## DiaSorin S.p.A.

## "Nine Months 2019 Results Conference Call" Wednesday, November 06, 2019, 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 Nine Months 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 and good morning, good afternoon to everybody. Welcome to the Quarter 3 conference call. As usual I am going to make some comments about the quarter and then I will turn the microphone to Mr. Pedron who is going to address the financials. As usual I am going to make my comments in constant exchange rate because the company enjoys a favorable effect coming from the strength of the U.S. dollars.

So first I believe that this was a good quarter both in terms of growth in the very relevant geographies where we play as well certainly as well as for the profitability. And I think we hit a record quarter in terms of...in cash flow generation.

If we look at the overall situation, I think that all the assets that have been developed by the company over the last couple of years are coming to fruition and mainly...and I am mainly referring to the availability of new products, the strategic alliance with QIAGEN and the launch of the LIAISON XS which I will comment separately during this conference call.

So as far as products are concerned, I think that as we discussed many times, there has been a clear strategic indication by the company to invest in certain clinical areas and then take these products to what we consider the main market which is the U.S. obviously. And we have now all assets

except one which we think will come very shortly, which is the QuantiFERON. We've all these products now approved by the U.S. and ready to go.

As far as the QuantiFERON is concerned in the U.S. we are waiting the approval. We have fair overall, almost 13 products lined up for approval, the first 2 were cleared in the last couple of weeks. One was Hepatitis C which was...which is the beginning of the Hepatitis strategy in the U.S. is one of the most complicated and got approved first. And the second one was Zika, which was approved last week, so we expect next to come would be the QuantiFERON and the rest of the Hepatitis menu.

As far as the U.S. is concerned, it's very clear today that the company does have a position on the market...a very good positioning on the market with commercial labs. And I am not only referring to Quest LabCorp and Sonic which are the main three commercial labs in the U.S. But we do have if we look at the commercial laboratory including regional labs in the U.S. which we estimate to be around 200, we have a penetration today which is close to 70% in this segment, whereas strategically and historically we've always been weaker on the hospital segment.

As we have discussed in the past, we have focused our research and development and the...and through the strategic alliance with QIAGEN TB to develop a set of products that are actually targeted to support the company in deploying a strategy in the hospital segment.

And in order to do so not only products are needed but also an organization, so we are in the process of actually reorganizing the U.S. commercial sale force and split our organization into two, one that will continue to serve the segment where we play today and one dedicated to

the hospital market. We expect that this investment is going to hit starting from the Q4 and Q1 of next year, and we expect that by midyear we are going to have all the resources deployed and necessary to launch effectively all the products in this very relevant segment.

Today, the U.S. is doing well as you have seen from the quarterly result there has been an acceleration and the growth in the U.S. was 10%, and we have now CLIA x-D growth of over 15%, we have molecular that is growing over 30% and we have softer than expected Vitamin D decline. On Vitamin D again, I warn everybody to the fact that rating Vitamin D results on a quarterly basis is crazy, and it should not be done. A good quarter or a bad quarter for Vitamin D today means really nothing. I keep to maintain my skepticism over Vitamin D. As on the fact of...the fact that this product has been commoditized and pricing clearly has been affected over the last few years, and then volumes are support...the decline [ph] as an effect of the reimbursement policy. But also then done today in 2019 Vitamin D again was better than expected, as far as...as our projections are concerned.

If we leave the U.S. we are again, I think, we have said a good solid track record, a good product line and a phenomenal future in front of us having QuantiFERON and the rest of these 2 products. And we go to Europe. Europe is fine clearly is growing 9%. We all know that the European market today are not growing at all, if not they are contracting in certain geographies as an effect of higher pressure on pricing, as well as, consolidation of laboratory testing in large private players that are certainly better negotiators than hospital when it comes to contracting and pricing renewal, but notwithstanding that Europe is doing very good for us.

We certainly have Italy that is doing well. Italy is doing very well...because has been the market...clearly domestic market is where we launch the CLIA QuantiFERON, so it should be expected that Italy was over delivering at the beginning of this and we expect then certainly Italy to go back to a more moderate growth going forward once the first wave of customers have been hit by the QuantiFERON conversion and development of the QuantiFERON business.

Germany is accelerating in the quarter almost plus 6% and that's the result of the Siemens conversion. I think we did comment in the past that the Siemens conversion was softer at the beginning and that there is the result of the fact that customers are very busy and the conversion did not necessarily come up as a priority.

However since we are approaching the time when this product line is going to be officially discontinued and this will happen by the end of next year then certainly there is more urgency on customers to convert and we are seeing more conversions to the CLIA technology which certainly do benefit DiaSorin in 2 ways, one is from a margin point of view. Clearly we move from a distributed product which is to [indiscernible] Elisa to our manufactured product so it's positive. And the other one is the add-on [ph] business and the viability and the accessibility of new customers which is the strategic reason why we decided to buy these 9 product line from Siemens.

The only black eye we have in Europe is France and which is declining 4% and that's not unexpected. Lots of companies are not doing well on France and that's the result of the ongoing consolidation and price...and price situation in France. I don't expect this trend to change shortly because again its structural modern company specific and I think that we will need to learn to live with France which is not a contributor for a

while, us meaning as an industry until things will stabilize. In Europe we've seen this in the past. We saw Spain in great difficulties at the time of the 2010-2011 crisis situations, and then eventually Spain recovered and now is a positive contributor for the industry. So I believe France is going to go through a very similar cycle. But overall Europe is fine, it is certainly the first geography where we launched QuantiFERON with the satisfaction, and I continue to consider Europe as a stronghold of this organization.

Now, let's move to China, China is fine, the growth has been 6.6%, but CLIA sales actually grew 11%, and result...the 6.6% come from the fact that we still have residual ELISA revenues, which are flattish plus we do have instrument sales which do not...are not a positive contributor actually they are a negative contributor to the growth due to the raising rental versus instrument sales policy. But overall, China is fine, we end up 2019 installing over 100 XL, which is the yearly rate that we've been hitting over the last few years. So we continue to deploy our strategy which is a combination of me-too's and some specialties especially in an area...in the area of hypertension which has been a recent focus of the company with products approved and there is a vast market in China. So China is delivering as expected.

I wanted to comment on export, because it's clear now from few quarters that export is not where the company wanted to be. Let me just qualify definition on export, export for us is where we don't do business with our own commercial subsidiary. Over the last 10 years, we've consolidated a lot of this export business into direct subs and we open up our own commercial subsidiaries in those countries where we thought the geography, the country per se, was offering a strategic opportunity to the company to grow the business. Today, what we have left in export are

difficult geographies, which are mainly located in South America, where we operate through distribution except for Brazil and Mexico.

Africa, North Africa and the Middle East which is contagiously becoming more and more complicated, and then finally Asia Pacific. So and when it comes to Asia per se, Asia Pacific is doing fine for us. So those...all those economies that are actually somehow connected to China are doing fine. And we are not suffering there. We are suffering clearly North Africa is a problem and we are suffering in South America. And that's because in this export country which are left as export, I think there is a combination of 2 factors.

The first one is that, we don't sell specialties in this geography, certainly we sell commodities even on CLIA and we see that the commodity market is becoming...is very affected by price and by business conditions, you notice that our cash flow is extremely positive also because we manage very well our receivables. We have a DSO to the other group level which is outstanding in the industry. But this means that quite often we need to...we make decision in certain geographies not to operate because, we feel that the credit worthiness of some of the...of these opportunities is not there. And somehow we pay the price, but by the same token, we don't have problems with receivable and we have a very nice cash flow.

The second problem I'm referring to is that in certain...in some of these export geographies, I honestly believe that we do have an export network of distributors which belong to DiaSorin 1.0, which is...where the company was 10 years ago; some of the distributors are still with us. And I think that we want to be more strategic about this. We really need to make an investment in the distribution...in the distribution channel not meaning we don't go there, right, but we find different partners.

We went through a complete reorganization or exporting, now we have new people, we have delocalized some of these people in the geographies that matters especially in Asia Pacific in Singapore. And I believe that we're going to fix this...we're going to go through a fix, I believe next year is not going to be a draw any longer and not necessarily sure is going to be a positive contributor. But, I think it's not going to be...it's not going to be a problem for the company any longer.

Certainly, we spent a lot of time and a lot of resources in the domestic market, and again working in the U.S., working in Europe and China. We neglected some of the export and I think it's time to go back and rethink about the distribution network. So from just the product opportunity as said HCV very important approved by the FDA. Zika is very important and we should not surprise anybody the fact that we had Zika before and it was sold to the U.S. market under a special permit that the U.S. was granting companies because of the fact that there was a national emergency and no kits available.

Now, what the FDA is asking is to you know, go through official process we did. Today our major...we certainly...the vast majority of this business in the U.S. is left with the 2 big labs. And we are very well positioned in these labs with the Zika product. So we are now...we are there...there are 2 companies in the U.S. with FDA approved products. We are the only one we can luminescence through...the truth of the matter is that Zika...today Zika volumes are relatively small, the epidemic and emergency that was expected did not materialize, but certainly we are there to capture any business opportunity that may...they may present in the future.

Last but not least, I said is the QuantiFERON, for the QuantiFERON we are waiting for the FDA to come back and approve. We don't see...there

are no more comments, there are nothing...there is nothing on the studies that has being contested and I literally expect that the approval will come very, very shortly.

All that said, I'm going to leave the microphone to Mr. Pedron, he is going to take you through financial and then we start the Q&A session. PG.

PIERGIORGIO PEDRON:

Thank you, Carlo. Good afternoon and good morning everybody. In the next few minutes, I'm going to walk you through the financial performance of DiaSorin during the first nine months of 2019. And I will also make some remarks on the contribution of the third quarter. As usual, I would like to start with what I believe are the main highlights of the period. We closed September year-to-date '19 with an increasing revenues at constant exchange rate of 4.2%. Quarter 3 grew at constant exchange rate by 5.3%, mainly driven by the good performance of the geographies where we are direct. Carlo has already covered the drivers behind this variance.

Q3, '19 gross margin confirm the very good results achieved in H1, '19, with the ratio of the revenues of 68.5% improving versus last year by 140 basis points. This brings '19 year-to-date gross margin ratio at 69.1%, 110 basis points better than 2018. September year-to-date EBITDA at €209 million increase by 9.2% at constant exchange rate compared to the previous year.

EBITDA margin again at comparable the FX rate is 39.7% vis-à-vis 37.9% of the first nine months of 2018. The margin of the quarter at 39.9% is confirming the very good performance achieved in the first six months of the year.

Lastly, we keep maintaining our ability to generate a very healthy free cash flow €138 million in the first nine months of the year, vis-à-vis €101 million of the same period of 2018.

Let me please remind you, that the net financial position positive for €133 million has been negatively affected by the introduction of IFRS 16 which accounted for about €30 million.

Let me now please go through the main items of the P&L. September '19 year-to-date revenue is at €525 million grew by 6.3% or €31 million compared to last year. The growth at constant exchange rate is 4.2%. The strengthening of the U.S. dollar against the euro is the main reason behind these 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 last quarter of 2019, even if still positive for the group.

Gross Margin at €363 million grew by 8.1% compared to last year, closing the first nine months of 2017 with a ratio of revenues of 69.1%, 110 basis points better than 2018. Q3, '19 margin at 68.5% is better than Q3, '18 by 140 points...basis points.

This increase, both in the quarter and year-to-date is the result of the following three main drivers. One, a positive sales mix coming mainly from lower export markets and instrument revenues offset by a very good performance of our direct market and higher specialty test sales. This effect is particularly material in Q3 '19 where export markets sales are represented slightly less than 11% of total sales, compared to north of 13.5% of 2018.

The second element is 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 mention the shutdown of the Irish manufacturing site.

And last, lower royalties coming mainly from the fact that at the end of 2018, some patents on key raw material of our molecular kits have expired, this royalty upside has been more sensible in H1 '19.

Total year-to-date operating expenses at €193 million have increased by 6.7%, compared to last year. The growth at constant exchange rate is a touch above 4.5%. Year-to-date OPEX ratio of revenues is basically in line with last year at 36.5%. Q3 OPEX ratio is at 36.5% vis-à-vis 37.3% of Q3 '18. Year-to-date other operating expenses at €6 million are lower than 2018 by €1 million. The main reason of this difference is due to the fact that in 2018, we booked some legal expenses related to litigation with Meridian which has now been settled. Actually it was settled last year.

Please note that most of this variance has been recorded in Q3, because of what just described, the EBIT in the first 9 months of the year at €166 million or 31.5% of revenues as increased compared to last year by 10.9% or €16 million. The growth in the quarter has been €9 million or 20%.

September year-to-date net financial expenses are higher than 2018 by  $\[ \in \] 2018$  million. This difference as already said the last quarter is entirely due to the reevaluation at fair value of the participation in our Indian subsidiary booked in 2018, after the takeover of full control from the Indian partner. The year-to-date tax rate at 23% is substantial in line with 2018. 2019, year-to-date, net result at  $\[ \in \] 127$  million or 24.1% of revenues is higher than previous year by  $\[ \in \] 10$  million or 8.5%.

Lastly, September, year-to-date EBITDA at €209 million is better than in 2018 by €22 million or 11.7%. The variance at constant exchange rate is positive for 9.2%. 2019 year-to-date EBITDA ratio and revenues is at 39.8% at current exchange rate and 39.7% at constant exchange rate vis-à-vis 37.9% of last year.

The year-to-date improvement compared to last year is mainly driven by the higher gross margin, we just discussed about and by the application starting from 2019 of IFRS 16 which accounted for about €5 million in the first 9 months of the year.

Let me now close and move to the net financial position and free cash flow. We would close the period with a very positive net financial position of €133 million after the introduction of the just mentioned IFRS 16 which implied booking a financial liability for €30 million.

In the first 9 months of the year, the group generated a very healthy €138 million of free cash flow vis-à-vis €101 million of 2018 [ph], thus recording an increase of €37 million or 37%. This increase is the result of the better economic performance of the period and of a positive variance of the working capital, mainly driven by very good DSO coming from a favorable geographical sales mix, as we said less export sales and more sales in direct countries with lower payment terms such as U.S. and by a very, very disciplined collection policy.

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. 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 Maja Pataki of Kepler Cheuvreux. Please go ahead.

MAJA PATAKI:

Yes. Hi, good afternoon. I have 3 questions, please, if I may. Carlo, I would like to start with the latent TB approval delay in the U.S. at the Q2 call in August, you seemed to be fairly confident or very confident that the approval would come through shortly and you indicated that there was a 3 month timeline during which the FDA would have to approve the tests, which would have brought us to October. Now we're in November we don't have the test approved yet. Could you just tell us why there was this delay and what makes you so confident that we should see it in the coming weeks before year end?

Then the second question relates to your guidance, you're reiterating your full year guidance for 5% to 8% local currency growth, which would imply to meet the 8% you would have to have a very strong Q4 in the high-teens. Do you believe that you can achieve the 8 percentage points, and if, so, yes could you tell me what the potential drivers would be for that in Q4?

And then the last question relates to Quest and their streamlining the business to one supplier and to fairly upbeat comments by Siemens about potentially getting that contract. Could you tell us what is in your medium-term guidance i.e., if Quest were to move to Siemens and would

allocate the Vitamin D business also to Siemens, what impact would that have to your medium-term guidance? Thank you very much.

CARLO ROSA:

Okay. I'll take the first and last, and PG I think will take the second. So let me start with TB. You're right, I made a comment saying that the procedure is 180 days, which from the end of August is taking through to September...to November, sorry. So the FDA is on time, as far as that we know, and they have to approve it within that window. What I think it happened is that there has been an introduction at the FDA level in the last process of the review over 3 weeks window period, whereby there is a newly appointed commission. And don't ask me what the name is, but it's a procedure whereby all PMAs before getting approval or there is a further review by a commission that will fundamentally validate what the reviewer does.

And so, I believe, we enter into this phase and this is why we saw a delay over 3 weeks. The questions that we are getting...that we got out of it are very formal and not really of any substance in terms of the challenging clinical data and everything else, which would be the one...are the ones that usually require time extension. So that's why I'm saying Maja that, as far as, I am concerned, we are very, very close now to the approval and us and QIAGEN are gearing up in order to get the benefit from this. We...as far as marketing the product you are not allowed to do much with the exception in the U.S. So you're not allowed to provide pricing to customers but you're allowed to do some pre-marketing activities and evaluation, which we have certainly done. And this is why I expect that, as soon as, we do have the approval of the product, then we can hit the market quite rapidly, and I know, because of the...from the European experience that the conversion and business development activities are relatively fast when it comes to moving from an ancient ELISA to a much better fit, which is the CLIA LIAISON.

Now, let me comment on the Siemens call and Quest and all of that. Look, there is one thing that I guarantee...today, we sell 20 some products into Quest, and I guarantee you that all these products are going to be assigned to DiaSorin. Okay, with one exception which is Vitamin D? And I guarantee you that because first of the contracts, as far as, all the other products go into 2021, but second I also see that Quest has fundamentally made a decision, which is mainstream consolidation with one supplier and then you have a...your specialty supplier, and I feel very comfortable with the fact that Quest has chosen DiaSorin your specialty supplier. This is proven also by the fact that very recently we got awarded by their calprotectin business which is a specialty, is a multi-million dollar contract. So I have no problems with how we are positioned within Quest.

As far as Vitamin D is concerned, the main driver for this...for the main...for the selection of the mainstream supplier is the fact that Quest as you know, is building a new lab in Compton, which will be the one of the largest, I mean, the largest labs I believe in the U.S. They're going to consolidate in Compton some of their operations and it is fully automated. It's that...so we said for the...you said fundamentally for what they call Operation 2.0 of the future. And I honestly, I said Compton, but it's Clifton. And I honestly believe that Siemens has a good chance to get the business because of the fact...the relationship that they have, because of the fact that if you think about all the suppliers, some of those will be excluded because they are also supplying to a competitor lab.

So Siemens may have a very good shot at getting this. And I think that...if that happens it's certainly clear that Vitamin D falling into mainstream may follow that contract. However, I see that in order to then deploy, change all the suppliers because we're not talking about only Vitamin D and DiaSorin, we are talking about multiple suppliers, clinical

chemistry, and all that and make all the deployment of the telecast [ph], if they win and have all the lab ready, which by the way, the lab is not going to be ready until 2021, it's going to take time. So I'm a very pragmatic person. So in my own calculation I think that there is a chance that when it comes to Quest we may lose the Vitamin D. But I am quite confident that loss is going to be partially if not totally offset by the fact that we have been chosen as a good partner for specialties.

You also need to keep something in consideration. I cannot disclose but pricing...but when it comes to the standards pricing for Vitamin D, my eye is getting to a point where it is not even funny, because when you look at an overall bid for all the Quest business for immunoassay and clinical chemistry, then you go...there's no differentiation in terms of price [indiscernible]. So you can allocate to Vitamin D whatever you want, and it gets to a point where you really need to wonder if that business is still worth it or not.

One more comment, I think that I made...when this company made a decision. Fortunately long time ago to try to balance the exposure that we have in the commercial labs with a different strategy. And that decision was taken a while ago because when you do that you start first from product development and you start with getting a product registered and designing a system that fit that space. And it is very clear that when it comes to the U.S. where today we have an...or we have a beautiful business with a commercial labs, but we are overexposed, we need to move the needle toward the hospital strategy.

I continue to say QuantiFERON is a tremendous opportunity to move in that space alongside with all the gastroenterology assays that we have and that is the way to balance the exposure and guarantee that in the U.S. we will continue to see growth, because as I think we discussed during my presentation on the Analyst Day. Now, I see the future, I see polarization, I see Quest and LabCorp, they are going to win a good chunk of that market because they are set strategically to be able to be more efficient. Therefore, you need to be at Quest and LabCorp because they will continue to gain market share, but they are formidable negotiators and the price that you enjoy with these accounts unless you are a few specialist player. It's been, okay because they're very good negotiators and they have tremendous volumes that nobody else has.

So to make a long story short, in my pragmatic approach, I believe the Vitamin D is at risk. But I'm not losing the sleep, because I know that we have a slew of products with these specific big accounts that would provide us an opportunity to offset this loss if it comes, but I'm quite comfortable that is not going to come necessarily next year. This is how we see it.

PIERGIORGIO PEDRON: So I will take the second question, the one regarding 2019 guidance. Hi, Maja, Pedron here. So when we gave 2019 guidance, I believe we qualified the 5% to 8% range saying that we had a few moving parts, which were kind of difficult to forecast. One of them was the registration of latent tuberculosis in the U.S. which we know is the biggest market for this kind of test. And the other one, I don't know if you recall, was the big tender in the export market, in the Korea market, which we didn't know if we would have been awarded the tender or not. So considering the fact that latent tuberculosis is going to be registered very, very likely in November, so later than our original expectations and the South Korean tender is unlikely we'll get it, I think that we will be shooting for the lower range of the guidance. So I see very likely...more likely the 5% than

the...than being closer to the 8%.

MAJA PATAKI:

Perfect. Thank you very much for your clarification. Carlo, just to make sure I got you right. So you're saying there is a good chance that you might lose the Vitamin D business with Quest, but you are confident that you will be able to compensate for those lost sales with the specialty menu that you will continue to provide with Quest. Is that correct?

CARLO ROSA:

Maja, yes. You know me, I'm very...I'm pragmatic and I never look at the quarter and I look at the development of the business with an account. I believe...if I look in front of me the opportunity that menu provides a viability of TB, which is a significant business in the U.S. and in this big account. If I look at the other specialties that we have achieved with gastroenteric and so forth, I believe that we do have the possibility to offset that loss with more business coming from the other products we have. If you are now asking me about how is this going to play in the next 12 to 18 months, I have no idea because I don't know about the implementation of Siemens [technical difficulty] whoever is going to win, okay.

MAJA PATAKI: Perfect. Thank you.

CARLO ROSA: Thank you.

OPERATOR: The next question is from Catherine Tennyson of Bank of America.

Please go ahead.

CATHERINE TENNYSON: Hi, thank you for taking my questions. I just have two. My first one would be on China. Can you just give us some color how you think the sustainability of low double-digit organic growth is for your CLIA business is there as we look to 2020? And have you seen any changes in China in terms of market softness, as what your competitors have seen? And secondly, if I can ask on the rate of conversion from your Siemens

clients from ELISA to CLIA, have you seen any pick up in that in Q3 or Q4 or is it likely to still be a H1 issue for next year? Thank you.

CARLO ROSA:

Okay. Let me start from the easy one which is conversion. I have seen a pick-up for a very simple reason we communicated to lots of customers that the product is going to be cleared [ph] comes the end of...mid end of next year. And so even if they don't like it...they don't like to do conversion because they have plenty of things to do. And so today they have a product that is the ELISA, which is suboptimal but it's a product and if they are rethinking about the layout of the clinical chemistry, certainly this comes second, but they are forced to do it, so yes, I see...we will see a pickup in quarter 4 of the Siemens conversion.

The...now, let's talk about China softness. I was in China last week, so it's fresh in my mind. I think it is sustainable because the growth...the double-digit growth of our CLIA because it is driven fundamentally by 2 factors. One is that we...it's a market that is expanding and we continue to sell mainstream products in China. Now, the thyroid oncology, the stuff that interestingly enough is still growing for us 7% to 8% and this in a more mature market you can imagine, okay.

Then we have a traditional franchise we call legacy which is prenatal testing where we now have very significant market share and that, yes, is soft, it used to grow a lot and so 20% to 25%. Now, we are really...the growth is more correlated to the amount of newborns in China because it is prenatal testing. And so that depends on...it may be a good year and bad year, but fundamentally still it's not a drag, it's a product line that is growing 3%, 4%, 5%, but I consider that mature.

Then you can have a practical opportunity and a strategic opportunity. The practical opportunity which is tremendous is hepatitis because it's a big market in China. There are 4 companies with hepatitis products approved, with plenty of ELISA. We had the Beckman relationship, so that is tactically growing double-digit but it's not something...again that strategically is keeping me excited because I believe that as far as China is concerned, there are 3 strategic opportunities. One is to again move away from the high...the big hospital segment into the mid-size, small hospitals and this is LIAISON XS strategy. So it is driven by the system.

The second opportunity is the fact that being, I mean it is...China is becoming a mature market and when markets are becoming more mature, it is certainly clear that you have...they turn from mainstream only to mainstream plus specialties, and as we have enjoyed specialty...a specialty strategy in all the markets, we are going to enjoy this conversion in China which today is a very untapped opportunity. One of the first products we are using to test the market with is hypertension because hypertension is certainly an issue in China. There is nobody there. We have 2 tests approved and we are working with some of the local institution and opinion leader to educate physicians on the use of hypertension, so this is just an example of an opportunity that I see to finally the specialty market to develop.

Last but not least is QuantiFERON because today there is a very awkward situation in China where QuantiFERON is approved but it's used for active diagnostic and not for latent diagnostics and so with Cassia [ph] we are going through registration of the DiaSorin and their products with the latent claim. It is going to take 2 years. It is because of the classification of the product but then if you ask me what is going to be your mid and long-term growth strategy, the guarantee is 11%, that is the this mix of different products.

Now, last but not least, we commented I think in the previous...in some of the previous calls when we were talking about strategy, that in China we do have an Achilles heel and that is the fact that we are a pure importer, okay. And as a part of the strategy to set up a manufacturing site which we are working on and then become for mainstream products a local manufacturer. That is giving you advantage versus competition because then you are classified as local manufacturer and you apply to certain tenders what today you are excluded from. To make a long story short, I think it's sustainable; it's the combination of these facts to continue to grow China at double-digit as we have done in the past.

CATHERINE TENNYSON: Helpful. Thank you.

OPERATOR: The next question is from Scott Bardo of Berenberg. Please go ahead.

SCOTT BARDO:

Yes, thanks for taking my questions. First question, please, I wonder if you could talk a little bit about how the QuantiFERON-Tuberculosis collaboration is working in Europe. I think historically if I am not misquoting you, you had expressed an opinion of around 50% conversion of the tests, that's for conversion globally. I just wonder whether some of the early evidence in Europe is pointing towards that and/or a little bit ahead, a little bit below, if you could share some thoughts there, as well as how the LIAISON XS platform is initially performing in that market, that would be helpful, please.

Second question is just really following up from Maja's questions surrounding Quest, so I just want to make sure I understand your comments correctly, so you are suggesting that your confidence that you are the specialty immunoassay provider of choice over the coming periods because you are still entering into new specialty contracts on your LIAISON XL system and you are still shipping LIAISON XLs which is

evidenced your minds that you are a continued trusted partner and is that correct? Thank you.

CARLO ROSA:

Hi Scott, listen; let's talk about QuantiFERON and development. To me, there is a very crystal clear evidence to the fact that ELISA is not a viable technology, okay. It's complicated, even if you make an effort to automate as I think QIAGEN has done very well in some very large accounts because then you need to put lots of processors to handle the plate, but also to handle the tubes. I see that ELISA is unsustainable and to that extent, I think that the fact that bioMerieux is coming to the market with the VIDAS and certainly the VIDAS is a small system, so they are good...they are going after stand [ph] out markets and so forth, to smaller account. But, it's very clear that there is a lots of pressure to automate, okay. So evidence in Europe is that it's more...it's not a problem of the customer to convert, it was the fact that we had to work with QIAGEN and gear up our commercial organization and their commercial organization to work together to make sure they will do this in an orderly matter, right. And also we exploit the opportunity of going after the Oxford business; you have seen Oxford, they I think reporting yesterday. There is still a hefty...there is a good chuck of business that today is done by Oxford, I think roughly 80 million worldwide.

Certainly, there is...that business has a U.S. connotation now in the hands of Quest, and then it is more in Japan and China, still some business in Europe mainly in the UK and that business is where strategically us and QIAGEN see the opportunity to increase our overall combined market share, after certainly some of the cannibalization of...let me say, transformation of the existing QIAGEN business from ELISA to LIAISON has happened. And with mutual satisfaction, meaning that it's very clear that on the QIAGEN side it's a defensive move, but by the same token, it's also a move allow to do the testing better and enjoy in several

cases better pricing simply because customers are available to pay some more for automation when you provide automation and efficiency.

So, let us though remind you that when it comes to the U.S. our strategy in the U.S. is different from Europe and this is because of peculiarity of the U.S. market. The U.S. market is as usual, highly polarized meaning that you have a good chuck of business in the hands of a few commercial labs because of the fact in the U.S. as we saw with Vitamin D everything within USA starts from the commercial labs because in the periphery the volumes are too small, and especially if you have a ELISA that small accounts don't want to use, they send it out, right. So today, there is a duopoly or triopoly today in the U.S. of few large labs that which dominating testing. In the U.S. what we want to do is to go after hospital market and send out. And there is plenty of opportunity and financially it makes a ton of sense because the send-out cost in the case is very high, okay. So the European model and U.S. model are different, in Europe it was defensive posture, an opportunity to move exhausted customers from ELISA to QuantiFERON, in the U.S. it's market development going after send-out where you are actually taking existing business done in the commercial labs to begin and turn it into end user revenues, okay, just to make sure everybody understands the difference.

Access is very relevant in the U.S. in Phase II because the initial efforts is certainly is going to go...is to go after, what we call low hanging fruits, which are accounted, so they are using ELISA certain volumes and they are fed up with the technology and then you want to move to a new box. Bu it's a strategic certainly on the long-term to mid long-term to allow the development of the hospital strategy in QuantiFERON, that's certainly true.

As far as Quest is concerned, I think I... Scott, I think I exhausted this with my...let me repeat it once more. I believe that Quest will give a very clear indication that they are going through transformation and they are going through transformation in the way they intend to do business meaning that they are consolidating into a very large lab some of their operations, they are investing massively into automation. And when they do that, they need to tackle the mainstream. So, the issue I don't think has never been specialties because by definition of specialties stay out of that. Adding specialties to a mainstream line is adding an unneeded complexity, okay. Now, Vitamin D use to be a beautiful specialty as a mainstream, so it's very clear that Vitamin D will go on that line in my option, it's going to take time because it's going to be related to the deployment of the full line of whoever is going to win that bid, it's going to take a substitution of multiple suppliers with the...with a unique supplier. It's going to take a software infrastructure...it's going to take time, okay.

So if we lose Vitamin D, I would be very surprised if that is going to be a sudden death. I think it's going to be...there is going to be soft lending. And if I look at soft lending, which again, how long it's going to take, I don't know, because it depends on the deployment of who is going to win that bid. Then, I am asking myself what do I have in mind, what do I have today in my quiver to counter the loss. And I have stuff, I have specialties, I have TB, I have good stuff that I think encounter the business that I am going to be losing in...in their account, this is it.

**SCOTT BARDO:** 

Okay, very good. With that in mind, if we can just perhaps just talk highly level thoughts into next year and you've mentioned that your export business is a couple hundred percentage points drag on growth this year that you think you can, if you like quell next year, and you are launching your hepatitis products, you expect the QuantiFERON tuberculosis products approved in the U.S. where I am not sure if there is any tends-up

demand also if you want to share in some thoughts. But, at the same side, the Quest contract for Vitamin D which I think is due for when you are the end of this year, I think it's about 15 million or so, 2 percentage of revenues could add to the headwind. So, what I am trying to understand in the framework of the group where you have this mid to high-single digit and high level is 2020 shaping up to the...any different from that sort of trajectory that you have whatever, over the medium term that would be helpful?

CARLO ROSA:

Scott, I'll give you...I think they are interesting because you pretty much summed up by yourself what and how I see it. But, in order to be more specific, I believe that I wanted to see the...U.S. QuantiFERON to kick in, because that is what makes it or break it vis-à-vis the speed of growth because we'd be both, again, we have been discussing this for a long-time the U.S. strategy is a hospital strategy, the U.S. strategy is QuantiFERON and gastroenteric-driven and that is what guarantees the future both in the main geography, okay. So I am not referring just to be specific, it's not that I am doubting about the approval, I give the approval for granted, no problem. But, I want to see the product and the program hit the floor. The customers, us and QIAGEN working in sync to make this happen because what I saw in Europe is that you really have an acceleration of the project and a lot of success when the 2 companies are working like one in deploying all of this, okay. And we went through months where we had to gear up in Europe, we brought many, many countries together, it was a tremendous effort and still today we have weekly calls between the 2 companies to manage our business, U.S. is simpler because it's one geography, but it will take to bring everybody in sync and move on.

So, to make a long story short, I have no doubt strategically that we have all assets that are necessary to do, to deliver what we said we are going to deliver, okay. To give you more specificities about the good...the good,

the bad and the ugly, now whatever is going to be the reality of all of it, I think I need a little bit more time. So, we are going to talk about this in I think March and at that point we will have 2, 3 months under out best of QuantiFERON development in the U.S. and that's going to be more specific on the short-term. But, as far as mid-term is concerned, I am super fine.

SCOTT BARDO: Very good. Well, I will jump back in the queue. Thanks very much

indeed.

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

CARLO ROSA: Okay, operator. Thank you very much. Bye-bye.