing as a consequence of the fact that some of these very large commercial labs were acquiring smaller labs, and therefore, their volume was growing and/or because the utilization...the usage of the Vitamin D test per se in the U.S. was still slightly growing.

Well, starting from quarter 2, we have seen a change in pace, and this is mainly due to a recent policy change with one insurance company, which is Cigna. And Cigna changed their reimbursement policy when it comes to testing where not it’s recommending to all doctors not to use the test for screening purposes but only to use it for diagnostic purposes. What's the consequence of this? The consequence is that the rejection rate has increased for certain labs, the ones that have patients they do...that are reimbursed under Cigna, and the testing volume has softened with those physicians which see patients again, covered under the Cigna policy.

Now we have seen this happening before in other countries, let me remind you Australia, let me remind you France. So it is something that does happen when it comes to an assay, like Vitamin D that is used in high-volume. And typically what we have seen in the past is that it takes the market a couple of quarters to settle down. So there is a decrease in usage and then the market does settle and then it continues at that pace. This certainly was not foreseen in our plan. The Cigna policy was actually changed at the beginning of quarter 2. And so we are recalculating or reassessing the Vitamin D opportunity or decline actually in the U.S. for the next 2 quarters, and that led to the fact that we had to revisit our guidance...top line guidance when it comes to 2018.

Now otherwise in the U.S., the CLIA...now that the elephant is out of the room in the U.S., the CLIA x-D continues to grow double-digit, and we expect a series...which is very important, we expect a series of new products to hit the market in Q3, Q4 this year when it comes to 2 stool specialty assays that are in the final round of discussion with the FDA to be approved. And also, as you all know, we expect to have the QuantiFERON-TB assay coming to the U.S. next year.

And last but not least, all the hepatitis, initial refinance to hit the market...start hitting the market next year and then continue into 2020. So from a strategic point of view, I have no concerns about the fact that we do have the U.S. well covered with new product launches. And certainly, we need to face the short-term reality of the fact there is this Vitamin D reassessment.

Now let me talk on margins because I think, it is very...it is noteworthy and important to see that the quarter has been very good with...in delivering margins. And this has to do with 2 things. First, good mix, if

you think about it in the past, the segment Vitamin D was declining, did affect margins of the company, and it does and notwithstanding the fact that again in the quarter, we took a hit on Vitamin D, more than expected, margins didn't suffer. And this shows that a) we don't have dependence on Vitamin D margins any longer because we launched recently many, many products which are highly profitable as well.

And so, again, Vitamin D...our dependency on Vitamin D from a margin prospective is not there any longer. The second consideration, which is very important to make is that as we have discussed, we've been working over the last 2 years into operational efficiency, which resulted into 2 things. First one has been heavy investment in the manufacturing side, in order to increase automation in manufacturing and decrease the cost of labor, and we start seeing this.

And last but not least, also the fact that we decided to consolidate some of our operations, and we came to the conclusion of closing Ireland last year. And what is very interesting is that notwithstanding the fact that Ireland is still active, as you know, we foresee to close pretty much everything by year-end, so the net positive effect is not there yet of closing Ireland. Still margins are good. Again, so from a margin's perspective, I am very reassured that we can maintain the profitability as a net-net result of innovative products that we launch and continue to launch, and the fact that from an operational point of view, the system is becoming extremely efficient.

Now, last but not least, it has to do with new product launches. And certainly...and I know questions will come on QuantiFERON, so let me try to give you some answers. You know, we do have this partnership with QIAGEN. You have listened to what the QIAGEN CEO has been saying about the assay per se, and the way the 2 companies work together. We

are on track to launch the product on the LIAISON in mid-September, CE Mark. And we foresee U.S. FDA submission happening sometimes in early Q4.

And so these are very important products for both companies. It is very important for us because it's going to give us access to a set of customers today that are using this product, and it's going to give QIAGEN access to a very large installed base of instruments that they do have in hospitals that today are still doing skin test. And certainly, we're going to work together to convert and increase adoption of blood test versus skin test. So QuantiFERON on time and to be delivered. It's going to hit the market in Europe in a month or so.

The last comment I want to make, again, is to be with the other 2 products, which are key here to us, which are the stool products that we decided to bring to the U.S., and we are in the...we are very close to get approvals. Stool is very important because the U.S. is the larger geography that we are missing actually.

And especially when it comes to is calprotectin, it's a growing market, and it’s a market today that is a high-margin, high-price market. It’s a market that is mainly a send-out market from hospitals into the big labs. And we're very well positioned to capture that way of initial testing and then move downstream the adoption into the hospital market. So overall, as far as short-term future is concerned, I feel very comfortable.

And at this point, I will pass the microphone to Mr. Pedron, who is going to take you through the numbers, and then we're going to go through Q&A. 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 the DiaSorin during the first half of 2018. And we would also make some remarks on the contribution of the second quarter.

Before we start, and let me please remind you that we began reporting the Siemens ELISA business from Q4 '17, and so the perimeter of consolidation is different from the one of last year.

Said that, as usual, I would like to start with what I believe are the main highlights of the period. The strengthening of the euro against all the currencies in which we operate has generated some notable FX headwinds on revenues during the first 6 months of the year. In revenues, as expected, that the impact has been less material in quarter 2 compared to quarter 1. We had €6 million in Q2 of headwind and €11 million or so in Q1. The variance has been mainly driven by 2 currencies, and the USD, which depreciated by almost 12% and the Brazilian reais, minus 20% in the first half. Considering the U.S. trend in 2017 and where we are now, I think it is fair to say that this effect will materially decrease in Q3 and Q4, 2018.

Moving to the second point, we closed half 1 with an increase in revenues at constant exchange rate of 9%, for almost €29 million. After a strong first quarter, the second quarter has been kind of soft for the reasons that Carlo just covered, recording a growth at constant exchange rate of 6.7%.

We closed half 1 EBITDA at €128.2 million with an increased constant exchange rate compared to last year of about 8%, and with better margins than what we expected., 39.1% at constant exchange rate versus 38% implied by our full year guidance. H1 '18 EBITDA margin net of the expenses we booked for legal action in the U.S. concerning the future

introduction of certain product into that market, and net of the tail of the Irish site divestiture cost would have been slightly better than last year.

Lastly, we grew the half with a very strong free cash flow, €69.2 million versus €61 million of 2017, with the growth a touch better than 13%. The net financial position at about €104 million has been affected by the payment of the ordinary dividend for €46.8 million in May and by a shares buyback program for about €60 million

Please pay attention to the fact that the net financial position does not include about €98 million of debt towards shareholders for the extraordinary dividend, which will be paid out in December, 2018.

Let's now go through the main items of the P&L. H1 revenues at €331.2 million grew by 3.7% of just shy of €12 million compared to last year. That said, the growth at constant exchange rate is 9% or €29 million.

Gross profit at €226.8 million grew by 3.5% compared to last year. Closing the first 6 months of 2018 with a ratio over revenues of 68.5%, which is basically in line with 2017 in spite of the diluted effect of the Siemens ELISA sales and of the price pressure on Vitamin D. This performance, which is better than what we expected is mainly driven, as Carlos just discussed, by higher manufacturing efficiencies and better product mix, and has been helped by a very good and solid quarter 2, which reported a gross profit margin of 69.4%.

As you might remember, we have discussed in the previous quarters and during our Capital Market Day, about several initiatives aimed at squeezing costs out of our P&L in order to save our EBITDA margin. I believe, we have started seeing the payback of those initiatives filtering through our numbers.

Total operating expenses at €119.2 million or 36% of revenues have increased by 3.9% compared to the first 6 months of last year. Please remember that about €7.2 million of H1 OPEX has been driven by depreciation of intangible assets coming from the Siemens ELISA and Focus business acquisition. Net of these elements, H1 OPEX increase at constant exchange rate versus since last year would have been 8.2%, and the additional revenues would have been 33.6% against 34% of 2017.

H1 other operating expenses at almost €5 million, have increased by €1.2 million compared to last year. As said, the period has been affected by some expenses related to legal action in the U.S. concerning the future introduction of certain product into that market and by the tail [ph] of Irish site divestiture cost, because of what we described, H1 EBIT at €103 million of 31.1% of revenues had increased compared to 2017 by 1.9% or about €2 million. The growth at constant exchange rate is positive for about 8.5%.

H1 tax rate at 22.5% is almost 10 percentage points better than 2017 which closed at 32.3% and is in line with what we anticipated and discussed during 2017 year-end quarter. This variance is mainly driven by the positive impact of the Italian Patent Box and the U.S. tax reform.

Net result at almost €81 million or 24.4% of revenues is higher than previous year by €14.4 million or almost 22%. This increase is the result of what described so far and have a lower net financial expenses, mainly driven by minor interest and FX losses compared to last year and by the reevaluation of the participation in our Indian subsidiary following the takeover of its full control from the Indian partner.

Lastly, H1 EBITDA, at €128.2 million is better than last year by €2 million or 1.6%. The variance at constant exchange rate is positive for just shy of 8%. First half EBITDA ratio and revenues is 38.7% at current exchange rate and 39.1% at constant exchange rate, thus confirming the strong profitability seen in the last quarters and actually improving it. Quarter 2 has done particularly well, closing at almost €65 million or 39% of revenues. Please remind that H2 2017 was materially affected by the Irish site divestiture cost. So the growth of H2, 2018 or the H2 2017 is going to be more material than what we had recorded in H1.

Let me now move to the net financial position in the free cash flow. We closed the period with a positive net financial position of about €104 million and about €118 million in cash. The net financial position has been affected by two elements, as said, the payment of ordinary dividends for €46 million in May and the share buyback program for €60.3 million. The group generated €69.2 million of free cash flow in the first 6 months of the year vis-à-vis €61 million in 2017, reporting an increase of 13% This variance is the result of the better economic performance of the period and of the lower tax cash out coming from the Patent Box in Italy and the U.S. tax reforms.

Lastly, in view of the group operating performance, the management has reviewed its 2018 guidance as follow. Revenues grow with a constant exchange rate of about 9% vis-à-vis 11% of the previous guidance. EBITDA growth at constant exchange rate of about 12% vis-à-vis 13% of the previous guidance.

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 Romain Zana of Exane BNP Paribas. Please go ahead.

ROMAIN ZANA: Yes, thank you. Can you hear me?

CARLO ROSA: Yes, we can hear you well.

ROMAIN ZANA: Yes, perfect. I have three questions, if I may. The first question is rather a clarification. Can you just clarify the pure organic growth reported in Q2, so without the contribution from acquisition? The second question will be on CLIA, excluding Vitamin D. In Q2, you obviously still had a very solid growth, but how should we extrapolate the slowdown, it seems, Mr. Rosa, that you see the slowdown as temporarily. Is that fair to say that you expect a return to double-digit growth along with the launch of new test like PCT would be good to have a flavor on that? And I have a follow-up question on the guidance; I will first let you answer the two?

CARLO ROSA: So, hello. Romain, I'll start taking the first question you made about the organic growth. So the organic growth in the first half is around 4% which means that the organic growth in Q2 is just north of 2%. If you remember in the last call with the...with you guys, we told that Q1 growth was around 6% and these you know, make all the math [indiscernible].

ROMAIN ZANA: Sure.

PIERGIORGIO PEDRON: Okay, when it comes CLIA x-D, I made some comments before, so let me just summarize. Yes, I see no problems with CLIA x-D growing by year-end at double digit. Year-to-date it is 10.5% growth; they...with 13% in Q1 and 7 point some percent in Q2. The difference in quarter 2 versus

quarter 1 has to do with two affects, mainly as said, the first one is to do with the fact that in Germany which was...Germany was a contributor in Q1, did not contribute necessarily in Q2 in growth because of the fact that we have been starting...we spent the last few months reorganizing the business and so we saw that our reps are spending more and more time in acquiring the Siemens business, rather than developing new business. And certainty, and Q1 didn't fit much due to fact, but you will start to seeing it in Q2. It's temporary because of the fact that...then the next step now that the business has been...is solidly in our hands and now it's going to be promoting and converting those ELISA customers to LIAISON. Let me remind you that Germany is not...is...well, is a significant portion of our European business. So the fact that they don't contribute to CLIA growth, clearly you can feel it in a quarter.

The second element has to do with the fact that, as far as, China is concerned, China and this has a lot to do with timing, because don't forget in China we sale to distributors, so depending when they schedule the shipments you see shift from one quarter to the other, but it grew 18% in Q1, and then it grew single digit in Q2, overall, it's growing 12%. And I believe the 12% for China growth of CLIA x-D is what we should expect from this business. So there are certain one-off elements when it come to the CLIA x-D that made the quarter too light, but I don't see this to be honestly a problem. Keep in mind that starting from quarter 3 and then quarter 4, you are going to have TB which is a CLIA x-D assay. You are going to have the approval of some of these products into the U.S; we just got Hepatitis B, CE Mark. So...and as usual, the funnel is delivering, and I am not at all worried about the performance of the CLIA x-D.

ROMAIN ZANA: Okay. Very clear. And last one if I may, about the guidance and the comments you made in the press release about the evolution of the diagnostic sector. Just wanted to clarify these points, I mean, are you

revising the guidance because of the changing guidelines of some pay-offs [ph] as you alluded on Vitamin D or is it rather like a PAMA impact or general comments that you are doing about the diagnostic sector as a whole?

CARLO ROSA: No, I've seen that, that statement is always there, and it is a general disclaimer, which fundamentally says, we don't have the crystal ball when it comes to the overall market. I believe, that the revised...the fact that we revised the guidance has to do with the business affects we have discussed, certainly Vitamin D which was not expected.

Second, the fact that contribution of growth of CLIA revenues in the second largest European market Germany did slowdown for the reason we have discussed in quarter 2 and we don't expect to recover that.

Last but not least which I did not mention because I don't believe it is strategic, it is more tactical, but does bear some consequences to the performance of the business, is the fact that when we infer it at the...when we bought actually the Siemens business there was half part of this business which is roughly...which is €3 million- €4 million which had to do with the very large tender that Siemens had in Brazil, historically for Zika. And because of the fact that Zika fundamentally disappeared or the infection rate has dramatically decreased, this tender has been postponed by the government. So that base business which...what we consider base business of roughly €3 million- €4 million which did not...which was in our forecast, all of a sudden was canceled. I consider this really tactical because tender…Zika tender in Brazil is very tactical, but certainly, it did somehow impact on the fact...on our...on the fact that we felt more comfortable decreasing growth from 11% to 9%.

ROMAIN ZANA: Thank you very much.

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

MAJA PATAKI: Great, thanks for taking my question. I would like to start off with the U.S. sales performance. Could you give us a bit of a feeling of some color on what CLIA growth was x-Vitamin D in the U.S? In the past you have given us a bit of a color to understand what is happening? And the second question relates to the softer performance in molecular test in Q2. Could you give us bit more color on that? And then the last question which relate to your comments about the change in the Vitamin D reimbursement policy with Cigna. Do you think that this is just the beginning of other following suit and hence, Vitamin D could once again, see an...a deceleration in the trends? Thank you.

CARLO ROSA: Okay, I'll take these questions. So let's start from Vitamin D. As said strategically, Vitamin D for us can only be lose, lose proposition because of 2 things. That first, there's still very relevant market share we have in the U.S. market. Thanks to the fact that we do have contracts with major labs. So from a volume perspective, we still have a very large market share in the U.S.

Second, that…the penetration, if you remember, we stopped talking about it because we consider this history. However, the penetration which is a number of...the percent of population tested by Vitamin in the U.S. is by far one of the highest in the world, next I believe to the hay days of Australia and France. So for that reason, it's very, very clear that Vitamin D is...destiny is to decline. And we always stated if you remember, you can go from 3% to 5% and we always said that...and I believe last year was actually less than 3%....was pretty flat last year. But if you remember, I warned everybody, you know, don't cork up your champagne because

next year can be different. Now Vitamin D is unpredictable, because of this.

Now what Cigna is doing, is fundamentally reminding doctors that Vitamin D is not a screening assay, which is a fact. I mean, Vitamin D also when we got approval for Vitamin D with the FDA it was never intended to be a screening assay. And it became...the success of Vitamin D in the U.S. is related to the fact that it became part of the employment screening and insurance screening programs. So it's not a screening...it's not really used as a screening but part of screening programs, okay, for Vitamin D deficiency.

And last but not least, there is a strong consensus amongst the physicians that there is a need of assessing the Vitamin D level. So let me tell you my gut feeling...but again, if I had crystal ball, I would play the lotto and retire. My gut feeling, when it comes to this is that with Cigna, what this will do is going to reassess, we're going to take away some of the misusage. Right, misusage means that you click...you check the box even if it doesn't...it's not needed. So that will go away.

And to be honest with you, my expectation is that this...now Cigna is a player but there are many, many difference in insurance companies that do have...that do serve the U.S. markets. So my expectation, to be honest with you is that this is going to be done also by some other providers. Is this going to be...this way…is this going to have a dramatic effect on Vitamin D assay, I believe not. I believe, again, as said as we have seen in other countries, we will see a reassessment of volume testing...of testing volume. And then there is going to be a new baseline, which gut feeling tells me may be 20% of volume will disappear, but the bulk of the volume will continue to be there.

What is...again, what I will like to remark on this, and I draw your attention to this, is that Vitamin D is still a very profitable assay for us, and notwithstanding the fact that we took the second quarter, did not affect by EBIT, our margins. So everybody should take note of that in terms of the ability of the company to diffuse that risk which was certainly there few years ago, but today we are not exposed to that any longer. Okay, I hope is taking care of the Cigna story.

Now, let's go to molecular. Unfortunately, for reasons that I have nothing to do with you, but it has to do with the first posing data to competition. We cannot show breakdown of revenues when it comes to molecular. However, we have always indicated that when we bought this business, this business had two components. The component which was...which is extremely, by the way, profitable which has to do with ASR. ASR means that we sell our reagents to the very large labs and this was done by Quest. I remember we bought the business from Quest. Quest was using this outfit to develop reagents to then be used in the Quest lab to develop ADTs [ph]. And they developed an interesting business, which is significant in the U.S. for...in which grows [ph] under molecular revenues.

Now what happened in quarter 2, two things about this business; a) it's since they buy reagents and they...for internal use they buy it in big chunks. And what happened in Q2 is that some of the orders did not fall in Q2. Some were anticipated in Q1, some will come in Q3. So you see a dive of the ASR component of the business which is the part that is more tactical and less strategic for us. The underlying business which is the reason...which is why we've bought this company which is the kit which have to do with the flu, the herpes viruses and the CDs, and all the other product that we have bought continued...it continues to grow strongly double-digit as a spectrum, okay. So ASR, what you should look at molecular is doing very well when it comes to the kit and then you have

this blip when it comes to the ASR business in the U.S. And we are very exposed to it because of again, the nature of the assay that we bought.

Now, last but not least, U.S. sales, we don't break down. However, the growth of our CLIA x-D in the U.S. is around 12%, okay? So it's good growth, it does represent today something like 40% of the U.S. revenues. So it is...it used to be almost nothing then we developed a very good business and it is the one that is fueled…it's going to be fueled by launch of new products, including stool and the TB, okay? Certainly, if 60% of your business declines by 10% then you do have a problem and that has to do with the fact that you see the Vitamin D...that the Vitamin D and then you see the North America revenues overall going down by 4.5%. The math is not complicated.

MAJA PATAKI: Great. That's very helpful. Just a follow-up on that Carlo, so you expect actually for the full year molecular to be in double-digits, given you have this you know, the lumpiness of the orders of the ASR kit, shall we expect for the full year, did you see double-digit growth for the total of molecular?

CARLO ROSA: I do expect the double-digit growth, but let me make a fundamental disclaimer, which you know a portion of our business is flu. So with a regular flu season, I do see double-digit growth. I don't expect flu to be a great contributor of growth, but I don't expect flu to be something that is going to depress revenues. So this is my assumption, you know. There is a flu component which has to be same as previous years, and then the rest of the business which is growing strongly. So if that happens, I'm seeing double digit...and then ASR being flattish pretty much, if that happens then we will see double-digit growth.

MAJA PATAKI: Thank you very much.

CARLO ROSA: Thank you.

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

MICHAEL RUZIC: Yes, thanks for taking my question. Just 2 from me. One, I was just recently reading the transcripts for Quest over in the U.S., and they seem to elude to the Vitamin D slowdown being a miscoding issue, and that this might actually be more temporary. So, obviously, a bit different than what you were saying, and I'm just wondering if you can help me kind of reconcile those 2 explanations. And secondly, I was just wondering if you had started to see any effect from PAMA? I know a lot people are talking about this, and you guys have spoken about it before, but I was wondering if that had started to bite your x Vitamin D CLIA franchise in the U.S. at all? Thanks.

CARLO ROSA: Look, without really trying to put myself in the shoes of my largest customers in the U.S. so take that as a disclaimer. But what I believe we are saying is very similar simply in different words because miscoding fundamentally means that how do you prescribe Vitamin D. And so if we use it for streaming or not, and if it is for screening then under Cigna, you would get some of these assays that are rejected. So why temporary? Because it is the same as I said. Temporary because it is going to take away some of the mis-codings, but then the legit use of Vitamin D, which is a clinical use will continue to exist. And this is why I think they alluded to the fact that its temporary is pretty much the same way...the same concept just said in different terms. But in fact, you're right, this concept of change of reimbursement recommendation certainly does impact some of the large labs, but because lots of Vitamin D testing today, it is actually with the very large labs. I'm not talking Quest; I'm talking about the commercial labs in the U.S.

Now let's go to PAMA. With PAMA, look, I am very agnostic about PAMA for 2 reasons. PAMA should if anything affect Vitamin D testing but again, as you see, and as I said before, Vitamin D...the Vitamin D market is actually…has been destroyed by competition, by price. From my perspective it's been completely devastated by some pricing...foolish pricing policy by very large companies. And it has been done.

Now, PAMA changing reimbursement, not doing much in my very humble opinion, but again if you see, nothing to do with changing their reimbursement. It has to do with changing the fact that you reimburse for a certain use. That is changing, that is affecting volume testing, and that does affect the market. Okay, so as far as PAMA is concerned in Vitamin D, no problem.

As far as everything else in PAMA, look, we sale products that are either very high in specialty, and so price is not necessarily a big issue. Or are products which are so small, so they are specialty, but so small in terms of volumes that they not draw necessarily the attention of any of the labs because it don't affect their math. So as far as DiaSorin is concerned today, PAMA, I don't see PAMA, honestly, affecting tremendously our orbit.

MICHAEL RUZIC: Understood, thanks.

OPERATOR: For any further questions, please press "*" and "1" on your telephone. The next question is from Patrick Fuchs of AGI. Please go ahead.

PATRICK FUCHS: Hello, I have just a question regarding, again, Vitamin D. I mean, when I look at the overall stage of development it comes from exchange rate in Q2, down minus 4%. So that's not completely out of the range that you

expected. So would you see the Vitamin D slowdown then more in H2, getting at a run rate at the end of the year below the range of that you have given previously on that? And the second question is just to get a view of potential impact to...currently what would be your estimate of Vitamin D screening in the U.S. versus 3D diagnostic use if the patient presents with some maybe Vitamin D relevant symptom or so? So this is question basically. And then, finally, the guidance cut that you've given, so you would basically say German situation and the Vitamin D situation is the larger explanation...or the largest explanation of the cut here. Thanks.

CARLO ROSA: Yes, Patrick, I would say, again, 3 things. When it comes to the guidance cut, it has to do with events that are mainly...to do with certain situations that stop growth in a geography but are not permanent, and Germany is a good example. The one-off tenders, which have been canceled, which we didn't comment too much, I just commented before, which is the Zika tender, very sizable business, nonstrategic but sizable. And that's gone because government canceled the tender. And the third element is certainly to do with Vitamin D. I think, we [indiscernible] that bird already 3 times, and we discussed Vitamin D. Yes, Vitamin D in H2 is...will decline compared to last year more than expected because of this phenomenon in Cigna of...in the U.S. and I believe that is going to...as said before, this will take couple of quarters to settle down. And then we have better visibility.

What does screening means? It's a very difficult question to answer because if you go in Cigna...I mean, if you look at the Cigna recommendation, it says, well, you should be testing for...if you suspect intoxication, if you suspect any issue with osteoporosis or you suspect any clinical condition associated with Vitamin D deficiency. Vitamin D for screening [indiscernible] what the heck does it mean? I don't know. It is interpreted saying, if you are just curious about Vitamin D volume, and

you cannot justify Vitamin D level, and you cannot justify without reimburse. That increased rejection rate, and it's going to actually, in my opinion, drive doctors to be more precise in terms of indication why they prescribe Vitamin D. It will not take away some of the flaws that today is certainly there, not only for Vitamin D, but for a lot of the products when there is a lot of flexibility on the reimbursement, as far as I can say this is it.

PATRICK FUCHS: Okay, thanks a lot.

OPERATOR: The next question is from Alex Cogut of Kempen. Please go ahead.

ALEX COGUT: Hi, thank you for taking my question. In the context of your reaffirmed 2019 guidance, could help me understand what you see offsetting Vitamin D decline to be able to let's say to confirm your guidance? Thanks.

PIERGIORGIO PEDRON: Hello, Alex. So we had a few elements which we believe will offset the Vitamin D thing that we just mentioned about. On one side, there is TB, which definitely will start to play a role in our numbers. Then we have the...we will see the full effect of the conversion of the Siemens ELISA business we just bought because so far it is true that we started converting a lot of customers to our CLIA technology, but still volume has not started. And what we see is that every time we convert a customer, we are able to gain much more revenues than the original ELISA revenue we bought from Siemens. Then we have the impact...the other element is impact of the stool menu that Carlo just mentioned about, for which we are expecting some decent growth, especially in the U.S.

And eventually, as you know, we also have in '19, the launch of the new platform, the LIAISON XS, which is going to be addressed also to new customer settings, and which will...we believe, will bring additional

growth to our revenues. All this compounded plus the normal growth we have in the like-for-like business, on the let me say, CLIA xD franchise without considering what I've just mentioned, makes up...makes us comfortable on our 2019 guidance.

ALEX COGUT: Yes. And that's assuming Vitamin D drops like 30% this year, and then sort of stay stable over 2019 going forwards, right?

PIERGIORGIO PEDRON: We will have been more precise in terms of our guidance for 2019, when we will do our 2019 guidance. The 2019 numbers we have now is the one we gave to the market when we do...when we did the Capital Investor Day. But all things considered, we still believe that 2019 is achievable because of what I just said. So the Vitamin D...the additional decline in Vitamin D is going to be offset by the elements...or the elements which I just mentioned.

ALEX COGUT: Okay, thank you.

PIERGIORGIO PEDRON: Thank you.

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

MAJA PATAKI: Yes, thank you very much. Carlos, just quickly to double check, did you say that the Zika tender was €3 million? Wasn't sure whether I got that right. And then, just quickly, you've really highlighted very well what has been driving the strong margins in H1. Is there anything that we should be focusing, that could represent a risk to margins in H2? Or should it just improve from here? Thank you.

CARLO ROSA: No, I don't think...sorry, let me…it's the quick one. The Zika tender was close to €4 million, when it was done under the Siemens watch. Clearly, it was not in our numbers last year because we bought the business at the end of it. But we assume it would actually be reissued this year and it did not happen. When it comes to margin, no, I don't see...to be honest with you, I don't see any issue why H2 margins should necessarily be affected. What I...and again, now more on the midterm, again, don't forget, margins so far are where they are still with all the cost associated with the Irish plant. We are just active because we are actually transferring...we are transferring manufacturing from that site to other sites. And so when it comes to the 2019, then we're going to have the benefit of the shutdown of Ireland, which if I remember correctly, we had indicated to be in the range of €7 million, €8 million.

MAJA PATAKI: That's right. Thank you so much.

CARLO ROSA: Thank you.

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

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