

DiaSorin Inc.

Third Quarter 2014 Results Conference Call

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MODERATORS: CARLO ROSA, CHIEF EXECUTIVE OFFICER

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OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the DiaSorin Third Quarter 2014 Results Conference Call. After the presentation, there will be an opportunity to ask questions

At this time, I would like to turn the conference over to Mr. Carlo Rosa, CEO of DiaSorin. Please go ahead, sir.

CARLO ROSA: Yes, thank you, operator. Ladies and gentlemen, good afternoon and welcome to our third quarter 2014 call. As usual, I will make some comments about the main events that characterize this quarter as well as the nine months, and then I will turn the microphone to Mr. De Angelis, who will take you through the financials.

As for the latest the quarters, although the exchange rate had a negligible impact on our sales, I will make my comments on sales at constant exchange rate, to allow a better understanding and comparison with previous quarters or the real trend of the revenues.

Now let me start from sales by technology commenting the CLIA ex-vitamin D products first and then the Vitamin D alone. In the quarter, the CLIA ex-Vitamin D continues to do very well as you have been seeing in the last quarters. In Q3, in fact our CLIA family grew 16% and 17.4% in the first nine months. This growth has been mainly driven by the strong performance of our assay throughout all clinical areas and in particular in few key ones, such the infectious disease, the pre-natal screening and the HIV and Hepatitis. The success of this test strengthen our confidence in the future growth coming from our CLIA test in all the clinical areas, making our CLIA ex-Vitamin D revenues, the driver that should be looked at when evaluating our Company today and in the future.

I am also proud of the success of the new products launched in the last twelve months with a particular evidence of our gastro intestinal infections and the new 125 Vitamin D, which are significantly boosting our revenues. This success is the proof that the continuous effort of DiaSorin to differentiate the CLIA menu which is possible thanks to great work of our research and development team is helping us to grow significantly also in a crowded market.

Another success I want to mention is the increase of our LIAISON XL installed base, at September 2014 we had more than 1,500 LIASON XL installed, and we go to the 5,700 mark for the total installed base. This again is the proof that our analyzer perfectly fit the needs of medium large labs.

Let me now move to Vitamin D. In the quarter, Vitamin D declined as we were expecting 7.2% with a deceleration in the negative trend vis-à-vis the last quarters. If we then carve out the discount we provided to LabCorp on Vitamin D in exchange of new CLIA products, the decline would have been only 3.7% in line with what we consider a physiological reduction in this product line.

Let me remind you in fact that 3% to 5% discount on every CLIA product is what the Company should take in consideration whenever re-negotiating large contracts with its clients. For this reason, the current Vitamin D decline can be considered physiological again and not exceptional as it used to be in the past.

In the nine months, the decline of Vitamin D was 8.3% but excluding the discount to LabCorp, the percentage is negative for only 5.6%.

Now let's now move away from products and let's focus on geographies starting from North America. In the quarter, revenues are up almost 3% versus prior year and still 2.2% down in the nine months. This positive trend in the third quarter was driven by the success of CLIA's Vitamin D revenues which raised 85%, thanks to the fact that the new test we introduced in the market as well as the success of the LabCorp franchise with all these products.

In the first nine months, the CLIA ex-Vitamin D sales are up 77%. At the same time, Vitamin D continues to decline due to the reduction in sales price including the price concession granted to LabCorp that we have discussed before.

Overall, let me consider the Vitamin D situation in the US under full control with our US business starting again to grow after all the issues we had to experience in the last three years.

Now let's move to Europe, Europe continues to show a good growth and the revenues were up 4.4% in the quarter and over 5% in the first nine months. In particular, I would like to focus on Italy where revenues are accelerating with a 6.8% growth in Q3 and a 5.4% growth in the nine months, despite the fact that as you all know, there is a negative trend in the local market which is declining 0.3%, 0.5%. And again, the success in Italian market was mainly driven by the CLIA assays which grew 8.2% in the quarter and Vitamin D also has been a contributor because it is picking up in Italian market as well, although the level of penetration in this market is far behind what we see in markets like the US, France or other European markets.

Now let's move to Germany. Germany continues to be a successful story for us growing over 10%, now we are at 10.8% in the quarter and 14.6%

in the first nine months. And this is the result of the success of all our CLIA assays on top of what we already had established as a customer base in the previous quarters. And again, the gastrointestinal Infection as well as 125 had been the two assays which have been the most successful in the last quarter and they have contributed to growth of revenues in this very competitive market.

France is down, almost 6% in the quarter and 8% in the nine months. As we already discussed in the last conference call, a recent National Healthcare Reform cut the number of claims approved as reimbursement for the Vitamin D prescriptions, this reform affected our sales in the country with a significant contraction of Vitamin D volumes in France, which offset the important strong success we experienced with the rest of the product catalogue. I remind you that the CLIA non-Vitamin D products are growing in France over 25% in the third quarter.

Now, let's move away from Europe into Asia Pacific, and concerning Asia Pacific, the region showed a growth of 17.6% in Q3, and 8.5% in the first nine months. So we had an acceleration in this region in the third quarter. This, the quarterly acceleration in revenues is a result of the increase of test sales in all the countries in the region where we sell both directly and we are distributors.

Now, let's first focus on China, China grew 19.1% in the quarter and 10% in the first nine months following an increase of sales in CLIA test as well as the Murex line. Furthermore in Q3 alone, we installed 30 new LIAISON XL in China reaching a total installed base in LIAISON XL in the country of 98 instruments confirming the strong interest on our new analyzer as well as on the CLIA test that are run on board of the XL.

Finally, yet importantly, let me analyze to you the success we experienced in China with Murex in the third quarter where we picked up some of the sales that we have lost in Q1. And in the third quarter, sales almost doubled with an increase off and in the nine month, sorry, we now registered increase of 11.5%.

As far as Australia, which is the other geography where we operate directly in the region, in Q3, the growth was equal to 6.5%, 3.3% in the nine months and as far as the third quarter is concerned, we just consider CLIA sales net of Vitamin D, if we do that, the CLIA ex-Vitamin D brand registered a strong increase equal to 43.2%. So again, we are successfully diluting in Australia the risk of Vitamin D and moving the customer base from a Vitamin D only to Vitamin D and CLIA ex-VIT.

Now let's move to South America, which has been very disappointing así but we expected that as we have discussed in previous call. And this is mainly due to the poor performance of two geographies, two countries, Brazil and Venezuela, whereas in all other geographies in South America, we had been experiencing strong growth including Mexico which is the other country where we are direct.

As far as Venezuela is concerned, the country declined by 2.7% in the quarter and 13% in nine months due to the socio-political instability which has strongly affected our distribution network and the ability to sell products in our currency.

We don't expect this to recover, it was a very important market for us where we had almost \$5 million in revenues and today we expect to become no more than a million by year-end.

As for Brazil, in Q3 revenues were down 17% and 12% in nine months mainly due to the effect of the change occurred in the previous quarters of 2014 of our distribution network on the Murex business line.

As I think that we have discussed before, Brazil has been very difficult for us in the last two quarters for two reasons. First, because a lot of accounts (ph) and tenders have been frozen due to the recent election on one side and the World Cup in the previous months as well as the fact that we changed distribution model for the Murex line moving away from the previous distribution network who belong still to Abbot to a new set of distributors and some delays in moving away from all the distribution network has caused our inability to participate to some key tenders. We believe that this business may continue to suffer in Q4 and stabilize showing a small growth in 2015.

Now, if we go now to discuss the research and development, in Q3, we launched an important new CLIA product, the HIV high throughput, which allows us to strengthen our presence in the blood bank market. And the strategy of DiaSorin in blood banks has developed through the acquisition from Abbot in 2010 of the Murex line which was a leading brand of blood banks.

And following that acquisition, then we developed a full complete menu of bank banks on our LIAISON XL platform. Thanks to the completeness of our menu, we recently won a very important tender in Turkey with Red Crescent with the Murex line where we were awarded for the full blood bank business for the whole country for the next four years. So it's been a very relevant win for us using our platforms.

Now let me move to profitability. As far as the profitability is concerned, the EBITDA margin is equal to 36.7% in the quarter, nevertheless, if we

exclude the positive effect that we registered you know with exchange rates and the negative impact of the molecular business, the EBITDA margin would have been 35% to 37.5%. We have been starting from the last few quarters, we have been trying to carve out the contribution of the molecular business which is still absorbing profitability, so has a negative impact on the EBIT as well as the exchange rate which has been working against us, at least in the first and nine months.

If we look at the nine months, the EBITDA margin was equal to 36.2%, but if we exclude again the one-off effect and non-recurring cost occurred in the first half of this year, we already discussed in the last conference call, and that number is equal to €1.2 million. The negative effect of the euro appreciation that is equal to €1.3 million and then molecular business impact, that is equal to €4 million give or take, the Company adjusted EBITDA level margin is 37.8% which in my opinion represents the way our business goes as far as at constant exchange rate and without the effect, the one-off effect and the molecular investment, that again I said before, molecular is still taking some profitability because of the R&D effort in developing menu.

Now, we will turn the microphone to Mr. De Angelis who will take you through the numbers and then we will open the Q&A session. Please Pier Luigi.

PIER LUIGI DE ANGELIS: Thank you, Carlo, ladies and gentlemen, good afternoon. Today, I would like to focus your attention on few key indicators. As far as our financial statement is concerned, I would like to highlight the cumulative net financial expenses at the September 30, 2014 was equal to €0.05 million, decreasing if compared to €3.8 million registered in the same period of the previous year, due to the following reason. The effect of

exchange rate difference that were positive for €1.6 million in the nine months of 2014, while in the same period of 2013, it was negative for €1.3 million. The exchange difference realized by the parent Company on dividends paid by the United States and South African that are equal to €0.06 million and the change in the value in euros of the inter-company loan disbursed in local currency to our Australian subsidiary by the parent Company equal to €0.02 million.

I would like to focus also your attention on the lower impact of the tax rate if compared with the same period of last year. The tax rate for the third quarter 2014 was 33.9%, down when compared to the 35% tax rate of the same period of last year. In the first nine months of 2014, it was 35.5%, a decrease compared to 2013 37.4%, due to a different geographical composition of taxable income within the Group, the reduction with all the impact from lower dividends, and most recently, the reduction in the tax rate in Italy since the introduction of measures for economic recovery.

As far as the consolidated net profit for the third quarter 2014, it summarizes €21.3 million increasing when compared to the €20 million of the same period of last year. For the first nine months of 2014, the net profit amounted to €61.3 million increasing if compared with the net profit of €61.1 million in the same period of last year and with a margin of 18.8%.

Furthermore, let me highlight the main points related to the cash. In the third quarter of this year, cash flow from operating activities amounted to €39 million increasing compared to €36.7 million in the third quarter of 2013. In the first nine months of this year, the cash generated from operating activities amounted to €91.9 million.

Net cash used in investing activity in the third quarter 2014 amounted to €6.10 million, decreasing compared to the €8.7 million in the third quarter of 2013, mainly due to a decrease of investment in medical equipments, which totalí summarize €4.3 million in the third quarter of this year compared to the €5.4 million of the same period of 2013.

In the nine months of 2014, it amounted to €21 million, compared to the €21.6 million of nine months of 2013. The net cash used in financing activity in the third quarter 2014 amounted to €3.1 million comparable to the €3.1 million over the same period of last year. It is worth mentioning all €3 million of debt repayment in the third quarter of 2014 and the €3.4 million of positive impact from exchangesí in exchange rate on financial items, especially on the stock denominated in United States currency available to the Group at the end of the period of analysis.

In the same period of 2013, the Group registered a negative impact of €1 million. In the nine months of this year, cash used in financing activities amounted to €30.2 million, while in the same period of last year; it amounted to €76.3 million. The free cash flow for the third quarter 2014 amounted to €32.1 million and for the first nine months of this year, amounted to €71.2 million, an increase when compared to the €36.9 million over the first half of 2013.

As for the consolidated net financial position at September 30 2014, it was positive by €143.9 million, an increase of €45.9 million compared to December 31st, 2013 due to the significant cash flow from operation for the first nine months of 2014. In view of the Group's operating performance after September 30th, 2014, we confirm the guidance for this year.

CARLO ROSA:

Thank you, operator. So I would then [technical difficulty] session.

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 Patrick Wood of Morgan Stanley. Please go ahead.

PATRICK WOOD: Good afternoon, and thank you very much for taking my question. The first is on the agreement with Roche. I think you guys were expecting to have an update on the hardware side in integration there round about November's time, so round about now. If you could just let us know how that's going, that would be good. And the second is on the cash side. I know you are bored with this question, but you have a quite a bit of cash on the balance sheet. How are you thinking about that? How are you thinking about uses? Obviously, a lot of M&A markets getting very expensive now. And then the final one is just on the stool panel, howí how are things going there? Obviously, it was up a little a little while ago, and it seems a lot of the market is moving over to a molecular solution, rather than using some of the CLIA solutions. Is that just people talking of their own business? Or is there any truth to that? Thanks.

CARLO ROSA: Let meí okay as far as Roche is concerned, I cannot make any comment, because we have the meeting with them in order to come to the completion of the development at the end of the month. And so, we remain positive to the fact that we expect next year to start seeing the impact of the Roche collaboration with placements. Meanwhile if you remember, we are continuing to participate to tenders which involved our automation along with other partners using the fact that today our system is connected to other systems currently in the market.

As far as use of cash, we discussed before, yes, we do have a very healthy cash generation. Yes, you are right, assets are expensive. However, it is very clear that we are determined into looking into possibility to acquire companies that would increase the differentiation of our product catalogue and they would allow us to take content and distribute it effectively on our installed base of systems, almost 6,000 systems installed are the real assets that this Company can offer vis-à-vis a target that we could buy and then integrate. So stay tuned on that.

As far as stool is concerned, I'd just comment on molecular, I think that there is one single exception where the market has converted in fact which is the CDs, that conversion already happened longtime ago in the US. They are not even the assay does not even allow registration on new products based on the immunoassay for CDs. However, that does not apply to all the other products that make this stool portfolio. Today, we have six products already approved and launched on our platform; a very key one is coming our way, which is the Calprotectin. And we are very happy with the development of this product line, as you know we focus for the time being mainly on the European market where we have an installed base of systems and we can rapidly penetrate the customer base.

PATRICK WOOD: That's perfect. Thank you very much.

CARLO ROSA: Thank you, Patrick.

OPERATOR: The next question is from Massimo Vecchio of Mediobanca. Please go ahead.

MASSIMO VECCHIO: Good afternoon. My first question is on the ELISA sales growth in the quarter, for which was quite surprising for me. I understand China and Asia was a source of the surprise. But can you add more color on the

performance of this edition? And also, what can we expect in 2015? Was this order a one-off, or is there a more sustainable trend? Second question on the very strong instrument placement in the quarter, which would like lead you above the 500 unit target. Any one-off in there? Any particular tender, what we can expect going forward? And the third question, can you expand a little bit on Vitamin D volumes in Europe? And what's the competition there? Thank you.

CARLO ROSA: Okay. First of all, Massimo, congratulation for the newcomer.

MASSIMO VECCHIO: Thank you very much.

CARLO ROSA: For the enlarged family. Now going back to the products, as far as ELISA is concerned, yes, you know, these are normal, you should not be looking at the quarter in order to understand trends in this business, because a lot of this business is tender related. So take China for example, beginning of the year it seems that the business had gone South, but it was pretty much the way that the seasonalization of different tenders.

As far as the outlook, we believe that the outlook is positive and again, this is pretty much related to the fact that we want this immense tender in Turkey, it's all the blood banks and we will start the delivery of products starting from the second quarter of next year. And we are going to have a great contribution coming from this tender alone for 2015. So I think it will stabilize this will pretty much stabilize and possibly slightly increase our ELISA business. Also taking into consideration that it was made public very recently that our largest competitor Bio-Rad got into legal issues about I think malpractice in certain markets and that clearly is helping us out.

Today, in this market, ELISA market blood bank, pretty much there are three players of which us and Bio-Rad are the leading companies and then following is Siemens that does not really see this product line as strategic.

As far as Vitamin D volume is concerned, what weí we pretty much continue to see the same trend as we have seen before positive or negative. We see in the US the business isí the overall Vitamin D business is relatively stable, growing low single-digit because of the over penetration. We have beení we see the benefits of being present in one of the largest labs in the US because these guys continue to buy more and more labs and every time they buy a lab, we get the volume. And so as far as LabCorp is concerned, volume ofí our volume of Vitamin D business continues to grow and outperform the growth of the market.

You saw also that they announced that they bought Covance (ph). So again, as I keep saying, when you are inside a big lab, these big labs, yes there is alwaysí there is always discussion about pricing, but then since they are expanding so much, you always gain on the volume side. So, so far for us, it has always been good to be there. And thatø US Vitamin D. As far as outside the US, this business is usually in Europe, with the exception of France, where the change of reimbursement really hit the market. I think the expectation is that volume will decrease 30% to 40% in France as a result of thisí of the reform which has nothing to do with reimbursement, but has to do with claims. Outside Europe it continues to grow double-digit. And again, donø forget that there is still an elephant out there which is called Japan that sooner or later will kick in and that is going to have a positive impact on the Vitamin D business.

MASSIMO VECCHIO: Thank you very much. Very clear.

CARLO ROSA: Thank you, Massimo.

OPERATOR: The next question is from Peter Welford of Jefferies. Please go ahead.

PETER WELFORD: Hi, thanks for taking my questions. Just a couple left. Firstly on molecular diagnostics, I wonder if you could provide us an update on both the number of placements at the IAM (ph) and also the rollout timetable for the hemo oncology pipeline menu of tests. And secondly, I wonder if you could possibly have an outlook to the tax rate further going forward. There have obviously have been a number of changes as you said assuming sort of business stays as it is now, could we have some long-term tax rate and possible outlook, that would be very helpful. And finally then, just returning to the cash comment where I think as highlighted, your cash is an all time high. Clearly, M&A is on the agenda, but also I was wondering what the sort of current priority was with regards to both dividends and also share buybacks. I guess it's been a couple of years now almost to the day since either have been proposed. Is there any particular reason why the Board has decided to wait over the last two years before acting again? Thank you.

CARLO ROSA: Okay. I will go on reverse order. As far as cash is concerned, so far as said there has been a statement saying that we look forward to invest cash into the Company. And as far as dividends or buyback, that is more responsibility of the Board of Directors, but our priority so far has always been to put cash into operation, because it makes sense for us and the return is greater than just distributing the dividend. But again, that is more that's a decision that eventually the Board of Directors will have to take.

As far as tax rate, I think you can use 36% for your long term projection, very clearly, there is today there is a strong imbalance between US where the effective tax rate is around 38% for us and Italy where it's 31%, 32%.

So Italy believes I mean, US is becoming a very expensive country to do business and that has mostly to do with sales tax, the medical sales tax.

Going back to your first question, as far as molecular diagnostic, as you remember, now there have been few calls where I stated that we are focusing our effort into the Onco-hematology strategy simply because the infectious disease field is becoming price-competitive to a level that is I think everybody who plays in that business is paying a price. I don't know if you noticed, but some of the very larger competitors that are in infectious disease molecular diagnostics kept showing the slowdown vis-à-vis the pace of growth. And that has nothing to do with volume, because adoption rate is not slowing down, it has to do with the fact that today, there is an ongoing price war with prices going down 20% per year which is difficult to bear for a company.

For that reason, we shifted gear into Onco-hematology. We recently launched the first assay on Onco-hematology and Onco-hematology, as we discussed is an opportunity because there is no real competition is mostly home-brew testing, the price is clearly in the \$50 range, it's a home-brew testing, there are limited number of accounts. If you take Italy for example, there are 50 primary centers doing Onco-hematology and 40 secondary centers doing Onco-hematology. So they can be reached quite easily with a limited commercial effort. Let me remind you that one of the problems in molecular is that a sales person that is highly educated usually is costing twice what a regular salesperson costs for to support the rest of the business. And so, we launched the product on Onco-hematology and then we are going to be launching the next two in 2015. I think that I, yes, I think I touched on all the points.

PETER WELFORD: That's great. Thank you very much.

CARLO ROSA: Yes, thank you.

OPERATOR: The next question is from Luigi De Bellis of Equita SIM. Please go ahead.

LUIGI DE BELLIS: Yes, good afternoon. Two question from me. The first one is a follow up on the Vitamin-D, are there some major important contracts like LabCorp expected to be renewed in 2015 or we can assume that the decline on Vitamin-D will be maintained at around minus 3%, minus 4% for 2015? And the second question on CLIA ex-Vitamin-D business, given the pipeline of the tests launched in the last 12 months, can you confirm double digit growth also for 2015 for this business? Thank you.

CARLO ROSA: As far as Vitamin-D is concerned, what we said is that I think we got better visibility. In fact what we projected for 2014 pretty much is what we are confirming. What we saw in 2014 which is good. We keep saying that ex special situations like the LabCorp one where we traded price for other products, we don't expect in 2015 as the renegotiation on any existing large contracts. And so, we believe that as said, the let me say effect on pricing on Vitamin-D should stay between 3% to 5% per year. As far as CLIA ex D, we keep saying that again, on an increasing installed base as well as on a continuous output of new products, we feel comfortable that the double-digit on CLIA ex-Vitamin-D is sustainable.

LUIGI DE BELLIS: Thank you very much.

CARLO ROSA: You're welcome.

OPERATOR: The next question is from Mark Pospisilik of Kempen & Co. Please go ahead.

MARK POSPISILIK: Hi, thank you. Thanks for taking my questions. Just two from me, maybe just further clarification on the Vitamin-D, if I maybe to ask that, one if I understood correctly, if I just caught your last comment, stabilization would be minus 3% to 5% per year, or did I misunderstand that. And so, a related question to that which I think we heard about stabilization now for couple of quarters now, so just maybe a little more color on what the trajectory is there. And then on use of the cash or potential acquisitions you mentioned, is that likely to be a priority for you that that would be in a CLIA technology space or would you also considers molecular diagnostics? The reason I am wondering that I'd be interested to hear your comments is whether your focus on the LAMP technology in the molecular diagnostics in anyway limits the potential acquisitions there? Thanks.

CARLO ROSA: As far as Vitamin-D, you are right, you've got my comment minus 3% to minus 5%, which is I think the current rate for few quarters. \$this quarter, ex LabCorp decline has been minus 3.6% if I remember correctly. And therefore, we believe that that is the sustainable Vitamin-D rate.

As are as acquisitions are concerned, never say never, but my priority will not be molecular diagnostic for two reasons, too expensive, very expensive and where you are payingí you are paying a lot of opportunities that should materialize years from now. And I think it's a very dangerous and also because of the unpredictability of the way reimbursement and pricing will go. So we made a decision to invest directly into developing technology, into research and development project. So these are variables we can control, cost to the Company is relatively limited because we are talking about \$10 million per year of OPEX which we can clearly sustain. And so, to make a long story short, I believe that we should continue to look at opportunities in the area of immunoassayí content of immunoassay and the reason is very simple.

We now have a very extensive installed base, almost 6,000 platforms, every time we develop a new product and we can very rapidly put it on the installed base and generate growth. And sinceí as you can imagine, we will not be buying anything that goes on mainstream, but would be more content for specialty. That clearly, would also drive the profitability up of the technology.

MARK POSPISILIK: Great, thanks. Very clear.

CARLO ROSA: Yes.

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

CARLO ROSA: Okay, thank you, operator. Bye.