

01-May-2013 DiaSorin SpA (DIA.IT) 03 2009 Earnings Call - 10/30/2009



MANAGEMENT DISCUSSION SECTION

Operator: [Abrupt Start] afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the DiaSorin's Third Quarter 2009 Results Conference Call. As a reminder, all participants are in listen-only mode. After the presentation, there will be an opportunity to ask questions. [Operator Instructions]

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. Good afternoon, and welcome to the third quarter results conference call. I will give a brief overview on the quarter results, and then Mr. Andrea Senaldi will drive you through the presentation on the financial details. As a general comment, I can say that we have experienced growth of almost 24% versus quarter three 2008.

In terms of geography, North America continues an impressive growth driven by key factors, one is vitamin D and the other one is the infectious disease sales which are increasing now 40% compared to the previous quarter. In terms of the installed base for the LIAISON in the United States in the last three quarters that we placed more than [ph] 136 (01:49). And I think the good indication here is that almost 40% of that base, and now carry the infectious disease along with Vitamin D. In the last quarter, 58% of the LIAISON installed in the U.S. carry infectious disease and Vitamin D. So I think that their theory, which was initiated at the beginning of the year, that Vitamin D [indiscernible] (02:23) to support infectious disease is, in fact, working.

In the U.S., we are continuing the migration from central labs to the hospital markets securing that market which we bring through company higher profitability related to average in price which is significantly higher than what we used to get in the central labs.

When it comes to the other geographies, Europe continues to experience a double-digit growth with certain countries like France where the growth is around 30% as well as in the Nordic. The other two geographies in Asia Pacific, China continues to grow driven by, again, LIAISON installations, total installed base in China now has reached 170 units, so it is a very successful program in a country to a point that, as already explained before, starting from January next year, we will be direct in China serving the main provinces, Beijing and Shanghai, with our own device health-wise.

Last but not the least, when it comes to South America, we have to two different situations. Mexico continue to grow very rapidly. When it comes to Brazil, because of the fact that a lot of growth has been driven last year by significant sale [indiscernible] (04:08) was won in the middle of the year. That tenure has not been renewed. So, compared to last year, we have sales in [indiscernible] (04:18) which are flat because of the – again, the lack of this large tenure.

Going back to the total of installation of LIAISONs, we have installed in the quarter 92 systems, which is bringing the year-to-date total to 360. It is, in essence, traditional in the third quarter, a slowdown of placement, so less than 100 – average of 100 because of the slow month of August and late July in New York which usually slowing down operations rate.

The LIAISON is becoming increasingly important as a technology in our revenues, and this clearly drives up margin. As you have seen today, the gross margin has been improved by 29.5%. Then at the EBIT level, this has increased by 36.7% [indiscernible] (05:34) And this is clearly due to the fact that, clearly, an impressive result as our level of net earnings improved by almost 140% in quarter three compared to the similar quarter in 2008. Before Andrea will pick up from here, just one comment on Vitamin D in the U.S. Finally, there has been final ruling which has been published by the government. In terms of the reimbursement policy for Vitamin D in the U.S. for Medicare and this ruling has been very favorable to DiaSorin's Vitamin D testing. It has been finally included as indications for measurement of Vitamin D specific code, the code for Vitamin D deficiency to monitor the efficacy of replacement therapy.

And one of the comments that has been made to this new code is that annual testing may be appropriate depending upon the indication or a mitigating factor which [indiscernible] (07:01) means that besides supplementation, Vitamin D monitoring one per year is relevant to properly assess the deficiency or sufficiency of Vitamin D. I think this has finally resolved a potential issue in the U.S. with the Medicare reimbursement. So, I think the company is very happy about this and it clearly did give a lot of solidity to the configuration of Vitamin D testing in the U.S. Andrea?

Andrea Senaldi

Thank you very much, Carlo, and good afternoon or good morning, ladies and gentlemen. I would get it from what Carlo just said, so I would invite you to turn to slide three where the quarter three income statement is summarized. I would draw [indiscernible] (07:52) through number nine, and then I will add some further information on the revenue for the [indiscernible] (08:01) and the margins.

So, as Carlo said, our revenue in the quarter had grown by almost 24% versus previous year with a total of C74.2 million. On a constant exchange rate basis, the 24% would have been 22.8%. So, there is a slight improvement versus the exchange rate [indiscernible] (08:27) of the dollar versus the previous year, but their effect is diminishing.

At the same time, I would like to remind you that we now, quarter-on-quarter, the consolidation areas of the growth is comparable because we started including the revenues of Biotrin, which was acquired in July last year, from quarter two 2008.

And this revenue actually driven up the gross profit, which had improved more than proportionately to the top line. Gross profit for the quarter is almost &52 million with an improved, at margin level as well, by 3 percentage points, in fact, versus 2008. The quarter three margin has moved from 66.5% to 69.5%.

Operational expenses are growing far less than proportionally. In fact, quarter-versus-quarter, the total operating expenses grew by just above 10% with a lower incidence of sales. In fact the incidence of the structural cost of the company has decreased by 4 percentage points. This, in fact, has been almost entirely offset however in the quarter by other operating expenses, some of which are of a non-recurring nature. I would mentioned that if you [indiscernible] (09:57 C_2 million for the quarter. The majority of this is composed by costs that we'll sustain as we discontinue distribution agreement for regions or for areas where we just want to enter directly in the near future. Another important component is non-recoverable withholding tax on dividend, which are held by the subsidiaries to the holding company plus some other minor items.

On the other side, in 2008, we had favorable other operating income and because of the reversal of the due diligence cost we capitalized on the shareholding of the Biotrin acquisition. The effect – the combined effect is

bringing the EBIT improvement in line with the improvement in gross margin. In fact, our EBIT grew by 37% with an influence of the turnover, which moved up by 3.2 percentage points from 31% to 34.2%. And the same thing is true for EBITDA, which improved by 3.4 percentage points from 36.8% to 40.2% with a growth rate versus previous year in excess of 35%. Net financial expenses for the quarter are fairly neutral as opposed to last year where we had, you remember, a strong impact – adverse impact from notional exchange rate differences on the debt that we carry in dollar.

And as far as tax is concerned, we experienced for the quarter a tax rate which is lower again, following quarter two is again lower than usual due to the use of law provision which has allowed us to realign IFRS accounting to the fiscal accounting.

So, the closing of the quarter for net results is fairly explained as more than doubling last year, and their effect would – and this growth would reflect those would remain more than double even if we took out the tax effect that we're enjoying in the quarter, which is worth about C1 million.

If we turn to the next slide where the revenue breakdown by technology is explained, you will see usually [indiscernible] (12:32) in essence, so LIAISON sales are driving the top line. Quarter-versus-quarter, LIAISON sales grew by more than 40%, 4-0. And this further shifts the weight of CLIA within our portfolio to a 64.7% weight. In the quarter also, we had a slightly lower incident of instrument sales, so they will further – slightly further improve the gross margin.

In terms of revenue breakdown by geography on slide number five, if we start from Italy, Italy in the quarter grew by 6%, which is a lower growth versus what we experienced in the previous quarter. You have to keep in mind that in the summer months, we experienced a prolongated closure of some of the [indiscernible] (13:27) particularly affecting the month of August, which we expect [indiscernible] (13:32).

The rest of Europe grew close to 10%. The U.S. or the North American market grew by 64%. As reported clearly, comparable exchange rate [indiscernible] (13:47) slightly lower at 55.5%, and the rest of the world grew by 13.2%.

I would like to mention some of the outperformers in terms of percent in the regions. France is growing in the quarter more than 38% to the Nordic region 33%. Israel is going – is close to double its turnover quarter versus quarter. China is nicely growing at 46% and reached the installed base of about 100 all in the Chinese territory. And the third-party distributors are contributing to the growth, increased by 36.5%, and is mainly due to the Australian distributor.

On the next slide, you find the drivers that continuously improve the profitability of the group year-on-year. Improvement in the technology mix is something – is now used to see in a number of projects. And the fact that [indiscernible] (14:56) mentioned revenues which carry a higher margin than any other technology account for 64.7% versus 57.1% in absolute drives the margin up. Vitamin D, which carried the highest margin in our portfolio, clearly has been a factor as well as we continue to leverage the installed base whereas the – as I mentioned before, the lower incidence of OpEx that was experienced in the past as is in the quarter offset by other operational expenses.

Net result, as I already commented before, have reached now a percentage of sales which is above 20%, affecting the quarter to 22.8%.

As we come to the cumulative year-to-date performance, the group has closed at just nine months of the year at \pounds 225 million turnover which is represents an increase by \pounds 27.8 million versus previous year as reported. At current constant exchange rate, that would be a growth of close to 25%.

The margin improvement there consistently is more than proportional from 65.4% and moved up in 2009 to 70.1% of the turnover. Our operating expense has continued to grow far less than proportionally, and therefore, the leverage provides us a 3 percentage point improvement.

And as far as the EBIT is concerned and the EBITDA, EBIT increased in the first nine months by almost 55% versus previous year, being up margin-wise by 6 percentage point. EBITDA grew close to 50%, coming up again by almost 6 percentage points from \pounds 61.7 million in 2008 to almost \pounds 92 million in 2009.

Net financial expenses are significantly lower than previous year reported. The majority of this difference is explained again by the adverse exchange rate difference of 2008 versus 2009. And the tax rate has enjoyed the effects that I just mentioned earlier for quarter three and I mentioned for quarter two.

So, all in all, the net result is almost – again, on a cumulative basis is almost doubling because we are up 97% versus previous year at ε_{54} million as compared to $\varepsilon_{27.3}$ million in September year-to-date 2008.

As far as the balance sheet and the cash flow are concerned, I would like to mention that we closed the third quarter with a net capital inflows of $\bigcirc 200$ million, which is entirely [indiscernible] (18:07) through equity. In fact, if you see the net financial position of the company, it's, for the first time, positive, i.e., had a cash surplus of just about $\bigcirc 400,000$ as opposed to an initial net financial indebtedness of close to $\bigcirc 200$ million. The company has generated in the core terms an operating cash flow of – in excess of $\bigcirc 200$ million before capital expenditure of about $\bigcirc 5$ million, which brings the total operating cash flow for the nine months to $\bigcirc 46.4$ million before CapEx of about $\bigcirc 200$ million.

I already mentioned the positive financial position which has been achieved after paying out a payout of dividend for &6.6 million in July this year, plus the exceptional outflow of taxes in order to [ph] offset specific (19:13) taxes for &4.3 million altogether to enjoy the future tax benefit we mentioned before on the [indiscernible] (19:22) statement of the IFRS disclosed [indiscernible] (19:28) account.

Last but not least, I will mention that at the end of the third quarter, the group had cash available for \notin 40.6 million. This is as much I wanted to say in terms of the presentation. I would now leave the stage for a Q&A session. Thank you very much.



QUESTION AND ANSWER SECTION

Operator: Excuse me. This is the Chorus Call conference operator. We will now begin the question-and-answer session. [Operator Instructions] The first question is from. Mr. [ph] Fritz Peters (20:17) of Goldman Sachs. Please go ahead.

Hi. Good afternoon, everyone. Three quick questions. First off, you've already talked a bit about the run rate on the LIAISON placements, and it's been definitely below where it was last quarter. It also seems to be below last year's third quarter which I think was 110. There was seasonality of last year but not quite so much. I think before you had said there was going to be approximately 120 per quarter for the rest of the year. So, just wondering if we should still expect there to be a significant increase in placements in the fourth quarter next year versus where the run rate had been not just for this quarter. And also if there's any kind of difference that you're seeing between the placements between the rates in Europe and then United States where, of course, you're seeing – not necessarily just a difference between the two, but if you're seeing a change in the trend there or seasonality in one or the other.

Andrea Senaldi

Sorry. You said you have three questions.

Oh, yeah. Okay. I'll ask – yeah, I'm sorry, I'll ask all three. Second, just wondering how the LIAISON XL rollout is progressing if that's still going according to plan? And third, it's relatively a minor issue, but you've already discussed the rule, but the tax on the dividend received, I mean, as part of other operating expense, I'm just wondering if – I know that we had seen in previous quarters. I'm just wondering if that's something that should be ongoing or if that's going to end at some point? Thank you.

Andrea Senaldi

Okay. Let me just take first the technical question and then I leave to Carlo on – to comment on the upgrade for the LIAISON [ph] placement (22:09) excellent progress. We do clearly – first of all, if you look at the – we're talking about a withholding tax of the dividend which are paid by a U.S. company to Italy. Now, part of these dividends are – part of this withholding tax is not recoverable through the tax treaty. It is something that you have already – or we have already reported, I believe, in Q1, and normally this happens twice a year.

Now, the magnitude of the withholding tax, which for the quarter accounts for about €0.5 million, clearly depends on the amount of dividend that we try to grow from the participation. And I would say it is probably recurring in the future as far as we generate to more and more cash in the U.S. operation and if we want to attract it to Europe. So, all in all, I would believe that an amount of about €1 million per year is something that is probably recurring in the future as well. Okay.

Carlo Rosa

Okay. Let me go to the placement question. First, I honestly don't see an issue or a pattern issue different from what we expected. Keep in mind that we always stated that our, generally speaking, our target for replacement is in the range of 400 systems per year. Now, second is that in the first two quarters, we had also requests which are coming from different geographies, we should typically slow down in quarter three. Also, it is clearly the company's interest to push for placement in the first two quarters because when you generate more revenues in the last – in the current year.

All said and done, in quarter three, again, [ph] the signs in Europe (24:36), there has been another event which has affected the placement issues. As you well know, China has experienced some extraordinary two weeks holidays which pretty much has blocked the Chinese placement of systems in demand.

In the fourth quarter, I think we will exceed 100 systems and I think we will go back to what we've indicated, actually we will exceed what we have indicated since the beginning of the year which today we are at 360 systems, we have a 100. We're going to end up with 460, 470 systems, which is a very strong installed base for the company, in line with what traditionally has been our expectations.

In terms of LIAISON XL, the LIAISON XL, again, let me just make a remark first and keep telling me you know more about the LIAISON XL than our customers and then we should be is that we are very careful with such a strong demand of the current LIAISON, very careful on the rollout, and we tell customers about LIAISON XL availability. We are extremely concerned that a perception of LIAISON XL coming too soon would freeze the fact that LIAISON plays in which should be a very [ph] strategic mistake for Diasorin.

All said and done, the planned – the rollout plan in terms of development and validation activities continues. We now have a system being installed on the three manufacturing sites, including one in the U.S. and three weeks ago [indiscernible] (26:27) tend to initiate the validation. So, I think this is more an issue with the Diasorin controlling the rollout and strategically making sure that the LIAISON doesn't freeze [indiscernible] (26:41)

Okay. Okay. Thank you very much.

Operator: The next question is from Mr. Massimo Vecchio of Mediobanca. Please go ahead, sir.

Massimo Vecchio

Yes. Good afternoon to everybody. I have three questions. The first one, you recently announced a change in your R&D department. I was wondering if you can share with us what this could imply going forward in your R&D activity with a particular focus on the entrants in the Molecular Diagnostics segment.

Second one is on the revenues per box, if you can give an update of what has been the first nine months according to our – to your, sorry – to your calculation?

And the third one is on the 2009 guidance to reach the €300 million level, you basically have an implied fourth quarter which is quite low. I was wondering if you can expand a little bit on that. Thank you very much.

Carlo Rosa

Sorry. This is [indiscernible] (27:48), we didn't get the – you made a comment on your last question about quarter four. Can you repeat it?

Massimo Vecchio

The last question was on the guidance.

Carlo Rosa

Yes.

Massimo Vecchio

You were guiding probably for sales in 2009 above \bigcirc 300 million, or probably you were talking about the growth rate. And to get there, this would imply a fourth quarter which is probably around \bigcirc 75 million one of sales, so, let's say, with a limited growth year-on-year. I was basically wondering if you can expand a little bit on your 2009 guidance and give some update after this stronger third quarter.

Carlo Rosa

Let me make one comment and then the R&D, Andrea will follow up. I don't understand the cost on limited growth honestly for the last quarter of 2009. I think that today, there are two things that we should take into consideration. First, the rate last year, during the last quarter of 2008, was a very strong rate because the company frustration and last year was the [indiscernible] (29:07).

Second, you need to consider that we will cover to the effect of the dollar quarter-on-quarter. Now, you're seeing an inversion. So, the dollar in quarter four, if it continues to be around €1.50 is [indiscernible] (29:22) quarter-on-quarter impact which is not as favorable as before.

Then Andrea is going to elaborate on this. So, let me just make a comment on the R&D. On the R&D, it's very clear that Molecular and [indiscernible] (29:40) rollout are posing an important challenge for the company. We were lucky enough to find a gentleman that was coming from a very established molecular diagnostic company [indiscernible] (29:54) is a Swedish and he was leading the European research and development team. And we made an investment in order to strengthen our R&D capability, also in light of the fact that Mr. [indiscernible] (30:12) has been with the company for now 30 and some years. He's leading the operating role and working more on the board in order to – strategic directions. So, I would say was an investment that the company has to make in order to guarantee continuity, and we use the opportunity to invest in [ph] personal monitoring (30:34), not this new monitoring [indiscernible] (30:35).

I wish, however, that [indiscernible] (30:39) would allow DiaSorin just for that to be successful in this field. It's a very difficult area, and with lots of big competitors, so we have a long way to go. But I think this [indiscernible] (30:54).

Andrea Senaldi

Okay. Let me just go back to the last quarter. Now, as Carlo already pointed out correctly, last quarter of 2008 was &68.5 million in revenues, whereas the end average of the previous three quarters was below &60 million. So, it was a very strong quarter. Now, going back to what was happening in the last quarter of 2009, if we aim to overachieve &300 million versus previous year, will place us with a growth rate in the mid-teens. So, I honestly don't believe this is a low growth rate.

As far as the revenue to [indiscernible] (31:36) is concerned, you know that I hate to do it on a quarterly basis. But if you noted the time line of the first nine months that we are now approaching ϵ 70,000 per machine.

Massimo Vecchio

Okay. Thank you very much.

Operator: The next question is from Mr. Martin Wales of UBS. Please go ahead.

Martin Wales

Good afternoon. First, if we come back to the LIAISON placement question. You're talking of 450, 470 (32:10) for the year, I think I recalled you were talking slightly higher numbers after the first half. Any particular – obviously, Q3 has been slower, looking for a recovery in Q4. How should we regard these progressing into 2010, both from a LIAISON and a LIAISON XL basis? I know you're not going to want to give any comment at this point, but I was just curious in your initial thoughts.

And secondly, could you comment on how we should think about tax rate – overall tax rate going forward and, obviously, Q4 also going to 2010? Thanks.

Andrea Senaldi

Okay. Martin, let me start with the tax rate and then Carlo will give the comparison. As far as the normalized tax rates for the Diasorin [indiscernible] (32:54) as you know, those should be in the range of 36%, 37% and which is now very much affected by the tax rate of the U.S. – is going to affect the U.S. operation. A significant proportion of our [indiscernible] (33:08) is generated in (33:11) with the fact that in the U.S. it's 25%.. So, I would view as a projection 36% to 37%.

Martin Wales

Okay. Thank you.



Operator: The next question is from...

Carlo Rosa

No, no, no. Sorry, I need to – sorry, I need to answer [indiscernible] (33:37) one question of Martin. Martin, comparing it with you, I've done a mistake. I think it would be a great mistake on your side where you're looking at the business to judge quarter-on-quarter placements.

Martin Wales

Absolutely. [indiscernible] (33:58) longer term rather than one quarter.

Carlo Rosa

Okay. So, I mean, let's say, that usually we work with our sales force with two objectives. The first objective is very clear. The sooner the place systems the better it is because then, you have more contributions already in the current year. That's mathematical. And so, there is a very strong incentive from our own team to go in Q1, Q2 and load these boxes because, clearly, again, you'll have more sales this year. In this way, traditionally, you see these effects of loading up of boxes in the first quarter.

Second, I think that it's stated. It's always stated, this company can sustain a reasonable growth. And which I find reasonable, which is with placing 100 boxes before it reaches 400. I think that because of the success of our U.S. strategy and because of seasonality and geographies that's more than the geographical expansion, we will be reaching this year 415 [indiscernible] (35:25) which, again, is taking you to overrun the systems placed in quarter four.

Now, what to expect in 2010. I go back to my usual mantra. I think that in 2010, we should expect this company to place north of 400 systems that will continue to support the kind of growth that makes sense for DiaSorin, which as we've indicated, is anything around [ph] 53% (35:58), okay?

So, in my word and it's the way I feel no doubt, honestly, I don't, and I don't think quarter three, honestly, is an indicator of a further slowdown.

Martin Wales

Okay. And just one follow-up. You talked about the Medicare reimbursement for Vitamin D which stands very positive for you. What impact do you think that will have on Vitamin D testing market going forward?

Carlo Rosa

I think, honestly, this does not have an impact, a positive impact, necessarily. It does not have a negative impact because a different ruling on Vitamin D that would have denied coverage by Medicare on – for application other than the traditional one for bones and kidneys which was – this has been – this is not currently in traditional use for. This year, it would have hampered the growth of this market.





I think that Medicare, and rightfully so, question about all this service of Vitamin D testing, I think that the American Medical Association, as many other clinical associations, were asked whether this makes medical sense. And also, whether it makes sense for me here to have to [indiscernible] (37:28) increasing costs. We all know that the U.S. situation as anywhere as international situation has been difficult. And so, governmental agencies are looking to – but at the end of the story where they've got out of it so from the clinicians is that Vitamin D is becoming a marker that is not only [indiscernible] (37:47) related terms which is really relevant here.

Second is that monitoring is very important in order to follow up the efficacy of the replacement therapy. And this is also very relevant because as you well know as we currently stand, in our business, a true business is not screening once in a lifetime because once screening till like market is gone, but it's very relevant for a market to continue to grow is the fact that we have fixed costs, and this clearly indicates that, in case of Vitamin D, a repeat testing is not a failure to monitor the possible issues. So, I would say it [indiscernible] (38:33) possible impact in the sense that this growth of [indiscernible] (38:36) the clinical people believe that the goal will align with the clinical consensus.

Martin Wales

Thank you very much, Carlo.

Operator: The next question is from Ms. Isabel Reuss of Allianz Global Investors. Please go ahead.

Isabel Reuss

Follow-up questions on Vitamin D. I just want to make sure I understood it correctly. The reimbursement of Medicare is subject to an indication for bones and kidney. Is that correct?

Andrea Senaldi

No. I am saying that, until today, the reimbursement for Vitamin D was related to chronic [indiscernible] (39:22) so we're pretty much related to calcium metabolism because this endorsement was established in the 1980s. There was then a generic code, very generic, that allowed us to do pretty much any kind of testing the physicians wanted to. Medicare, some regional Medicare institution challenged the concept saying shall we restrict it to only bones and so we take out this code in light of this surge of Vitamin D request, or shall we not.

And at the end of a very complex process that in the U.S. requires Medicare to send their opinion or their recommendation. And so, they send their opinion to the beneficiary. So, companies and clinicians, once they got the reply back, they decided that in fact not only they had to leave the opportunity of reimbursement for Vitamin D [indiscernible] (40:25) bone and kidneys but also to recommend the fact that monitoring is relevant. Do you understand?

Isabel Reuss

I see. So the indication for it is basically that you do have to show something before you get the reimbursement per se. Okay. That was – I understood your answer. The second question I have was on the LIAISON platform and that is using infection is 50%, 5-0, correct?

Carlo Rosa

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50% of the quarter three placement in the U.S. carry infectious along with Vitamin D. But even – let me just go back one second, let me read it you from the Medicare reimbursement indication, it says Vitamin D deficiency to monitor the efficacy of replacement therapy. Okay, this is the exact wording of the [indiscernible] (41:18).

Isabel Reuss

Okay. And the last one I have, Cardinal Health, how much of the sales of your machines in the U.S. is due to the Cardinal? Have they done a good job at selling them?

Carlo Rosa

Let me say Cardinal has represented 30% of the total installations in the U.S.;3-o. Now, originally, if you remember, our estimation was that Cardinal would represent 50%, and we would [indiscernible] (41:55). Well, what happened is that they did a number placements that they thought they could make, so they hit their number, but we paid more directly so they could dilute it . So, the answer is, yes, they are doing a good job. However, they represent [indiscernible] (42:11) 50% of our replacements in the U.S., which I think is very good. So, we're replacing directly more boxes than we thought.

Isabel Reuss

Okay. And the last one – I promised it's the last one. You said your Vitamin D has the highest margin also compared to the infections. If I have to model the infectious tests, how much less of a margin should I put on then to Vitamin D on it?

Carlo Rosa

[indiscernible] (42:38) if you take Vitamin D, especially infectious disease products, from a margin perspective, they are not that different. If you take [indiscernible] (42:53) in infectious disease, then there is a difference in margin.

Isabel Reuss

Okay. [audio gap] (42:58 - 43:00) Thank you very much. I appreciate it.

Carlo Rosa

Thank you.

Operator: The next question is from Mr. Stéphane Sumar of Exane. Please go ahead.

Stéphane Sumar

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Hi. Good afternoon, everybody. This is Stéphane Sumar from Exane in Paris. I've got two questions, the first one is on Vitamin D. Could you please let us know a little bit more about the growth which have been achieved for this specific product in Q3 and not specifically in the U.S.? And I would like also to know what is the starting price or the selling price of this product. And what is your view in the view of price evolution when new entrants are likely to come? We have [indiscernible] (43:40) and one also to launch product in Vitamin D.

And I've got another question which is on ELISA. Sorry. I just – And my last, my second question is on ELISA. In Q3, your ELISA tranche is declining 6% as per being at 25% over the previous quarter. What could we expect of the Q4 whether – why is this product has been done in Q3? Thank you very much.

Andrea Senaldi

No. Stéphane, sorry to interrupt you because I deserve to answer that question. So, if you can go to end of sentences, the first two questions and I am telling you I cannot answer because as we've said it, these are information that I don't want to provide to our competitor. So, anything that is not something to disclose then we don't want to give you indications about strategic growth of products as lots of people that are looking to Vitamin D. But I didn't gave you [indiscernible] (44:38)

Stéphane Sumar

Okay. So, on the price, you don't want to disclose. Normally, now my question, the third question was on the gross. You don't want to disclose or it wasn't the price? I was asking you about the selling price for Vitamin D.

Andrea Senaldi

The selling price of Vitamin D [indiscernible] (44:52) and not available to disclose, so if you have another questions, I'm more than to be able to answer which gives you at least a third and fourth question, if you could, please.

Stéphane Sumar

Okay. Now let switch to ELISA. ELISA is down almost 6% in Q3. It has been up 20 - almost 25% in H1, just to have more indication about the reason of this change in trend.

Andrea Senaldi

Stéphane, it's not a sort of change in plans, but the reason for the first support is that Biotrin was not included in the consolidation area.

Stéphane Sumar

Okay.



Andrea Senaldi

And Biotrin has only ELISA products. Now, it's comparable.

Stéphane Sumar

And what was the organic growth for ELISA?

Andrea Senaldi

It depends what you mean with organic. Remember what Carlo said during his introduction about the Brazilian tender. In Q3 last year, we've had a very high sales of ELISA because we won a tender versus the Ministry of Health. That tender has been repeated this year. So, on an underlying basis, I would say that ELISA sales are fairly flat.

Carlo Rosa

And by the way, in this tender we were presenting also - the tender was with [indiscernible] (46:23), so you should see the same number in ELISA of [ph] year-over-year (46:26).

Stéphane Sumar

Okay. Thank you very much.

Operator: The next question is from Mr. Paolo Mortarotti of Theorema. Please go ahead.

Paolo Mortarotti

Yes. All of my questions have been answered. Thank you very much.

Operator: [Operator Instructions] The next question is from Mr. Massimo Vecchio of Mediobanca. Please go ahead, sir.

Massimo Vecchio

Yes. I have a follow-up question on the proposed healthcare reform in U.S. I know it's still very draft and [indiscernible] (47:10) are not that clear, I was wondering if you can share with us what you're thinking on - what you think the impact could be on your sector. Thank you.

Carlo Rosa





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Mr. Vecchio, I wish I could to be honest with you, but I think that - I read some commentaries in the U.S. And then on one side, it is - I think it was a [indiscernible] (47:39) comment said every time there is a reform which is expected to spend [ph] \$800 million over 10 years (47:44), so you guys, you better watch out because the government will be looking for savings. And this is very clear to me. Somewhere somehow savings will come.

By the same token, it is very clear that in our diagnostic business, we've done well and probably implemented, provide savings in medical sense [indiscernible] (48:08). It's very obvious. It's also you diagnose the [indiscernible] (48:11).

However, these formal indications of division as well on the user diagnostic tool. So, it's a very complex matter. I think that today, we will have everybody there waiting to see what will happen. I honestly do not expect that this on the same process. [indiscernible] (48:37) and the company can suffer from this. What could be is that on the - from a taxation perspective, they may work on certain taxes on corporations, which are active in this sector in order to find financial resources. This is as much that we can say today.

Massimo Vecchio

Do you see the chances that the enlargement of the Medicare, Medicaid coverage and the insurance may also enlarge your potential market or, let's say, your sales or you only see risks in terms of additional taxation?

Carlo Rosa

Well, I want to say though, sorry – I was trying to be very charismatic. Yes, I think if you're going to turn this positively, you'll have a billion argument to say that [indiscernible] (49:30) reasonable explanations. By the same token, the government needs money, so money is taken from somewhere. I think that today, in terms of business related to Diasorin or business opportunity, I think that this should not be as big as in this quarter, particular opportunity for Diasorin. And still at Diasorin, we continue to make what it is we're doing in the U.S. pretty much in [indiscernible] (50:01) but irregardless, I believe [indiscernible] (50:03) today irregardless of this reform.

Massimo Vecchio

Okay. Thank you very much.

Operator: The next question is from Ms. Maura Garbero of One Investments. Please go ahead.

Maura Garbero

Good afternoon. I've got just one question. Just to know if we share any expected tax charges in Q4, for example, for the termination of distribution contracts? Thank you.

Andrea Senaldi

Maybe in one word, no, although, it is fairly achievable. And it is [indiscernible] (50:41) strategy of geographical expansion, whereby we'll increase our indirect third-party distributors by that distribution. But we periodically

reach agreements in different way or a different form. So, it's either buyout or terminated the distribution contract. Having said this, we do not expect this to happen in the near future again.

Maura Garbero

Thank you.

Operator: [Operator Instructions] Gentlemen, there are no more questions at this time. There is one question by Mr. [indiscernible] (51:39) of Goldman Sachs.

Hi, guys. Just one last follow-up question. You spoke before about infectious disease and its effect on the placements. I was wondering, in terms of the actual tests that are run on machine and in terms of the test that you're selling, if you can give us an idea of approximately what proportion of the North American sales are done or the CLIA sales are infectious disease [indiscernible] (52:04)? Thanks.

Carlo Rosa

Listen, since we just started the process compared to the large installed base of Vitamin D sales, the percentage is fairly small. I think that if you look at – from a running rate perspective, so what is, at the running rate, it – the infectious disease I think is [ph] getting to 5% (52:36) of total sales. So, I need to break it down when it comes to only CLIA. But just to give you a number, this is what we are looking at. So, considering that the [indiscernible] (52:53), so, this is [indiscernible] (52:54) in terms of growth opportunity and that the overall business still not affected too much. But I think what is very relevant from a strategic point of view is that it stabilizes the placements of systems which are better in half. It is really obvious that in fear of LIAISON in the lab, that doing Vitamin D, is it at risk because the customer wants [indiscernible] (53:25) available in other companies. The customers can only decide to consolidate that, too, and remove the LIAISON. The more you run that box with other products, the more you anchor the platforms [indiscernible] (53:39).

One other thing that we should take into consideration that in the U.S., differently from several companies, we have contracts with customers that are basically five years, and every time we've placed a box to Cardinal, we have a contract of five years. Okay, so it is contractual business done in the U.S.

What is contracted, though? Because I seem to remember you saying before that there weren't minimum purchase agreements?

Carlo Rosa

No, there is no minimum purchase agreements. Well, no. Let me say it correctly. If the contract states that there are – there is a certain turnover that the customer intends to do is that the minimum, no it's not. Clearly, it's a minimum, but the system is there with the reagent rental contract which is clearly binding them to work with that certain amount of time.



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Now, this means that if a customer wants to [indiscernible] (54:47) of the contract, they cannot take you out, I think, and eventually, as I always said, when a company that manages these contracts or not, you're out, but if you continue to serve the customer, and the customer is - exactly this, this contracts are valid. So, they have a protection in terms of your installed base vis-à-vis competitor. They are not [indiscernible] (55:12) whatsoever when you're not serving them right.

Okay. Thank you very much.

Operator: Gentlemen, there are no more questions.

Carlo Rosa

Gracias.

Andrea Senaldi

Thank you.

Operator: Ladies and gentlemen, thank you for joining. The conference is now over. You may disconnect your telephones.

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