DiaSorin S.p.A

"First Quarter 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 Quarter 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. Good afternoon and welcome to the conference call where we will be discussing the quarter 1 results. I will, as usual, first give some color and comments to the performance in the quarter. And then Mr. Pedron, our CFO, is going to go through the detailed numbers.

First, let me just start reminding that on June 10th, we are going to have our Investor Day, where we are going to present…where we're going to publish actually on June 10 the result, the plan for the next 3, 4 years. And then we're going to have the day after, on the 11th, we're going to have the Investor Day, where we're going to be discussing with the financial community the Plan. So it's a very important day for us because it's going to give everybody a taste of how the company sees the next 4 years.

Now let's go back to the quarter results. First, let me just summarize saying that the quarter is a good quarter and in terms of where we expected to be from a revenue point of view and we're going to discuss the performance. And it's actually above expectations as far as the profitability is concerned. In fact, you saw that in quarter 1, the EBITDA margin was very high. And I will explain how we got there. So let's start from the revenue.

And first I would like to go back to where I left everybody when we did comment about the year-end 2018 and guidance for 2019. And I said there are 5 points, 5 main business points that make 2019 a year we are going to have…our expectations in terms of our revenue growth can really vary depending on the outcome of some element. And I said, certainly the flu season is one.

The second one had to do with a very large tender in Korea for blood bank, where we are participating with Siemens.

The third element is Vitamin D and volumes growth or decline associated with the current situation in the U.S. with payers.

The fourth point has to do with contract renegotiation. Everybody knows that between end of '18 and '19, 3 main contracts were going to be expiring and renegotiated. One has been closed at the end of last year very successfully. And now we have 2 that will be discussed in 2019. And the last 5th point has to do with QuantiFERON approval in the U.S

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So I…let me just go one by one and give you an update on these 5 points, and then I will go back and comment on geographies.

So the first one with flu. Everybody saw that this has been a very mild flu season compared to last year. Actually, if I may say, this has been a flu season that is more back to where the flu season normally is. And in 2000 …last year between '17, '18 was a very strong flu season. Now for us, if you look at our numbers, without flu, the growth of the Group would have been over 4%. And the net effect of the flu, which is negative flu volume compared to last year, puts us behind €4 million to €5 million, and clearly this is quarter 1. So this has been a strong effect on the quarter result.

Again without that effect, the company, the rest of the business would have grown over 4%.

The second element has to do with a tender in Korea. Tender in Korea, we don't know anything…we said that we expect to hear news from Siemens around quarter 2, so nothing to report so far on the tender in Korea.

The third element is Vitamin D. Now as far as Vitamin D and volume, I think all of you have followed what Quest and LabCorp has been reporting about the effect of the payers and payers' policy vis-à-vis the Vitamin D volumes. Quarter 1, as far as the vitamin D volume is concerned, has been good. Meaning that we have seen in the quarter…we've not experienced a volume decline in the U.S. versus what we really saw in quarter 4. But I caution everybody to say that this doesn't mean anything. I think to really understand the effect of this change in policy of the payers' we need to wait until I believe we have more quarters under the belt. But this quarter has been good.

Let me also attract your attention to some of the comments that the big labs actually made on this, saying that they are going to get, and in some cases already got permission by the payers' now to go and try to get back the money so…from the patient itself. Without getting too technical on this, it means that if the test is ordered by the physician, if denied by the insurance company, then the lab has the right now to pursue the patient and get the money back from the patient. So in this sense this I think is alleviating some of the pressure, but again, very difficult to make projections. Let's leave with a good quarter 1 and see what happens going forward.

When it comes to the fourth element, which is contract renegotiation, again, no news. We expect the contract renegotiation to happen in the second part of the year.

Now when it comes to QuantiFERON, the fifth element. QuantiFERON in the U.S. So far we are on track. We received back from the FDA a letter with questions, we replied, letter, submitted to them. We don't expect more questions to come, so we are waiting to see when the approval will come.

Now I would like then to go back and discuss a little bit the geographies at this stage. And I would like to start with Europe. Now I'm going to make comments on Europe as I think I did last time on constant exchange rate and looking at the direct business, which is the relevant part of the European business. So Europe in Q1 continues to do extremely well. The growth has been 9% in Europe direct. And actually these are a remarkable results because as you well know, a lot…in a lot of countries the market is not growing. So it means that we are in fact getting market share from other companies. So it's a sound growth…it's not a growth driven by volume.

The exception, the positive exception is Italy, where the growth of the company has been outstanding. And this is certainly driven by a couple of elements. The first one is the fact that to the contrary of every other state in Europe, the Italian market is growing. It's a net result of a different attitude from the current government vis-à-vis public expenditure. So certainly healthcare and ourselves would benefit…will benefit from this. And also the fact that we have introduced QuantiFERON, certainly in our home market, so it is…Italy is going very well for the company and overall Europe is growing well for the company.

The second geography I would like to talk about is China. China did very well as it did also in Q4. So we grew 15% in China. Deployment of the strategy is okay. The move toward a different distribution network, which was achieved starting from last year, I think, is starting to bear some fruit. So China is sound and solid.

The third geography is the U.S. In the U.S., I think is…I need to comment the numbers separating the molecular business because again, as you know, the vast majority of our molecular business is in the U.S. and there is the geography where we felt the pain of the low flu season. Now if we look at the immunoassay business in the U.S., again taking away the molecular portion, the business grew 1%. It's a combination of, as usual, a good CLIA x-D and a decline in Vitamin D, which again is not necessarily driven by an outstanding volume decline, but is driven by a price reduction, which continues certainly to happen in this space. But the CLIA x-D is able to actually counter the decline of Vitamin D.

As far as the molecular business in the U.S., I think that we should look at the business without flu and with flu. If we look at the business without flu, there are two elements which are very relevant. Well, first the business itself is growing almost 11%, so it's doing fine. But last but not least, we were able to secure a very large contract with one of the major labs in the U.S. and this contract is going to be implemented through the year. And that this is going to certainly push our ex-flu business in the U.S. with molecular. With this laboratory…historically, Focus never had a lot of business because it was seen as a competitor belonging to Quest, and the fact that now with DiaSorin, that allowed to really get a partnership and business with molecular as well. So this is a very good news. And this will actually come from now on later in the year.

Now, let's go also…now let's talk about the 2 geographies where we have problems. The first one is Brazil. In fact, if you see South America. South America is not growing for us because Brazil is actually declining. But Brazil is declining for us for a reason. And the reason is that the government…everybody understands the current situation in Brazil. The government tenders are frozen. And when that happens in Brazil as it unfortunately happened to us in the past as well, there is a high risk of actually losing money in terms of having receivable not paid.

And so we made a conscientious decision to stay in Brazil on the safe side and to shy away from certain tenders and stay in the business, in the profitable business that generate money and that can be collected. And today in Brazil, we have a DSO of 70 days, which is outstanding solid business, but certainly at a price, meaning that certain opportunities for the time being we decided not to pursue. Just waiting to see what happens to the country and how the government is going to shape up and be stabilized.

The second one is export, which is something that we put on the table already in the last quarter. And specifically it's not export in all areas because South America is relatively stable and in Asia Pacific, it's growing. It has to do with the Middle East where we had good business. And this business in certain countries is annulled, is frozen. And again it's a combination of 2 things,: company policy, because we don't want to run risk of building business on quicksand. And the other one on the fact that certain government tenders as for example, it happened in Egypt where we had a good presence…at this point, they are annulled or they have been postponed later in the year.

So overall, I would summarize this saying the number, the revenue growth is as expected. The flu…the flu season was slow and we felt, certainly in

quarter 1, the underlying business is growing as expected. And in the main geographies where we launched already new products, including QuantiFERON, things are going very well for the company.

At this point, I would leave the podium to the CFO, Mr. Pedron. We're going to go through the detailed financial numbers and then we're going to take questions.

PIERGIORGIO PEDRON: Thank you, Carlo, and good afternoon, everybody. In the next few minutes, I'm going to walk you through the financial performance of DiaSorin during the first quarter of 2019. As usual, I would like to start with what I believe are the main highlights of the period.

So we closed the quarter with an increase in revenues of 3.8% or about €6 million. The increase at constant exchange rate is 1.4%. As just discussed, during Q4…now and over our Q4 call, we were expecting a growth skewed towards the second part of the year. And Carlo has already covered the relevant business drivers behind this result. Gross margin was particularly good in the period with a ratio of revenues of 69.5% vis-à-vis 67.6% of Q1 2018. This is one of the best performance we have had over the past last quarters. Net result at €40 million or almost 24% of revenues, records an increase compared to 2018 of 5.4% or €2 million. Lastly, we keep confirming our ability to generate a very healthy free cash flow, €36 million in the quarter with an increase compared to 2018 of €8 million or 28%.

Let me now go through the main items of the P&L. Q1 revenues at €171 million grew by 3.8% or €6 million compared to last year. The growth at constant rate is 1.4%. The strengthening of the US dollar against the euro is the main reason behind this FX tailwind. Considering where the U.S.

dollar is trending now compared to 2018, we should be able to enjoy some more FX tailwind also in quarter 2.

Gross profit at €119 million grew by 6.7% compared to last year, closing the first quarter with a very high ratio of revenues of 69.5% compared to 67.6% of 2018. This performance is the result of the following main drivers. A positive sales mix coming from lower revenues in export market covered by our network of distributors, which benefit from lower prices compared to final customers in countries where we are direct. Better manufacturing margin and lower distribution expenses coming from the several cost reductions initiatives started in the last couple of years.

And just to remind one of them, please let me mention the divestiture of the Irish manufacturing site we discussed about last year. And finally, 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.

Total operating expenses at €63 million or 37.1% of revenues have increased by 8.4% compared to last year. The growth at constant exchange rate is just short of 6%. OPEX ratio of our revenues is 37.1% vis-à-vis 35.5% of 2018. And this is somehow penalized by revenue growth, which as discussed in 2019 is expected to be skewed toward the second part of the year. Other operating expenses at €2 million are just a touch higher than last year. As a result of what was just described, Q1 '19 EBIT at €53 million or 31% of revenues has increased compared to 2018 by 4.4% or €2 million.

The tax rate at 23% is substantially in line with 2018, which closed at 23%. 2019 net results at €40 million or 23.7% of revenue is higher than previous year by €2 million or 5.4%. This increase is the result of what is

described so far and of lower net financial expenses by €0.6 million, mostly driven by a reduction in FX losses and by higher interest income.

Lastly, quarter 1 EBITDA at €68 million is better than last year by €4 million or 6.6%. The variance at constant exchange rate is positive by 3.4%. Q1 '19 EBITDA ratio on revenues is 39.6% at current exchange rate and 39.3% at constant exchange rate vis-à-vis 38.5% of 2018. The improvement compared to last year is mainly driven by the higher gross margin we just covered and by the application, starting from 2019, of the International Financial Reporting Standard 16, which accounted for just a touch above €1 million in the quarter.

Let me please remind you that IFRS 16 introduced an accounting criteria based on the so-called right-of-use of a good. Therefore, there will be just a single methodology for the lessee to account for goods in leasing, which is all assets. Also in case of operating leases, it will have to be booked as fixed assets against the corresponding financial liability which translated for the P&L impact basically means lower rental fee on our OPEX and more depreciation. As we will see shortly, likewise this has had an accounting impact also on the net financial position of the Group. So let me now pass to the net financial position of the Group and the free cash flow.

We closed the period with a positive net financial position of €75 million after the introduction of the just mentioned IFRS 16, which implied at the booking of a financial liability of about €32 million. In Q1 '19, the Group generated a healthy €36 million free cash flow vis-à-vis €28 million of 2018, therefore recording an increase of €8 million or 28%.

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 this 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: Excise me; this is the Chorus Call conference operator. We will now begin the question and answer session. The first question is from Romain Zana with Exane BNP Paribas. Please go ahead.

ROMAIN ZANA: Hello, thanks for taking my question. I have 3 please. The first one coming back to your result in Europe is there a specific reason that could explain an acceleration of market share gains in this region in immunoassay such as more lab consolidation, squeezing smaller competitors for example. I would be happy to have more color on that.

Second question is regarding your full year guidance. Thank you again for the color you gave on the different moving factors. It however implies a material acceleration on sales but rather cautious margin development given the very solid start. So is that fair to assume that the incremental revenues expected will come from lower margin products origin?

And last question quickly, quick. Can we have a clear picture of the level of QuantiFERON-TB sales achieved in Europe this quarter? Thank you.

CARLO ROSA: Yes, Romain. Look, I start from…I don't know which is to your third question. We are not going to make…give any data on QuantiFERON, also because as said, this is today a QIAGEN product; it's an alliance with QIAGEN. And I think that when it comes, which is very relevant, is what

QIAGEN says about market development, market growth and so forth. So you have to actually talk to them to understand dynamics in the European market. The only comment I'll give you is qualitative, which is the 2 companies are working very well together in Europe, which is remarkable. And…but more than anything, I see the two companies are anxiously waiting for the U.S. approval because we both see strategically in the U.S. the tremendous opportunity through the viability of the system on a closed system to take it and decentralize it, because today, a very good chunk of this business sits in very large labs in the U.S. And so this is what I can say about the QuantiFERON.

On the first one, and then I think PG is going to take the second question. Look, I think Europe…we've been investing significantly in Europe. And I consider an investment, the Siemens acquisition because we broadened customer base and certainly new products including QuantiFERON that has been launched already in Europe for regulatory reasons. So I believe that, and this is third element, which I think you actually pointed very well, but this is something we have seen also in the past.

Consolidation, when consolidation happens, usually it's good for DiaSorin because what really consolidation does is it's taking away specialties in volumes to certain labs, where usually DiaSorin is or now can get inside because the level of specialty is going high and even smaller lab that although are consolidators, now enough volume to consider specialties. And this is certainly true for France. In the past this has happened with…after the [indiscernible] decree and the consolidation of big labs, all small labs and small private labs, we have seen positive affect there. Certainly, we are taking away market share because a lot of these products, they pretty much follow market growth and market dynamics vis-à-vis volume. And we have taken market share in this case by…from older technologies that are slowly, slowly disappearing.

Now when it comes to the second question, PG, you want to answer the second one?

PIERGIORGIO PEDRON: Yes, absolutely, the question about margins. So we closed last year with an EBITDA margin of 38.2%. The first quarter was a 39.6%. One impact which is a kind of one-off is the lower sales in the export market, which as I said are characterized by lower prices, which we think is not going to be there in the following few quarters. As soon as QuantiFERON sales will pick up also in the United States, we will have, as I believe we discussed, to pay royalties to QIAGEN, which somehow will impact our gross margin. At the same time, we are having very good manufacturing efficiencies.

So all in all, all compounded, I believe that I'm not…the guidance of maintaining the same EBITDA margin of last year. Once we incorporate the IFRS 16, it means that we will be more close to the 39% mark rather than the 38.2% we had in 2018. So said in different words, I believe with some minor ups and valleys, I'm not expecting major variation and we will be close to where we set our guidance.

ROMAIN ZANA: Okay. Very clear, thank you. And just if I can have a very quick follow-up, what was the organic growth on EBITDA? It was pure, I mean at the constant exchange rate growth was equal to organic this quarter?

CARLO ROSA: ELISA is ups and downs. So now it's a basket where everything is inside, so don't take that as meaningful.

ROMAIN ZANA: Thank you.

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

MAJA PATAKI: Yes, thanks for taking my question. I would like to start with a financial question. So just to clarify that your EBITDA margin guidance is not including the IFRS impact? So basically we really look at what is reported last year, then we should add on the IFRS impact to get to the kind of margin that you're expecting, and of course, the FX? That would be the first question.

Second question, Carlo, you stated that you won a bigger contract in the molecular business. Can you confirm whether this is part of your…if this is part of the guidance that you have stated for the full year? And is there any chance that you could give us a bit of an indication how big that contract could potentially be?

And then lastly, I was just wondering, QIAGEN has been quite vocal about competition entering the market when talking to investors. And there has been…there has been [indiscernible] to come in 12 months time. Of course, you have expected competition. You said it all along from the beginning that you don't want one trick pony. That's why your talk is also on tick disease or tick-borne test, but competition has also stepped up there. Where do you see the future of your partnership with QIAGEN? And has anything changed in your playbook? Thank you.

CARLO ROSA: Okay, I will take the QIAGEN question, and then I think PG is going to go through the rest. Look…and also we cover the contract. As far as QIAGEN is concerned and competition, I think that as it happened before, Vitamin D and HPV, I mean you can write a book on this one. It's very obvious that when a specialty becomes a high volume product, that will attract competition. In this specific case, I believe that QIAGEN did a

phenomenal work in developing the brand to the contrary of the HPV because don't forget, they have been the ones employing over 100 people in the market. I think 70 of which alone in the U.S. going and visiting physicians, and promoting with physicians the switch from tick to from…sorry to the Mantoux test, skin test, to the blood test.

So my take on this is, yes, competition will come. I'm not really sure if it is going to be bioMérieux or not. BioMérieux…if it is bioMérieux, bioMérieux has a small platform in immunoassay. And so probably bioMérieux may go after decentralization. I don't know, but that, that market is primarily a U.S. market, so you need to add the time it takes to register the product. So to be honest with you, for me competition is a given here. And this why we are eagerly pursuing registration of this product and collaboration in Europe because what is very relevant for both companies is that as soon as competition shows up, we pretty match are able to defend the existing QIAGEN business as a combination of long-term contract that they have plus the dissemination of the product, of the testing on our platforms.

Now as far as tick is concerned and Lyme disease, look, it was supposed to be super secret until it was actually published in a German newspaper. So yes, indeed, we are working on tick. And what we are understanding…and this is what I'm saying, these between the two companies is more than [technical difficulty] on the LIAISON platform. Is really is a collaboration to understand how we can explore it, together this space.

And the Lyme disease is a perfect example where there is technology that is coming from them, which has to do with the selection of the peptides that are necessary for this stimulation. And the fact that we own today the Lyme disease market, I mean, I think we have 50%, 60% market share

with the current IgG and IgM. And the algorithm that we're going to be promoting is an algorithm that is going to take IgG, IgM and T-cell together. So by the way, there is plenty of clinical need. If you should really follow, especially what's coming from the U.S., the NIH and lots of other public institutions in the U.S. have put out a call for better technology for Lyme disease.

So to make a long story short, we are actually doing clinical studies together, and we hope that by year-end, we're going to have news in terms of product viability, product reliability, improvement to the clinical and so forth. And again, this is telling you the 2 companies are working together on a program because we believe that QuantiFERON is very powerful in T-cells, very powerful. And TB is just the beginning of the story. In doing so, I believe QIAGEN has developed a know-how that is not trivial to reproduce. So it's not like Vitamin D or HPV, where making the product was relatively simple, and in fact, eventually competition caught up. In this case, there is a lot of know-how, but the know-how is on the [2] peptide selection and so forth, okay.

Now, as far as the contract is concerned, look, yes we did in fact expect to have a contribution in 2019 for this contract. What we…the problem usually with these very, very large labs, what you have is how long does it take for the implementation because it's not a contract where you gain one product. It's a contract in molecular where you gain many, many different products. So the uncertainty there is the…what's going to be the contribution this year versus the annualized value which we know that we're sure we're going to get certainly in next year and 2020. So this is as much as I can say about this. PG…

PIERGIORGIO PEDRON: Hello, Maja. Going back to the margin question, you have it right, yes. In 2018, the EBITDA margin was at 38.2%. When we said that we confirm

the guidance, the EBITDA margin of 2018, once you add up the IFRS factor let me say, we should be just south to 39%. So it is going to be a bit higher than the 2018 because of this accounting effect.

MAJA PATAKI: That's brilliant. And Carlo, I'm sorry, I know you have elaborated a lot, but can I just follow-up. From your statement where you said the primary market for TB is the U.S., and it takes quite some time to establish or to get a test to the market. Shall I read into that comment that if you expect competition to come, you don't expect it to come within the next 12 months?

CARLO ROSA: I wish I had the crystal ball, which I don't, but I don't honestly expect competition to come in the next 12 months because it takes time also to validate technology and to validate the test.

QIAGEN has 15 years of data supporting their TB. So not that simple. Again, this is not Vitamin D, where at a certain point you know they develop an assay and then that assay from a quality perspective very rapidly was adopted. And also clinically speaking, Vitamin D has a certain clinical utilization, but latent TB is a different ball game. So I think it's going to be…certainly competition is going to be there. Certainly, we're working together to fend it off. But I think it's going to be more complicated to take business away from QIAGEN.

MAJA PATAKI: Brilliant. Thanks so much.

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

SCOTT BARDO: Hi, thanks guys. Several questions, I'll start with a few. Just firstly on the U.S. market. I think you highlighted that Vitamin D was actually slightly ahead of your expectations, but with that said, I think you're still posting a

broadly flattish, I mean diagnostic performance in North America. So I wonder if you could talk a little bit as to what is required and needed to really get the U.S. CLIA business moving. And why it's not doing so currently. That would be question number one, please.

The second question, more of a bigger topic question. Carlo, I think you mentioned that we're going to have new midterm targets coming from the company on June 10. But in the same side you talked to a couple of relatively significant contracts that you're negotiating in the U.S., the won't be struck before June 10. So the question is, how do we have comfort with that the target you set on June 10th are relevant and valid in the absence of contract negotiation that you're looking to conclude by year-end? So they are the first 2 and I've got a follow up. Thanks.

CARLO ROSA: Okay, Scott. Let me talk about the U.S. In the U.S., DiaSorin I think has been discussed many times as a business which is split between very large labs. And I'm not only mentioning Quest LabCorp, but [indiscernible] BioReference, that segment, which does represent a good chunk of this business. And then we have the hospital business. The Achilles heel has always been for us this polarization, meaning that we were extremely good in developing the big lab business.

And the big lab business…it's relatively easier to develop because you pretty much talk to one entity, you take care of one group. When you get it, you get a lot of business. When you lose it, you lose a lot of business. And you always lose on price every time you renegotiate. But by the same token, you also follow their trend in terms of consolidation, them buying business; your volume grows 1% to 2% per year. So that's the business you're in. Today, if you think about it, that business actually dominates and drives our performance in the U.S.

Now we have discussed a few times that what we have to do is to develop also the other side of the business, which the hospital market. But to get to the hospital market, we said we need to have 2 things. We need to have a certain degree of specialty products and we also need to…sorry, 3 elements, we need to get contracts with IHNs, IDNs, and then you need to get it right? Now we have the catchy [ph] products. And the catchy products, as we have discussed many times, we have actually 3 out of 4 for that market. We have PCT. We have calprotectin. We have H pylori stool and we're waiting for the fourth one, which is the TB. That plus the viability of the LIAISON XS, the LIAISON XL and the LIAISON XS, is actually opening the possibility now of DiaSorin to go to that market. Because these are assays that today are actually sent out, and they are sent out because it's complicated…it's ELISA, even for QuantiFERON, it's an ELISA technology. And the viability now of an important assay, an assay that makes…that is used in good volumes. And where everybody makes money because then a reimbursement for this assay is very good. It's making now this strategy viable.

Okay, we've been working at this in terms of developing products and bringing those to U.S., exactly for that reason. Then certainly we will need to address the problem of and resources in terms of how we are going to be reaching that market, which is you know, we've actually met 1,100 hospitals that today are actually interested in these products. The…being with QIAGEN certainly helps because a chunk of these hospitals today are actually…are already doing ELISA. And so having access to that market with…with a closed system helps. But certainly, we also need to develop the other side of the market, which is what…which is the send out hospital chains that don't do it and send it out. It…again, primarily for technology reasons, and now they're going to be available to do it.

So long story short, that 1% growth that you see today is a combination historically of this beautiful…this beauty queen Vitamin D that is still generating a lot of profit but going down. And our CLIA x-D that now developed to a point where it it's able actually to mitigate the decline of Vitamin D. But the expansion can only, only happen if we're going to be able to go from that segment to a different segment as we have, I think, discussed a few times. And now we have the tools. These programs require products and registration that takes years to get, and we are almost to the end of it. QuantiFERON is literally months away from approval, so we were very confident about that, but that strategically it is what it takes. By the same token, I don't know if you noticed, but in Q1 we also launched another very interesting assay which is Elastase, which is which is completing the package of calprotectin plus Elastase for stool testing. So we really have a menu that now is very hospital driven. Scott, can you remind me your second question.

SCOTT BARDO: Yes, thanks for the very comprehensive answer. So the second question was, how are you going to provide midterm guidance when you haven't got a contract struck?

CARLO ROSA: Because we…you're talking about…yes, we're going to provide a guidance for…but now you're talking about the discussion about the 4 Years Plan. The 4 Years Plan, look, in the 4 Years Plan, we're going to make certain assumptions and…but in the 4 Years Plan it's a time frame where are you going to a lot of elements, very positive elements. Again the QuantiFERON full development, the Beckman launch in the U.S. with hepatitis, the beginning of the PL [ph] strategy, the hospital strategy in the U.S. So let me say that the good thing about this plan is that it completely dilutes out the effect of Vitamin D, which is certainly what we've been doing. And now already Vitamin D today represents a relatively small portion of our business, but you will see by 2022, this company is going to

be not depending at all by Vitamin D. So in that sense, I think we'll be able to give an indication of what we're going to do even if we put at risk some of the Vitamin D contracts and certainly, that is going to be part of a range that we are going to provide in terms of guidance. But losing one contract now is going to eventually or having to concede on price is going to affect only one year, but doesn't affect pretty much the expectation of growth of this company over the next four.

SCOTT BARDO: Great, thank you. And last follow-up question from me please. It's my understanding that you have got a relatively big launch event for LIAISON XS in Europe coming up. I just wonder if you could talk a little bit as to how important that event is and how you can gauge that as…or use that as a barometer for success for LIAISON XS? Maybe just touch a little bit…you talked on bioMérieux earlier on, but can you just help explain why is LIAISON XL different from other bench top type immunoassay systems, like the VIDAS for example, if you could just give us some feeling as to the quality and differentiation of the product?

CARLO ROSA: Yes, look, the launch actually is not far away. It's going to be on Tuesday. Next week we have over…almost 700 customers coming from all across the world, coming to Torino. And…but really, that event is actually more than LIAISON XS. It is to really explain to these people what's the difference between a specialist and one of the big top 3 companies, so reminding them that what we have in the quiver in terms of new products, innovation and content and continuing to remind everybody that if you want full automation, efficiency in 20-meter line, you go to Roche and go to Siemens and this is their address. But if you want content innovation, new products and new products where especially in certain geographies, you could make good money out of it, DiaSorin is your partner. So that's the theme.

As part of this, we launched LIAISON XS. And LIAISON XS compared to the VIDAS is…well, first its 25 years later because the VIDAS was launched very successfully many, many years ago. Second, it's a different segment because even the VIDAS 3 is a much smaller box than the LIAISON XS. And third, we position the LIAISON XS now as the system that allows us to push through the, what I call or what the business calls the hub and spoke. So now in a lot of situations and this is certainly true in the U.S. with this…with IDNs and IHNs and hospital groups, you have a core lab where everything goes and then you have, in the periphery, you have clinics and the smaller labs.

And now we will be able again to go there, to go to this kind of decentralization and say, core lab you can use us but you can decentralize some of the specialties if you want to using the LIAISON XS into your clinics, okay. So that…but let's not anticipate too much, otherwise what am I going to say on Tuesday? So allow me some suspense.

SCOTT BARDO: Alright, very good. Thanks very much.

CARLO ROSA: Thank you.

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

MAJA PATAKI: Yes, sorry, I was on mute. Just a quick question Carlo, on Lyme disease. Currently the test market isn't really that favored because of the shortcomings of the test. What do you think the underlying market potential could be once you have a test in the market that is reliable? Thank you.

CARLO ROSA: Let me just give you one number because that's…in Europe, there are 5 million, 5 million tests which are done annually with IgG and IgM, 5 million. In the U.S. today, there are 300,000 cases which are actually diagnosed every year, but not me, but the NIH is estimating that, that represents only 15% of the real cases, okay? And this explains why it is a real issue these days. And what I find very interesting Maja is that…and try it yourself, every time we go to New York and I have meeting with investors and you talk about Lyme disease, most of these people have it. Because it's on the East Coast, in the Appalachian region, in the East Coast and Midwest. This is a chronic disease, okay? So today again, just to give you a number, 5 million tests done on IgG and IgM in Europe. And probably 3 million, 4 million tests which are today done in the U.S. That's the current market of…that is using our test, which is the only thing that is out there…its immunoglobulin determination.

And we believe that the T-cell is not going to necessarily kill that business because what we see is that in order to get early in the infection diagnosis, you use combination of the 2, which is going to be very interesting. And the gamble also…which again has to be proven because you need to finish tick [ph] studies, is that T-cells can be an indication, or declining T-cells, it can be an indication of effectiveness of treatment. The treatment is usually relatively simple, it's done with antibiotics, but there is no way to measure whether…the effectiveness of that treatment. So it is very interesting. It is a very interesting field and QIAGEN has been working on this for many years because, again, lots of know-how. And I think that now we are coming to a point where we may have very interesting products in the following year.

MAJA PATAKI: And I believe you once mentioned that there the profit share would be more balanced compared to the…to the TB test, is that correct?

CARLO ROSA: Well, I said maybe something a little different. I said that TB is 100% franchise of QIAGEN. [Indiscernible] to them, they develop it and we are their automation partner and we are rewarded as their automation partner. Which is very interesting reward, but certainly it's…the vast majority of the profit goes to QIAGEN as it should. When it comes to this application, where now we are now in the process where we collaborate for the validation, the R&D and so forth, certainly the reward is going to be different. But by the same token also, there is a cost associated with this is split by the 2 companies.

MAJA PATAKI: Okay, thank you.

CARLO ROSA: You're welcome. Thank you, operator.

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