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DiaSorin SpA (DIA.IT)

Q2 2013 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon. This is the Chorus Call conference operator. Welcome, and thank you for joining the DiaSorin First Half 2013 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

CEO, Executive Director & General Manager, DiaSorin SpA

Yes, thank you, operator. Ladies and gentlemen, good afternoon and welcome to the first half results conference call. As usual, I will provide some comment to the main elements of the business and events which happened in the second quarter, and then Mr. de Angelis will go through the financials.

Let me start with the revenues. At constant exchange rate, revenues in quarter two were in line with previous year, notwithstanding the decline of the Vitamin D business in certain geographies like the U.S. and France. And I will comment on this later when we talk about geographies.

In fact, Vitamin D fell in the quarter 9.5%, in line with company's expectations. However, it is noteworthy that the decline, which is primarily related to the price pressure, is softening compared to what has been recorded in the

previous quarters. In the U.S., for example, Vitamin D revenues in quarter two were higher than in quarter one, and this has not been the case for the last six quarters.

Outside of U.S., with the exception of France and Israel and some other minor geographies, the CLIA Vitamin D business is now stable or still growing, like in Italy, Germany, Brazil or Australia.

Let's now focus on the CLIA non-Vitamin D. The CLIA non-Vitamin D business continues to double-digit growth, which has been seen already in the previous few quarters, and this is driven mainly by the success of the LIAISON XL, as we have now more than 850 LIAISON XL treatments installed in the world. Also, it's positive the impact of all the new products that we launched in the previous quarters.

Now, let's now turn to discuss the main geographies, and let's start from Europe. Europe has experienced a solid growth of 4.4% in quarter two, mainly driven by the two main European markets, Germany and Italy, and notwithstanding the poor performance of the French market.

France today is a clear opportunity for the company to grow its installed base because the current consolidation process is moving away business from the small labs to the midsize labs, which are perfect fit for the LIAISON XL. However, due to the size of the Vitamin D business in France and its weight on the company revenues, price pressure as well as competitor strategy to go after the send-out business, which has been feeding the LIAISON in the larger labs, these affected the results of sales in France. We expect that, things being equal, we should see business stabilize in Q3 and Q4 and see growth again fueled by the non-CLIA – non-Vitamin D CLIA in France starting from quarter one next year.

In Asia-Pacific, we continued to see solid growth coming from China, 15% up versus last year, and Australia, 37% growth year-on-year. However, in this quarter, the distribution business in the Asia-Pacific has been weak versus last year due to a large shipment of products which occurred in Q2 last year and will be more spread out evenly in the four quarters of 2013.

Now, let's move to Latin America. Latin America is growing steadily at 15% in the quarter, driven by Brazil, which is up 22% versus last year in the export business. In Brazil, the CLIA Vitamin D business is still growing 80% in volume versus prior year. And notwithstanding the fact that – and notwithstanding that – notwithstanding the fact that the CLIA Vitamin D business makes a minor portion of our sales, it is still very important to stabilize the growth in the country.

The LIAISON XL platform has been just introduced to the market and the hepatitis HIV panel just approved by the regulatory authorities. We believe this product line will be the engine to guarantee long-term growth, also due to the fact that the company already holds 20% market share in the blood bank segment in Brazil through its Murex product line.

Finally, let's move to the U.S. As said, we have seen for the first time revenues in the quarter to exceed the ones of the previous quarter. Q2 revenues were, in fact, 4% higher than quarter one as a result of softening of the Vitamin D price erosion, as we have discussed in the previous quarters and conference calls. In the U.S., the CLIA ex-Vitamin D continues to grow mainly in the clinical area of infectious disease where we see an opportunity to gain leadership with products that have been very successful outside the U.S. in all other geographies.

In fact, in quarter two, CLIA non-Vitamin D products represented close to 15% of the total LIAISON sales in the U.S. with a growth of more than 20% over previous year. As discussed before, the company has initiated a program of menu expansion that has resulted in the launch of 12 new products in the first half of 2013, of which

six were approved by the FDA in quarter two, bringing the total number of LIAISON products available in the U.S. to 35.

Let's discuss now instrument placements. In quarter two, a total of 186 systems were installed worldwide, of which 137 have been LIAISON XL. These proved the success of our platform, which is appreciated both in the midsize labs and the big labs. In quarter two, we have launched our new LIAISON assay for Chlamydia trachomatis. It is two products. These are specialty infectious disease products not available on any other instrument from our competitors, which will complement our infectious disease offering and is key to anchor our LIAISON installed base.

Let's now move to discuss our molecular program. In quarter two, two new assays have been made available on the LIAISON IAM platform, the Parvovirus assay and the toxoplasmosis assay. These two products belong to the infectious disease clinical segment and are key to complete our menu of the LIAISON IAM to be able to provide a molecular solution to all our microbiology customers who are currently already using our traditional immunoassay products.

Let me remind you, for example, that Parvovirus is a flagship product for the company and we have reached a leading position worldwide after the acquisition of the Biotrin product line. This new molecular product is intended to go to the existing customer base to strengthen our position as leader in the field of infectious disease. So far, roughly 30 LIAISON IAM systems have been placed with customers, mainly in Europe and Australia.

I will now turn the podium to Mr. de Angelis. He will comment on financials, and then we will open the Q&A session.

Pier Luigi de Angelis

Chief Financial Officer & Senior Corporate VP, DiaSorin SpA

Thank you, Carlo. Ladies and gentlemen, good afternoon. Let's start having a look at the income statement. I will not spend too much time on the revenues trend because Carlo already did it deeply. Let me only remind you that in the first half, revenues were €219.7 million, in line with previous year at current exchange rate and up to 0.7% at constant exchange rate, and that molecular business contributed for €1.7 million to the total turnover.

When we look at group marginality, it's worth mentioning that the revenues trend in the second quarter and in the first half were accompanied by a strong performance of the economic margins, in line with our expectation. Gross margin in the first half summarized to €151.9 million with an incident on the revenues of 69.1%, in line with last year. If we look at OpEx in the semester, there was an increase of 4%, mainly as the result of the cost incurred to support the launch of the new molecular business.

Let me now explain the numbers behind the other operating expenses registered in the second quarter for €3.1 million and in the first half for €2.6 million. These costs are mainly related to the exchange rate fluctuation occurred in the period. In fact, in the second quarter, the euro appreciated 1.9% against the United States dollar, 19% against South African rand, 7.3% against the Brazilian reais, and 4% against the Australian dollar. In the first half, the euro appreciation was equal to 17.7% against the South African rand, 10.5% against the Brazilian reais, and 3.2% against the Australian dollar. This trend of exchange rate resulted in a negative impact on EBITDA level at €1.9 million in the second quarter and €0.6 million in the first half.

On top of this, EBITDA was influenced by the operating expenses related to R&D and to the creation of a dedicated sales force for the molecular business, which accounted for €1.8 million in the second quarter and €3.6

million in the first half. As a consequence of this, the EBITDA margin in the second quarter was equal to 37.1%, but 39.1% when excluding the molecular business.

The remaining negative difference of 70 basis points versus the second quarter of 2012 is explained by the negative FX headwind in the quarter, as already commented before. In the first half, the EBITDA margin was equal to 38.2% and 40.1% when excluding the molecular business with non-material impact driven by FX headwind when compared to the first half of the last year.

Let me now spend some words on the taxation of the second quarter, which affected negatively the net profit. In the second quarter 2013, the higher tax rate was due to non-deductible tax withholdings calculated on a greater amount of dividends received by the group's parent company when compared to the last year. As far as the semester is concerned, there is not a material difference in comparison.

On top of this, the net profit has been affected by negative headwind on FX exchange rate, already commented before, totaling in the second quarter €20.5 million and in the first half €41 million, which is close to 19% of the revenues.

Moving to the balance sheet at June 30, the net capital employed amounted to €322.8 million, with an increase of €5 million when compared to the beginning of the year, mainly due to the increase of the net working capital. This was due in particular to the higher trade receivable and inventories, partially offset by the change of the current assets and liabilities.

The increase in trade receivable of €7.3 million reflects the good performance of revenue, in particular in Germany, Italy and Brazil, while also reflecting the deterioration of payment performance in certain European markets. The increase in inventory of €2.1 million is due to the higher inventory of semi-finished products in the production size of the group for products whose launch is expected in the coming months.

In the first half of 2013, once again, we are starting to register a very solid net financial position equal to €56.8 million, net of the payment of €27.2 million in ordinary dividends which – with an improvement of €9.6 million from December 31, 2012. This increase reflects the significant cash flow generated from operating activity in the semester, equal to €37.4 million. It is noteworthy that the second quarter of 2012, the company had received a payment of €9.6 million from the Spanish public administration as a settlement of trade receivables for previous quarters. This payment, not yet occurred this year, and is scheduled for the second half of this year.

Last but not least, let me conclude confirming that our strategy is working across all the products menu. And for this reason, we are comfortable in confirming the guidance for the full year 2013, both in terms of revenues, EBITDA and LIAISON and LIAISON XL system installed.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

Thank you, Pier Luigi. So, now we open the Q&A session.

QUESTION AND ANSWER SECTION

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

Analyst, Exane BNP Paribas SA

Q

Yeah. Good afternoon, gentlemen. Three questions, if I may, the first one on aldosterone. Could you give us more color about the market potential in the US for the assay renin as well as the medical guidelines associated to this assay as well as reimbursements? So maybe this one first and I'll ask the other one after.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Romain, do you mind just listing the three questions so we decide who is going to take it?

Romain Zana

Analyst, Exane BNP Paribas SA

Q

Yeah, sure. So one question, actually, is on Vitamin D. You have guided so far on a €10 million decline of sales for 2013. And according to my estimates, such a decline has already been reached in H1. So, could you explain why you are confident on the sharp stabilization in H2?

And the last question is on the EBITDA guidance, which implies basically roughly 7% growth of EBITDA in the second part of the year. So I was wondering what are the main drivers that should support the expected recovery. It's notably linked to the gross margin recovery that we've seen in Q2.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Okay, let me start from DiaSorin Vitamin D. It's very simple. As you said in quarter one, we have seen a steep decline year-on-year on Vitamin D as expected. In quarter two, we have seen softening of the Vitamin D decline, and then we expect that in quarter three and quarter four still some decline in order to get to the €10 million that we've indicated. By the way, we are not there yet. We are close but not there yet. Therefore, the weight on, let me say, on the decline – the weight on the growth of companies for the Vitamin D decline will decrease allowing then what is – I mean, all the other product line, which now are contributing double-digit growth then to express their full potential.

So, if you do the calculation, starting from the current EBITDA level and going forward, making the revenue – full-year revenue that we've indicated on the guideline and calculating an EBITDA margin in line with what we have seen in quarter one and quarter two, you will get, in fact, to the €178 million EBITDA, which is what we indicated in the guidance. So you do not necessarily need a margin improvement, what you need is a stabilization of Vitamin D, and then the [indiscernible] (19:47) of that – the rates of the growth, which is already happening, can be a positive contributor.

As far as Vitamin D, I think I already answered. I said yes, the vast majority of what we said we're going to lose – or estimated we're going to lose in Q1 – in the year already happened in quarter one and quarter two. Not there yet but, again, most of it is gone. Most of the hit was taken in Q1. Quarter two was better. Especially, in my opinion,

the positive indication here comes from the U.S. where, as I said here in my comment is the first time in many quarters where the quarter – one quarter is better than the previous one. And again, this is – since a good chunk of our U.S. revenues coming from Vitamin D, this is related to the fact that we see that year-over-year, the erosion and the effect on the price concession we gave in 2012, this effect is softening, let me say. So we are cautiously positive about the quarter three and quarter four.

As far as aldosterone, listen, we can spend an hour on this one, but let me just make it clear to you. As far as the U.S. is concerned, the existing market potential entities in terms of the use of aldosterone and renin and the ratio between the two in order to diagnose a primary aldosteronism, the market potential is fairly limited as we speak. We estimate something around \$5 million. However, the problem in the U.S. is that the clinical practice is not using these as a tool for diagnosis, which would be a great help because, as you understand, hypertension is becoming a chronic issue in the U.S. market.

So, sales development here are related – let me say strategic sales development behind the €5 million are more related to the fact that we work with the medical community, which is what we are doing right now, in order to develop guidelines which recommend the use of the ratio between aldo and renin in order to manage – diagnose and manage the hypertension. It's a long-term project. However, it does have great potential and also reimbursement today for renin and aldosterone in the U.S. is very high, and so it would allow positioning of pricing in the U.S., which is high.

The third element which is interesting is that with the exception of IDS, which is a relatively small competitor of ours, worldwide aldosterone and renin are not on the map of the big guys, like the Roches, Siemens and the Abbotts of the world. And that clearly is taking away a lot of pressure on one side, is allowing us to, as we did in Europe, develop a market and then work on the demand.

Sooner, it becomes – I'm anticipating your next question. What if this becomes all of a sudden a big market? Do you guys have a reagent to protect it? No, we don't. It's not an IP issue. However, in this case, again, aldosterone is a very complicated assay to develop. We develop a reagent which is unique together with the collaboration with a UK firm, and I believe the barrier of entry to the market, if this becomes interesting, is going to be high. But we don't have any IP protection on this.

.....
Romain Zana

Analyst, Exane BNP Paribas SA

Q

Okay. Thank you very much. And do you expect it to be a significant growth driver in the coming years or...

.....
Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

I do expect...

.....
Romain Zana

Analyst, Exane BNP Paribas SA

Q

...it will take a long time?

.....
Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

As I've indicated to you, I think that strategically there are two areas, clinical area, besides the traditional infectious disease products where I see opportunity. One is dialysis, PKD, so chronic disease – chronic kidney

disease management. And we have products developed on that and we have research and development on that. And then is hypertension where the product already hit the market and we are working to consolidate first the existing market that we captured through our renin products, selling also aldosterone, this is in Europe, and also creating demand using educational tool for endocrinologists that are today are managing either patient.

Romain Zana

Analyst, Exane BNP Paribas SA

Q

Thank you very much for the details.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

You're welcome.

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

Massimo Vecchio

Analyst, Mediobanca Banca di Credit Finanziario SpA (Broker)

Q

Good morning. Carlo, I have a question on the placings in the second quarter. I am not sure if you are ready to comment or disclose, but I was wondering if you can go into details between the different kind of customers that are taking LIAISON versus the XL size geographies, if you are willing to disclose that.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

You are meaning – you mean the LIAISON versus XL?

Massimo Vecchio

Analyst, Mediobanca Banca di Credit Finanziario SpA (Broker)

Q

Yes, the 49 LIAISON versus the XL. To put it another way, I'm impressed by the relatively high number of LIAISON which are still placed, so I was wondering what kind of labs is taking it and why and probably there is a difference in geography by geography.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

I think that there is something you need to understand, which may be misleading. We've always provided net placements, okay? Net placements means that the net number of systems between the one we place and the one we take off the market because that gives you growth of the installed base, which is relevant, net of cannibalization.

So, this quarter, in terms of placement of LIAISON, is not so different from what we have seen in previous quarters. And typically, obviously LIAISON, they do go to Asia-Pacific, mainly China, where there is still a very interesting growing customer base of midsize labs that can take the LIAISON.

In China, we have also launched the XL. Now we have 12 XL places and we have lots of hopes and expectations on the success also there on XL platform. But mainly, the LIAISON today goes to Asia-Pacific. Today, we have 400 LIAISONS installed in China. Placing rate has been traditionally between 70 to 90 LIAISON per year, and we continue to see that.

To a point that very recently, we have agreed to expand for four more years life of the LIAISON, signing up an additional contract with a current supplier to allow us to access the LIAISON platform for this market for the foreseeable future.

As far as the LIAISON XL is concerned, 130, 140 systems a quarter is what you have seen that we have done also in the past. The installed base is primarily going to Europe these days and the U.S. Europe, as you have seen from the numbers, Europe is doing very well for us. 4.4% growth in the current economic environment is extraordinary. The main drivers again are Italy and Germany that are taking lots of XLs, as well as France. The problem is that unfortunately it is frustrating, in France, you see a net negative impact due to the fact that Vitamin D really started from a very high number and is falling down, but there is a buildup of the LIAISON XL installed base also in that territory. I hope I gave you the right split.

Massimo Vecchio

Analyst, Mediobanca Banca di Credit Finanziario SpA (Broker)

Q

Yeah. Yeah. Yes. In China, you are direct in some areas, but you still use distributors in other areas. Is it correct?

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

In China, we – no. In China, we use distributors, as everybody else does. It's very typical of this country everywhere. But then we have a local infrastructure of service, people. We have sales manager, managing distributors, and we have marketing people. We have over 50 people dedicated to the Chinese market. And the difference is that whereas the LIAISON is sold in China to the distributor, for the LIAISON XL, we decided to use a different strategy because of the relevance of the platform strategically. We are not selling the XL to the distributor. We are placing the XL to the customers. We are servicing the XL ourselves, and the distributor is the one that is managing the reagent stream, so revenues are associated with the reagent.

As far as China is concerned, there's one thing which is very relevant. We expect by year-end to get approval of the full hepatitis and HIV line, and this is extremely relevant for us because the Chinese market for hepatitis is huge. There are over 200 million chronic hepatitis B patients in China. And we expect that going forward, our infectious disease footprint, which is the one we built around the TORCH and prenatal disease testing, would be further incremented using the hepatitis opportunity. So, China, we have short-term and long-term strategy because we have this whole new product line and we expect to be approved by December then we continue to feel going forward.

Massimo Vecchio

Analyst, Mediobanca Banca di Credit Finanziario SpA (Broker)

Q

Thank you very much, very useful.

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

Martin R. Wales

Analyst, UBS Ltd. (Broker)

Q

Hello. Good afternoon. Could we start with a simple clarification of your EBITDA guidance which is at constant exchange rate? What would the implied EBITDA be at current exchange rates, if it would hold for the rest of the year?

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Martin, I don't know, meaning that you're asking what would be – what would – sorry – definitely, should I understand, you're saying what would be the guidance at current exchange rate, right?

Martin R. Wales

Analyst, UBS Ltd. (Broker)

Q

Yes, precisely right.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Current meaning the first six months exchange rate?

Martin R. Wales

Analyst, UBS Ltd. (Broker)

Q

Meaning today's exchange rate, if it holds for the rest of the year.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

I don't have it in front of me. I don't know. We need to do a calculation. It's fairly complex because unfortunately, today we don't suffer from the exchange rate on the dollar side so, yes, because in Q1 and Q2, year-on-year, the dollar has been fairly flat. We expect to see an impact in Q3 and Q4 because last year, if you remember, the dollar in Q3 went – is up \$1.21, \$1.22 to the euro, okay?

Here today the major impact is related to two currencies where we have significant business. One is the reals which, as you know, is on a free fall, and the other one is Australian dollar. Australia, for us, is clearly significant. And these two currencies are getting weaker by the day, but again, it's a fairly complex mix and I don't even answer as far as what – how to translate to the EBITDA guidance.

Martin R. Wales

Analyst, UBS Ltd. (Broker)

Q

Okay. If we talk about Germany for a second, you indicated in the press release you designed some deals with various private lab chains. Can you give us a little bit more detail on that?

And secondly, now we're actually into the year, price cuts for diagnostic tests that your customers are suffering. Can you just reassure us that you're not seeing any price pressure as a result of that in Germany?

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

The deal we are referring to is the deal with press release is the Sonic deal. As you know, Sonic has been on a buying spree in Germany, and so we are really benefiting from corporate deals we cut with Sonic in Australia which...

Martin R. Wales

Analyst, UBS Ltd. (Broker)

Q

Sorry, I just thought when you used the word private, which I think you did, private laboratories, you meant for the non – obviously, Sonic's a quoted company, which [indiscernible] (33:30)

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

No, sorry. No, no.

Martin R. Wales

Analyst, UBS Ltd. (Broker)

Q

I see. I understand that, yes.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

This has nothing to do with financials. As far as price cuts, yes, we do see, let me say tightening of budgets and we do see price pressure overall, not only in Germany but throughout the continent. And this is why I believe that 15% growth in Germany, almost 6% growth in Italy, where the market pretty much have collapsed by almost 4%, is a fantastic result. So, we are delivering these results notwithstanding the price pressure that we see throughout all geographies.

But listen, Martin, these days, pretty much you'll see the same effect throughout the world because U.S. simply is – everybody's waiting to see what is going to be the effect of the reform. In China, the cut reimbursement, on average, by 5%, 10% per year.

Martin R. Wales

Analyst, UBS Ltd. (Broker)

Q

Okay. And in terms of your U.S. chemiluminescence business, obviously you've hit your target of 35 tests by the end of the first half. You've stated ultimately you would like to get to around about 50 specialist tests. Any sense of timeframe when we'll see the next tranche of test approvals because obviously you've had a phenomenal first half in getting tests approved there?

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

We have three tests, I think, submitted, and so we should get to 38 by the end of the year. And then there is another wave of products that we want to target, but some of these are part of a relationship with third parties, so I would prefer for the time being just to keep it confidential.

Martin R. Wales

Analyst, UBS Ltd. (Broker)

Q

Okay. And one – just again, another quick clarification. Could you just explain why the tax rate was higher in Q2 versus Q1? I didn't quite catch the explanation first time around.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

The tax rate, why in Q2 is better than Q1. Pier Luigi is going to address this.

Martin R. Wales
Analyst, UBS Ltd. (Broker)

Q

Thank you.

Pier Luigi de Angelis
Chief Financial Officer & Senior Corporate VP, DiaSorin SpA

A

Okay. The tax rate is higher because we had a different calendarization of the dividends. And in Q2 we got some dividends to pay – we've got some dividends from the state and this determined a higher tax rate. The second effect is this one, that we aren't having geographic results in Europe, for example, in Italy who is making more profit than other countries. And as you know, the tax rate in Italy is higher than the tax rate in the other countries. So the geographic concentration of the profit in the country where the tax rate is higher is determining this.

Martin R. Wales
Analyst, UBS Ltd. (Broker)

Q

Okay, thank you very much.

Operator: The next question is from Mathieu Chabert of Bryan, Garnier. Please go ahead, sir.

Mathieu Chabert
Analyst, Bryan, Garnier & Co Ltd. (France)

Q

Yes, good afternoon. Two questions, if I may. Carlo, you mentioned lately that you were open to a partnership with a larger player. I was wondering if you could give us some details from the set of discussion that you are having as well of the rationale of such a need for partnering.

And secondly, it has now been a couple of months since you launched the molecular products. Could you comment on the feedback you are receiving from customers? Thank you.

Carlo Rosa
CEO, Executive Director & General Manager, DiaSorin SpA

A

Yes. Okay, let me just discuss about the strategic partnerships. I need to step back one second to explain – to frame this within the current environment. What we have seen worldwide is that as pressure is put on the healthcare system to increase efficiency, finally, government understood that the real way to do it is not simply to put more pressure on reimbursement but to optimize labs. And you have seen this in France with the current tax incentive for small labs to consolidate. You have seen this, as we speak, in Italy, where in a lot of different provinces and cities, multiple labs are in the process of being shut down and consolidated into one lab.

So, what we see is that there is a tendency – and sorry, also in the U.S., which has been traditionally a consolidated market, if you think about the announcement that Quest made, that as part of their strategy to improve margin out of its 23 labs that they are running, they want to reduce it to eight. So there is a worldwide ongoing process to consolidate labs into, what is called in the industry, mega labs.

Now, mega labs already exist. And typically mega labs today, when they need to select a certain vendor for their routine products, they call the big suppliers, so the Roches, Siemens, Beckmans of the world, and they ask them to provide them product offering for, let me say, whatever they can provide, which is 60%, 70% of the routine test. And then once the lab is selecting the major supplier, then the lab goes and finds smaller suppliers for the products that the big companies cannot supply. This is what has been happening until yesterday.

Now, what we have seen recently is that for these big labs the situation is changing. So, the lab goes again to the Siemens, Abbott and the Roche of the world, but rather than asking them to provide only what they can provide, they ask them to form alliances and be able to make an offer for 100% of the testing that the lab needs. That means that these big players are forced to identify strategic partners to do business with. And by the same token, smaller companies like DiaSorin are forced to find alliances with some of the big partners in order to be able to serve this segment of the market.

In this sense, strategically, we have been having discussions with several companies. And it is our strategy to select a company that would treat, as a strategic partner, our view and our interest and then create a true partnership with this company in order to be able to address this segment of the market. The discussions are ongoing. This is a very relevant decision for DiaSorin because it means we want to select somebody that would be able to first give us the biggest possible opportunities in terms of our product offering and, by the same token, selecting a partner that we believe can be the winner in this particular segment of the market.

So, discussion ongoing and we expect that we will come to a solution to this and selection of the partner by year-end, the beginning of next year. We need to be very cautious on this because we are betting on somebody else.

As far as molecular is concerned, what we have seen is that, as I've indicated in the previous quarter, this is a market that is much more sophisticated than what we are used to. It's a market that is conducting thorough evaluations of products. And also, because of the complexity of the specimen that is tested and the variety of specimens, quite often they don't have it so they collect it from the clinical routine, and this slows down significantly the sale process.

However, at the end of this evaluation, you then have a customer with lots of loyalty because they have spent a lot of time in the evaluation phase. We do have now again over 30 systems, which are placed with customers, some of which we are evaluating, some of which have completed evaluations. We have a positive outcome from this evaluation in terms of appreciation of their technology. Work in progress, to make a long story short.

Mathieu Chabert

Analyst, Bryan, Garnier & Co Ltd. (France)

Q

Okay. Thank you very much for the details.

Operator: The next question is from Andrea Balloni of Fidentiis. Please go ahead, sir.

Andrea Balloni

Analyst, Fidentiis Equities Sociedad de Valores SA (Italy)

Q

Hi. Good afternoon, everybody, and thanks for taking my question. My first question is about CLIA ex -Vitamin D growth. The trend over the last three quarters was pretty strong, plus 19% in Q4 last year, plus 16% in Q1, and now plus 11%. A pretty strong trend, but looks to decrease. Just wanted to know if you can give us some more flavor about your assumption for the rest of the year. And since you mentioned during your speech, maybe you can give us also some guidance about 2014.

My second question is about Spain and the amount of receivable. Do you have anything about the amount that you would like to cash in in H2 is something in the range of €10 million like last year or something different?

And my last question, I apologize, is about tax rate again. I got the reason why tax rate has increased in H1, but I didn't get the guidance you gave about full year. Could you repeat it, please?

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

The guidance for the full year – for the full-year taxation is...

Pier Luigi de Angelis

Chief Financial Officer & Senior Corporate VP, DiaSorin SpA

A

[indiscernible] (44:41)

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

No, no, what we expect the tax rate to be in line with previous year, right?

Andrea Balloni

Analyst, Fidentis Equities Sociedad de Valores SA (Italy)

Q

Yeah.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Sorry. Again, as a reminder, we didn't – we never provided a guidance on taxation, but we expect that with the exception of this quarter where – as Pier Luigi explained to you, this is primarily driven by mix on one side but also by the fact that dividends were paid within the group. And so withholding tax was paid in moving some of these dividends from controlled companies to DiaSorin SpA. This is fairly exceptional. Therefore, we believe that a 37% tax rate – around 37% tax rate is what we would expect for the group.

Regarding Spain, what we expect to be – to receive in the second half is around €6 million. Remember that in Spain what happened – and so far in Q1 – in the first half we have collected €2 million, okay? Now, what is happening in Spain is very simple. The majority of the municipalities, they don't have the cash to pay for receivables. They receive cash centrally from Madrid and this transfer of cash happens once a year. So, to do – I mean – at the end of the story, the Spain DSO is going to be 360 days going forward until something is changing or will change in the way the central government wants to control and hand out payments.

Nothing to do with the fact that there is a risk associated with this receivable. These are all receivable with the public hospitals in Spain, and the receivable clearly is guaranteed by the Spanish government.

Andrea Balloni

Analyst, Fidentis Equities Sociedad de Valores SA (Italy)

Q

Okay.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Regarding growth of CLIA in 2014, we clearly don't discuss 2014 guidance. In terms of sustainability, we expect and said that the CLIA non-Vitamin D should continue to grow double digits in the next two quarters, all fueled by – you see the installed base, which is growing significantly, as well as the new products which we have launched in the last – in the previous quarters.

Andrea Balloni

Analyst, Fidentis Equities Sociedad de Valores SA (Italy)

Q

Okay. So we can assume growth stabilize in the range of 10% to 12% as shown in Q2?

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

As I said, double digit is what we expect and what we have been experiencing.

Andrea Balloni

Analyst, Fidentis Equities Sociedad de Valores SA (Italy)

Q

Okay. Thank you.

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

Peter J. Welford

Analyst, Jefferies International Ltd.

Q

Hi. Thanks for taking my questions. I've got, I think, a couple left. Firstly, just on the operating expenses. We saw sales and marketing tick up quite a lot in the second quarter year-on-year. Now, I appreciate your comments that, overall, operating expenses are growing relatively slowly. Should we anticipate the sort of trend for the first half to be representative, so sort of continuing slow growth of expenses, or is there something in the second quarter that happened that we should read into for the full year?

And then, just going onto – I guess, going back to Martin's comments about the foreign exchange. I think you said that the impact of foreign exchange on EBIT in the first half was about €0.6 million – I think it was €0.6 million; €1.9 million in the second quarter. If we look at EBITDA, therefore, if we take that €1.9 million in 2Q, would it be sensible at this point in time to assume a similar sort of €2 million foreign exchange impact in the third and the fourth quarters, and then should we use that to try and think about the EBITDA?

And then finally, just on Vitamin D in France. I guess when could we see the effects there of pricing a normalized? So if you could give us some sort of idea, I guess, about when pricing started to bite there. Thank you.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Yes, and on the ForEx – on the exchange rate, I don't want to add more to what I said and to what we have indicated. This happened in quarter one and quarter two. As said, I think, looking at quarter three and quarter four, there are other elements that you need to take into consideration, which have to do with the dollar. Don't forget, so far we have not experienced much on the dollar because so far in the first two quarters has been flattish compared to last year, but you will see an effect in quarter three, in my opinion. But no, I'm not a magician, so otherwise I would be in a different business.

As far as OpEx for sales and marketing, there are two effects. One, which is the majority of it has to do with what we have invested in molecular, which is €1.8 million in the quarter, €3.6 million in the first two quarters. If you compare – I'm sorry, this is growth versus last year. This will soften in Q3, Q4 versus previous year because we had the full operating structure in sales and marketing pretty much in Q4 and let me say half of it in Q3. So you will see less of an effect in the next two quarters because, again, by the end of last year we had the team already in place.

As far as Vitamin D in France, it's a very awkward combination. To be honest with you, I don't think that the major effect has to do with pricing. Pricing for Vitamin D in Europe has already been put under pressure a long time ago, and now it's fairly stable. This is more to do with two effects. The first one has been that we traditionally had lots of volume going through big labs where we were dominating, and then we still have the same accounts in the big labs.

However, viability of competitor assays on the very large installed base has grown volume from central labs. So, this has been a volume loss and this continues because the French market is – and it's true that it's over-penetrated, but it's still growing in volume. So you see more and more volume capture on the periphery by a variety of competitor platforms which are placed in many, many labs that are still available in France.

Let me remind you that in France today there are still – there used to be 5,000 private labs. Now it's down to 3,000, but there is a large, large number of smaller labs, much bigger number than anywhere else in Europe and very – and typically, these labs were send-out labs where we are not present because we don't have enough let me say product offering, putting together clinical chemists and immunoassay to be there, whereas some of the larger competitors do have platform there, consolidating all the lab testing of these small labs.

And what we've seen is that more and more volume is shifting from central to periphery, okay? The vast majority of these, in our opinion, has been done but maybe still some lingering effect in Q3 and Q4. But it's not price-driven. It's volume going from central to periphery.

Peter J. Welford

Analyst, Jefferies International Ltd.

Q

That's great. Thank you.

Operator: The next question is from Scott Bardo of Berenberg. Please go ahead, sir.

Scott J. Bardo

Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)

Q

Thank you very much for taking my questions. Yes, I just wanted to follow up a little bit further on the discussion you had about strategic collaboration. I appreciate that it's still relatively early, DiaSorin discussions here, but if you could help us understand what this could mean for DiaSorin going forwards. I mean, do you anticipate this sort of strategic collaboration being a joint venture or potentially taking some equity share in DiaSorin? Perhaps you could help us to understand how far you're willing to take such a collaboration, that would be helpful.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Listen, I don't think that this is the right time to comment on this. We are talking about commercial relationships. So, we are talking about selecting a partner we can work with in order to provide access to this strategic partner of our LIAISON XL platform in conjunction with their own systems in order to complete the product offering and put the strategic partner in a position to compete with other strategic partners in the very large consolidated mega labs where DiaSorin would be naturally excluded. So we're talking about commercial deals.

Scott J. Bardo

Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)

Q

Okay. Thank you. That's a very clear statement. I appreciate that. And secondly, just a very quick question on royalties. You mentioned that you're benefiting somewhat, particularly on the gross margin level, from the deterioration of some royalty payments that you've made historically. Can you perhaps just give us a little bit more detail as to why those royalty payments are falling away and how you envisage that continuing? Thank you.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

The royalty, well, it's very clear, it's Vitamin D. We used to pay royalties for Vitamin D to the two original inventors, [ph] lucky them, (55:16) and one – we have two of them. One payment was stopped at the end of Q1 last year; the other one was in December last year. So starting from quarter one this year, there is no royalties for Vitamin D. And this clearly helps in the gross margin – at the gross margin level. However, by the same token, let me remind you that there is now sales stock in the U.S., which clearly goes to a different line in order of gross margin that is hitting our business. So when you look at let me say overall effect on profitability on one side, you see the royalties going down, on the other side, you see the nice contribution to Obama going to the operate direction.

Scott J. Bardo

Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)

Q

Thank you. Understood. So given the strong gross margin development, I think 17% for the quarter, would you imagine – I mean I'm trying to understand whether you consider this to be abnormally high or something like a structural achievement that will likely progress going forwards? If you could just help us understand how you see that evolving, it'd be helpful.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Listen, I have been spending, I think, the last 18 months going around trying to explain to shareholders and potential investors that the big misunderstanding about this company was the fact that Vitamin D was an outlier in terms of the profitability vis-à-vis other products in this company is selling to customers.

Now, very clearly, we took a hit, a sudden hit, on price. Let me remind you that our overall Vitamin D – overall worldwide Vitamin D volume went up year-on-year the manufacturing volume. And what we have distributed, it was all price-driven, the effect that we have seen. By the same token, the CLIA ex-Vitamin D is going up and compensating the loss – the great loss we had on price of Vitamin D. And the mix has been – the mix of products that we sell as CLIA – in the CLIA non-Vitamin D business has a margin that has been able to almost offset the loss that we had when we – when the weight of Vitamin D was very high.

So to make a long story short, we have also tried, and I hope you appreciate the effort to provide you more read into our EBITDA margin in terms of also the erosion driven by, on one side, what we call the start-up company, which is the molecular business, and you see that we try to report, at least from a managerial point of view, the impact of the molecular and also some read into the exchange rate. Unfortunately, we are – the base currencies are going everywhere in different directions. And because of the weight of revenues in certain geographies, we are affected by it.

Now, long story to tell you, I believe that we have a certain profitability threshold of our immuno business that is sustainable, and this is what we have seen consistently in the last few quarters. I believe that it is just for a company like DiaSorin to invest in some of the proceedings in the new start-up, as I call – which is the molecular company, and give visibility how much that investment is and what the origin is. This is as much as I can say.

Scott J. Bardo

Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)

Q

That's very helpful. Thanks so much for the detail.

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

Maura Garbero

Analyst, One Investments Holding SAGL

Q

Good afternoon. Thanks for taking my question. I'm sorry I have to go back to the strategic partnership you just discussed before. And I was wondering if you can maybe share with us your thought about the risk of losing the direct relationship with your customers.

And secondly, how are you willing to deal with partners that can be also your competitors in certain tests? For example, I'm thinking about Roche with Vitamin D.

And a final question is if you can give us more color on volumes on Vitamin D in the U.S. as you gave some indication for France. Thank you very much.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Let me start with Vitamin D and then we talk about the strategic. The U.S. volumes, from a market point of view, they are, I would say, in general, flat. I would estimate it was small decline. And I'm saying it's very difficult to say because of the variety of different customers we have, the fact that they're buying each other out and also there are no worldwide – there are not U.S. statistics related to Vitamin D.

But if I read what the big commercial labs are saying, and I'm referring to, for example, Quest or LabCorp, I believe they have indicated that there is an overall testing decline that they experienced in Q1 and in the second half, something like 1%, 2%, 3%. So I would feel that Vitamin D being, general, limited today and its impact, I would expect that the overall market probably is flat to a small decline.

Now, as far as the strategic relationship, again, as much as I can say we don't intend to lose sight of the customer because we – and this is why we have ongoing discussions with different partners. The idea would be, again, to combine offerings, but DiaSorin being the one providing the system to the end user customer, selling to the end user customer through a contract that would include our products within products provided by the strategic partner.

In terms of competing products, yes, it's very clear that one of the elements that we'll need to keep in consideration in selecting who we want to partner with is also – has also to do with overlapping menus, a rule of engagement, vis-à-vis products that clearly we have and all these strategic partners don't have, but also some of the key products that we both carry on the catalogue. And this is why it takes time in order to dissect all these details before we come to a resolution of who's going to be the right partner for this company.

Operator: The next question is a follow-up from Romain Zana of Exane BNP Paribas. Please go ahead, sir.

Romain Zana

Analyst, Exane BNP Paribas SA

Q

Yes, thank you. A brief follow-up. Just the first one, a very basic clarification, but just to make sure. The stable EBITDA expected for 2013 is including the €6 million of cost associated to the molecular diagnostic platform, right?

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Yes.

Romain Zana

Analyst, ExaneBNP Paribas SA

Q

Yes, okay. And other question is regarding reimbursement in the U.S. We've seen CMS tightening reimbursement or even recording some assets. I was just wondering if DiaSorin has some exposure to these changes. Thank you.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Sorry, Romain, you mean for Vitamin D or for...

Romain Zana

Analyst, ExaneBNP Paribas SA

Q

For all the tests that you provide in the U.S. I mean, are you concerned by any reimbursement changes?

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

To be honest with you, as I said before in one answer I gave to one of your colleagues, I believe that the environment worldwide – nothing to do with the U.S. today – is an environment where prices and reimbursement – where reimbursement is capped and prices are put under pressure. No questions about that.

As far as the U.S. is concerned, don't forget that with the exception of Vitamin D which was an outlier, today the market is a very efficient market because you are talking about very large private organizations that drive through their labs lots of volume and they are very sophisticated buyers. This is very similar, for example, with Germany or Brazil.

So, there is a level of sophistication in terms of negotiation and volume today already, which – by the U.S. market, which is I don't think can be necessarily affected by reimbursement. I think that the problem is going to be more for the big labs – for the laboratory business rather than for us, or at least people like us that are selling products where – that do represent a relatively small portion of the cost of goods for the laboratories.

Romain Zana

Analyst, ExaneBNP Paribas SA

Q

Okay. Thank you very much and I wish you good holidays, if you take some.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

A

Thank you.

Operator: The next question is from Elisa Corghi of Intermonte. Please go ahead.

Elisa Corgi
Analyst, Intermonte Sim SpA

Q

Hi. Well, you have already answered. Thank you.

Carlo Rosa
CEO, Executive Director & General Manager, DiaSorin SpA

A

Thank you, Elisa. So I can go on vacation.

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

Luigi de Bellis
Analyst, Equita SIM SpA

Q

Yes, good afternoon. Just a quick question. You mentioned the volume plus 18% in first half in Brazil. Is it possible to have the weight of Vitamin D on total-facing Brazilian markets for DIA, and do you see this trend to continue going forward? Thank you.

Carlo Rosa
CEO, Executive Director & General Manager, DiaSorin SpA

A

Listen, again, yes, sorry. Unfortunately, Brazil, like the U.S., is a country where there are no national statistics. So we have no idea whatsoever what the market for Vitamin D can be for Brazil. One thing is for sure, it is highly underpenetrated, and so we continue to see quarter-on-quarter with very strong growth on volume requirements.

Last year – sorry – a couple of months ago when I was in Brazil, one of the major Brazilian weekly newspapers had a full article on what they call *la vitamina do sol*, so the vitamin of the sun, Vitamin D. What we have learned in Brazil is that it looks like there is an association today is promoted for well-being. And there is a certain number, as you know, of very wealthy Brazilians that are investing a lot in well-being. So a lot of driver – a big driver of the growth of the market is also given by that.

But to make a long story short, I believe that there is still a lot to go in terms of Vitamin D growth. However, as I said before, the Brazilian market is very sophisticated. It's made of big labs, so the price in Brazil today is already very, very competitive.

Luigi de Bellis
Analyst, Equita SIM SpA

Q

Thank you.

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

Carlo Rosa
CEO, Executive Director & General Manager, DiaSorin SpA

Okay. Thank you, operator.

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