

DiaSorin SpA

"Third Quarter 2018 Results Conference Call"

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MODERATOR: 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 Third Quarter 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: Thank you operator. Ladies and gentlemen, good afternoon and welcome to our nine-month third quarter conference call. I will start as usual, commenting revenues and I will make my initial remarks at constant exchange rate since as you know, the currency fluctuation had a relevant impact on our business in the first nine months of 2018. Moreover let me remind you that the performance which has been registered this year includes the positive contribution from the fact that we had nine months of revenues coming from the Siemens Elisa business, which was acquired in September 2017.

So at the group level, revenue grew by 9.1% in the first nine months as a result of the solid sales performance of our CLIA tests, net of Vitamin D, and the ELISA Business, which has been acquired by Siemens. Now this positive trend of the CLIA Ex D was partially mitigated by some negative trends that we...I think we have already discussed in previous calls. One is the Vitamin D volume decline, mainly in the US market as a consequence of the change in reimbursement policies by some insurers and a slowdown in the revenues of the Murex ELISA business in certain geographies mainly in distribution and in Brazil. This is associated to two events, delay of certain large tenders in one side, and as far as Brazil is concerned affected some of the distributors supplying public tenders in Brazil had issues of credit collection and therefore as a consequence we have frozen some of these distributors waiting for them to address the problem with the government and so we have actually stopped shipping some of these ELISA to these distributors.

Now let's talk about Vitamin D. As far as Vitamin D is concerned, as I already commented in the last financial conference call in August, starting from Q2 this year, we have seen a change in pace mainly due to a recent policy change with one insurance company in the US market. Let me remind you that when we experience on the market a change in the reimbursement policy, we also usually see a reduction of prescription from position which is then translated in lower volumes in a period of twelve to eighteen months and Australia has experienced something similar two years ago. And this is certainly related to the fact that doctors are recommended in order to test or to limit testing of Vitamin D compared to what they used to do when these measures were not in place.

We have no visibility at this point on this trend. We are starting to acquire some visibility certainly in the last month or so and as we have discussed previously our current, what we see currently in the US market is that we expect that the Vitamin D volume may decline up to 18%, 20% over the next twelve to eighteen months but it's a matter of just waiting and seeing what was their reaction in the market.

Now let's talk about the other geographies and let's start about Europe. When it comes to Europe with a solid growth 14% in the first nine months, Europe proved once again to be a strong contributor to our Group revenues and this is certainly thanks to the vast installed base, the availability of all the products in this region. As far as the fact that we have initiated the sales of Quantiferon certainly not in Q3 but we've initiated a commercialization of the product in respect to see benefits starting from Q4. Now specifically Italy grew by 9%, France grew by 16% it means that in some very key geographies the business is certainly moving fast. Germany grew 23% certainly this is related mainly to the fact that a lot of Siemens additional business was added in this geography.

We have inherited through Siemens roughly 800 accounts throughout Europe, of which 60% were in German speaking countries, and we are working on the conversion of these accounts from ELISA to LIAISON. We have three years to accomplish conversion. Roughly 10% of the accounts have been already converted and we have 50% of the accounts in the pipeline, so we expect roughly 50% conversion by the end of 2019. The said ELISA business is flat, the Siemens business we inherited net of conversion. Now let's talk about North America. Certainly as we discussed before, these geographies where we are experiencing the Vitamin D issue, and I am not going to talk about this any longer, but by the same token we had a continuous growth of CLIA EX D with a growing installed base in the hospital and midsize labs of the LIAISON XL. And the net-net of the decline of Vitamin D but the increase of revenues of CLIA x-D pretty much flattens out in this geography. So the growth of the Ex D is able to counterbalance the decline of the...but overall the US is flat.

We have in the US the good news is that we were able to sign an agreement with Meridian and this we got the approval by the FDA of H. pylori products and as a consequence of that we have launched recently this assay in the US in conjunction with Meridian to go and rapidly convert all the existing customers based on Meridian from aging ELISA to the LIAISON version of the product. As far as Asia Pacific is concerned grew...this region grew 16% in the first nine months and certainly the driver is China is CLIA ex D in China which is growing strongly. We are talking about 16% growth of CLIA ex D, so CLIA overall because also Vitamin D is growing strongly in China.

And this trend is consistent with what we have announced in the last conference call, so please consider as we have discussed before that by the same talk in changing business model where we don't sell instrument to

distributors any longer but we try to place a ready rental to drive placements into the Class 2 market we have decreased in instrument revenues, it's where revenues typically for DiaSorin clearly bears much lower profitability this is a master for us because it's the only way to control actually the shift of focus obviously of course, in China from Class 3 to Class 2. But overall business...the underlying business again CLIA does benefit from it as I said growth of 16%.

Now let's talk about the 2018 guidance, so we confirm our revenue growth at 9% at constant exchange rate and EBITDA growth at 12%. However, we would like to underline a couple of aspects of the business which have to do with the fact that in Quarter 4 there are two events that may shift revenues from one quarter to the other, the first one is Iran and it has to do with the fact that for us Iran is a very relevant geography and recently, actually yesterday a series of measures have been published by the US government and so we need to understand how to continue to supply this market and through which bank system we can continue to operate since as you know, a lot of international banks actually stopped operating in Iran.

And the second one is a very large tender some of which have been...which entails a chunk of instrumentation some of which have been shipped in Q3 but there is a large installment that has to happen and we forecast to have it made in Q4, but clearly since it is a lot of instrumentation we need to understand when that...if that can be fully completed in Quarter 4.

Now before giving the microphone to Mr. Pedron I would like to conclude my comment with a couple of remarks. First one is to do with new products. We have launched so far four CLIA tests and we have one additional in the pipeline and which we believe we are going to launch in

Q4 and then six new molecular products. So, so far so good in terms of continuing the effort of delivering new products to the market.

And talking about business development, we as you know, have provided a lots of color to different projects. The one that I would like to stress is QIAGEN and the collaboration about it. We have successfully launched that in Europe and that actually happened in...at the end of September so we are today engaged in the initial conversion of customers together with QIAGEN from ELISA to the LIAISON version. I know [indiscernible] did provide colors and comments during his Q3 conference call, so I actually invite you to go and check what he said. Things are going well and I have seen the two companies are now working together to enlarge the scope of the collaboration and add more content to this line which we deem as strategic. And we have also been strategic to enlarge mainly viability on the LIAISON system with QuantiFERON application and it has been made public that the next in line for us to align this product where we are currently running preclinical testing to verify claims and applicability but fundamentally two companies are aligned in terms of dedicating R&D mainly in an effort to bring forward the new application on the LIAISON system.

Now I would actually give the microphone to Mr. Pedron who is going to take you through the numbers and then we are going to take questions. Thank you.

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 nine months of 2018, and we will also make some remarks on the contribution of the third quarter. So that as usual I would like to start with what I believe at the main highlights of the period. The strengthening of the euro against all the currencies in which we

operate has generated some not a board effects headwind on revenues during this first nine months of the year. Almost €18 million even if as expected the impact has been negligible in quarter three compared to half one. This variance has been mainly driven by two currencies, the US dollar which depreciated by 7% and the [indiscernible] minus 22% year-to-date. Considering the US trend in 2017 and where we are now I think it is fair to say that also in Q4 like in Q3 we should not expect material effects headwind.

Moving to the second point we close September 2018 with increasing revenues at constant exchange rate of 9.1% or almost €43 million whereas the growth in the quarter has been 9.5%. September year-to-date EBITDA at €187.1 million recorded an increase at constant exchange rate compared to last year of 7.5% with a margin at comparable exchange rate of 38.3% versus 38.9% of 2017.

Quarter three EBITDA at €58.9 million increased by 6.8% at constant exchange rate vis-à-vis last year. Please note that September '18 EBITDA margins net of expenses we booked for the legal action in the US with Meridian are now settled and net of detail of the Irish site divestiture cost would have been inline with what we recorded last year.

Lastly, we closed September with a strong free cash flow about €101 million and then very healthy positive net financial position, just short of €130 million. The net financial position has been affected by the payment of the ordinary dividends for €47 million in May and by shares buyback program for about €65 million. Please remind that the net financial position does not include €98 million of debt towards shareholders for the extraordinary dividends which we will be paid out in December 2018.

Let's now go to the main items of the P&L, September year-to-date revenues at €494 million grew by 5.4% or about €25 million compared to last year. The growth at constant exchange rate is 9.1% or €42.8 million. Carlo has already covered the business drivers behind these variance. Gross profit at €336 million grew by 5.1% compared to last year closing the first nine months of 2018 with a ratio of revenues of 68%, which is basically in line with 2017. In spite of dilutive affects of the Siemens ELISA sales and of the price pressure on Vitamin D. This performance which is slightly better than what we are originally expected is mainly driven by higher manufacturing efficiencies and better geographical and product mix.

Q3 '18 gross margin at 67.1% of revenues is substantially in line with last year, the reduction compared to the previous quarters, which we also experience in quarter 3 of the last couple of years is mainly driven by the product mix and by the seasonality of our business which usually sees lower activities in some geographies especially in Europe during the summer months.

Total operating expenses at €179.8 million or 36.4% of revenues have increased by 5.7% compared to the first nine months of last year. Please remember that about €11 million of September reiterate [ph] OPEX have been driven by the depreciation of the intangible assets coming from the Siemens Elisa and focus business acquisitions. Net of these elements the year-to-date OPEX increased at constant exchange rate versus last year, would have been 8.5% and the rational revenues would have been 34.1% against 34.3% of 2017.

September year to date other operating expenses at €6.9 million have increased by €2.1 million compared to last year. As just said, the period

has been affected by some expenses related to the legal action in the US with Meridian and by detail of the Irish site divestiture costs.

As a result just described September year-to-date EBIT at €149.3 million or 30.2% of revenues has increased compared to 2017 by 3.1% or €4.5% million. The growth at constant exchange rate is positive for just short of 8.5%. The tax rate at 22.2% is almost 10 percentage points better than September year end, year-to-date 2017 which close at 32% and is in line with what anticipated and discussed during 2017 year-end call.

This variance is mainly driven by the positive impact of the Italian patent box in the US tax reform which we already discussed about in the previous calls. Year-to-date net results, at €116.8 million or 23.6% of revenues is higher than previous year by €21.1 million or 22%. This increase is the result of what I said so far, and of lower net financial expenses mainly driven by a reduction in interest and FX losses compared to last year and by the revaluation of the participation in our Indian subsidiary following the takeover of its full control from the local partner.

We also discussed about this element during the last quarter call. Lastly in September year-to-date EBITDA at €187.1 million is better than last year by €5 million or 2.7%. The variance at constant exchange rate is positive by 7.5% EBITDA additional revenues is 37.9% at current exchange rate and 38.3% at constant exchange rate, that's confirming the strong profitability recorded in the last quarters.

Quarter three EBITDA margin at 36.2% of sales has been affected mainly by two elements. The impact, the one-off cost just described and some seasonality in sales. Again, Europe mainly Europe and some product mix. Please remind that Q4 '17 was materially affected by the Irish site

divestiture costs, so the growth of Q4 '18 over Q4 '17 is going to be more material than what we ever recorded year-to-date.

Let me now please move to the net financial position and the free cash flow, we closed the period with a positive net financial position of €128.8 million and about €141 million in cash. The net financial position has been affected by two main elements, the payment of ordinary dividends for €47 million in May and the shares buyback program for €65 million. As said, the net financial position does not include €98 million debt towards shareholders for the extraordinary dividends, which we will be paying out shortly in December.

In the period, the group generated €101 million free cash flow vis-à-vis €97 million in 2017. Lastly, in view of the group operating performance, the management confirms 2018 guidance for both revenues and EBITDA with a growth at constant exchange rate of around 9% for revenues and 12% for EBITDA. As was mentioned by Carlo, please note that this guidance might be negatively affected by the delay to 2019 of some tenders originally foreseen for Q4 '18 which took place in geographies, which are served by our distributors network. 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: Hi, excuse me. The first question, I am sorry if I missed that during the call is just a clarification of the organic growth component for the group in Q3. The second question is regarding Quantiferon-TB and I was

wondering if you would commit, let's say on at least range of the incremental growth that it could bring to your revenue growth in 2019. And just also clarification regarding the comments you made regarding some potential postponements of revenues in Q4. I'm referring to Iran for example, does it mean that you could actually have missed this...the current guidance, but it could be an add-on to next year, or it won't be material enough let say to jeopardize the current guidance. Thank you.

CARLO ROSA:

Okay. So I will comment on the second and third question and then PD will cover the first. On the effect on TB and contribution to 2019, you need to wait for the 2019 guidance and the plan that we create a new three years plan which we plan to be cast in the first-half and it is certainly going to give more color to the what we expect on from TB. As far as the comment on Q4, look, we have a significant business in Iran and what we are trying to understand and this because the actually the U.S. just came up yesterday with a list of the banks which have been blacklisted. We need to understand how financially we can continue our business in Iran. So far we expect that looking at the list of banks, we will be able to continue with some of the current banks and then we'll be able to make complete shipments in Q4 but then just warning that in case we need to move to different banks, it may take time and that means that our regular business and our regular shipment in Q4 would be moved to Q1, that has nothing to do certainly we are losing business but has to do with the fact that some significant portion of sales, significant for the quarter would be moved from one quarter to the other. The other one is to do with a very large blood bank tender that where that entails sale of a large quantity of systems, some of which already happened in Q3, but some is scheduled to happen in Q4.

And again, we are waiting for instruction and we need to understand whether this is going to happen in Q4 is going to happen in Q1, so we're

saying these are events that should not impact our revenues but there is a shift of these extraordinary components that may be shifted from Q4 to Q1. Now as far as organic growth.

PIERGIORGIO PEDRON: Yes, hello. Organic growth both in Q3 and year-to-date was around 4 to 4.5% and I believe, I didn't mention it my call that's why you didn't pick it up.

ROMAIN ZANA: Okay, thank you. Just a short follow-up on Iran, what is the sales exposure of the group to this country?

PIERGIORGIO PEDRON: Now, we don't. It's sensitive information, we don't share this information.

ANALYST: Okay. Thank you.

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

MICHAEL RUZIC: Yeah. Hi Guys. Thanks for taking my question. Just a quick one from me. I was wondering how many of the Siemens accounts you had currently converted from ELISA to CLIA? I guess percentage-wise.

And as well just on the large system order to better understand if that slips to Q1, I guess in terms of percentage of revenues, can you quantify that or be a bit more clear? Thanks...

PIERGIORGIO PEDRON: Let's talk about the conversion. I think I provided some data. I said that we converted today 10% of the customer base. And then we have in the funnel 50% conversion by year end...year end meaning 2019.

CARLO ROSA: Okay. So we expect to convert up to 50 by end of 2019, which...it means that we will have one and a half year to convert the remaining accounts.

Certainly, the weight in terms of revenues is not 50-50 because we are converting in phase one larger accounts. So you're going to have that the revenues is not outweighed in terms of the number of accounts converted.

As far as the...I think the question was the...I'm sorry, can you repeat the second question?

MICHAEL RUZIC: Yeah, I was just wondering if you could quantify the system order for Q4, how important that was for the revenues perhaps percentage wise if that were to slip to Q1?

COMPANY REPRESENTATIVE: Unfortunately cannot do it because this is the...this is part of a transaction which involves Siemens...is part of the Siemens business that we inherited, so cannot share.

MICHAEL RUZIC: Okay. Thanks a lot.

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

MAJA PATAKI: Yes. Good afternoon. I have a couple of follow-up questions. And I'm sorry if I am asking probably the same questions again? Carlo, the postponement...the potential postponed into Q1 is related to Iran? And to what would be the second reason, I wasn't quite sure whether everything is down to Iran or there's another reason.

My second question would be around your molecular performance, which came in below what I was expecting and you did discuss at the first half results, a bit of seasonality in molecular. I was wondering if you could give us an update and how we should think about it maybe going into Q4.

And then the last question would be really relating, you know, since you are giving us an indication that they could be a shipment or like a postponement of some revenues moving into Q1? Would you confirm and nevertheless, the 2019 guidance and then we would just have to ask you one on top of that would be...would that be the right way to look at it? Thank you.

CARLO ROSA: Okay. So the first...I said there are two events, very different. First one is to do with Iran and again and we have covered that.

The second one has to do with the very large tender in blood bank in Asia. And these include...this is part of the Siemens business we inherited and we cannot quantify, is a significant business, is done through partnership and therefore we cannot provide more details.

So our... the question on the table is whether shipments will happen in Q4 or will happen in Q1.

MAJA PATAKI: Perfect. Thank you.

CARLO ROSA: Okay. So we are just moving from one quarter to the other quarter.

MAJA PATAKI: Understood. Okay.

CARLO ROSA: As far as, yeah, that's clearly it is shifted to Q1 is additional business to what we foresee for 2019.

MAJA PATAKI: And I mean, you know, we have now, the world has gone a bit slightly crazy. And you know, you talk about issues also in Brazil due to debt collection and you know, stopping for the moment with some orders, we

are seeing Iran, we are seeing this large order in Asia. Do you still feel that your guidance that you've provided three years ago for 2019, that are you still comfortable with that?

CARLO ROSA:

Look, my....the 2019 guidance, I think if we do it at plan exchange rates. Okay. So, which is already a complication, entails a growth next year of 10%. Okay.

And what are the factors, the add-on factors and what are the risks? The add-on factor is certainly understanding that we have a base business today net of new initiatives and the new initiative would be launch of [indiscernible] in the US and with the MERIDIAN...conversion of the MERIDIAN business, the launch of QuantiFERON, and some launch of the nuclear products.

So we have, I mean [indiscernible] growth rate of the business, which sits around 5%, okay? And then to that you need to add the component...the growth...the organic growth provided by again TB and the [indiscernible]. So the question in my opinion for 2019 is more to do with how...where vitamin D in the US is going to go because today I am making a projection which is based on data that we are seeing today and I am also making projection on what we have seen in other geographies so I am guesstimating that within a certain period of time vitamin D volume may go down between 18% and 20% okay? And then I think as we discussed already my...from previous experience I expect that volume will bounce back and I always refer to what happened in Australia, very similar situation, measures were put in, our reimbursement was cut which is very exactly the same as in the US and then eventually bounced back...the volume bounced back in the following two years, but there is a hit that you take when it goes down.

So the effect of this in 2019 in my opinion is still to be seen and evaluated and this is why we are careful for what we see today, I believe that the 2019 guidance that we are given provided that again we have good outcome from TB which is starting very well and a viability in the transaction with Meridian which pretty much is opening up the US market to H. pylori working with Meridian conversion, I have a positive feeling about 2019 and the guidance.

MAJA PATAKI: Right and on molecular?

CARLO ROSA: I am sorry, yes...question number two was about Molecular. You see the problem with Molecular is that as you know as I discussed a few times, we bought the Molecular business which as two components, one is ASR...famous and famous ASR. The other ones are the kit. We don't break it down but as far as kits are concerned, there is a growth which is significant...20% growth worldwide of this product line. Then you have the ASR. with ASR you are really at the mercy of the NGOs which guess what very large NGOs have started very large labs in the US that they use it for LDT and there you see dynamics which are difficult honestly to predict because LDT means that they develop their own press so you don't...difficult to understand and project efficiency so I will match of your reagents that actually turn into **assays** that they report and therefore consumption.

So historically, when we bought this business, this ASR...the ASR in the US was growing double digit okay? What we have seen this year is that this ASR component is not growing naturally, specifically with one account is declining and the net-net effect is that we are diluting the growth of what is the strategic business which is the kit business. It is still less than 10% of our overall business so it does not have a great impact plus or minus on the growth. It is very positive. On the kit side, there is

this ASR component which is difficult honestly to predict great, great, great cash count, but not necessarily so strategic but is diluting sometimes the good result of the kit.

MAJA PATAKI: Thank you very much. At second quarter call, you were kind of expecting that the ASR business would at some point in time see an acceleration in this year, just as you pointed out the lumpiness and the big customers but do you still believe that at some point in time we are going to see a turn of it or do you think this is something that is going to remain sluggish.

CARLO ROSA: I think it will not. My expectation in 2019 is that this not going to be a drag and the reason being that there is large contract that was awarded to us and they are doing validation again some big lapse and this should cover some of the negative impact that we are seeing from reduction of use by other accounts so in my projection, ASR should not be a drag, should probably continue to grow slow in low single digit and I see it as a cash cow and this would allow clearly the kit performance to be more visible keeping in mind that we have the influenza syndrome as everybody else so we are carefully watching what is going to happen with the influenza this year. You know was a light season in the pacific and I think we are all waiting to see how the influenza will do in this winter and so it does impact I think the business of a lot of companies that actually play into the molecular space, ex blood banks.

MAJA PATAKI: Okay. Thank you very much for that.

OPERATOR: As a reminder, if you wish to register for a question, please press "*" and "1" on your telephone. The next question is a follow up from Michael Ruzic of Berenberg. Please go ahead.

MICHAEL RUZIC: Yeah, hi just a quick follow up from me. I think the market has been kind of spooked by these potential delays in Q4. I think it will be really helpful maybe not splitting the milk but just together if you could quantify in terms of the headwind if both were to go in the negative case and flip to Q1 do you think there will be a 1% headwind to sales. Does that feel a bit right or would it be more or less? Thanks.

CARLO ROSA: More or less one percentage point.

MICHAEL RUZIC: Okay, thanks a lot. Very helpful.

CARLO ROSA: Welcome.

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

CARLO ROSA: Thank you, operator.