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DiaSorin SpA *(DIA.IT)*

Q4 2012 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon. This is Chorus Call conference operator. Welcome and thank you for joining the DiaSorin Full Year 2012 Results Conference Call.

As a remainder, all participants are in listen-only mode. After the presentation, there will be an opportunity to ask questions. [Operator Instructions]

At this moment, 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. Good afternoon and welcome to the DiaSorin Full Year Results. I'm going to comment on the full year results, with focus on the last quarter.

First, let's discuss revenues. As usual, I will comment separately Vitamin D from non-Vitamin D sales. DiaSorin non-Vitamin D sales grew 14% in 2012, with an acceleration in quarter four where we experienced a growth in excess of 19%. In particular, sales were strong in Europe, Asia Pacific and in the U.S. and, in general, were driven by either the launch of LIAISON XL or the introduction of the new products in the previous quarter. All these clearly had positively affected the end of the year.

Worth noting is the strong growth, especially in Q4, of the instrument sales, which grew 40% over the previous year. This is related to the launch of the LIAISON XL in certain strategic countries covered by third-party distributors and it will affect positively reagent sales in the coming quarters.

Vitamin D declined 13.5% in Q4, mainly driven by U.S. pricing since all contract renegotiation which happened in the previous quarters are coming into full effect.

From a geographical point of view, Europe has finally shown signs of recovery and in all countries, I would say, with the exception of France that I will discuss later. In Italy, notwithstanding a sharp market decline of more than 4%, which has been reported by the local association of diagnostic manufacturers, DiaSorin grew 5% in Q4 and was able to offset the negative results of the first half of 2012.

In Germany, sales grew 8.6% in the quarter, and this is tied to the continuous growth of LIAISON XL installed base and the fact that we were able to sign up in the previous quarters some big laboratory chains and we saw the first impact in quarter four.

Finally, France. In France, we saw sales stabilizing after we have taken the hit on Vitamin D volume throughout the previous quarters. If you remember, we did discuss in the previous calls the fact that at the end of 2010 until the first quarter of 2011, a competitor withdrew the Vitamin D, we did benefit for increased volume in France, and this effect has disappeared throughout 2012.

Asia. In Asia, we saw an acceleration of sale, which grew 27% in Q4 over the previous year and it is mainly related to the performance of sales in China and the launch of LIAISON XL in certain key markets in this region.

In Latin America, we, as other companies, had been hit in quarter four by the strike of the ANVISA, which has limited our ability to import products through the months of October and November. So, we were allowed only to live with local inventory and a few shipments that went through. This clearly has affected our ability to supply customers. This is – has happened with many other competitors. And this explains why we had a very awkward fourth quarter in the region. Importation resumed regularly end of December and we're currently experiencing a regular flow of products and sales in Q1 of 2013.

In the rest of the Latin America region, sales continued to grow double-digit, especially in Mexico where the LIAISON XL was launched recently in Q4.

Now, let me comment on the installed base. As far as the installed base is concerned, placements of LIAISON XL were very strong. And in the quarter, we placed 125 systems worldwide, bringing the overall base of XL to exceed 600 units. So, this is a very good result for the company.

Now, I would like to discuss margins. As far as margins are concerned, it is important understand the reason for the erosion which we experienced in 2012 and particularly in quarter four. As you may remember, we predicted that Vitamin D would have affected EBITDA margins by roughly 200 basis points in 2012. What we have seen is in fact in line with expectation, with a contribution of price repositioning of Vitamin D of a little bit short of 250 basis points. The remaining 100 basis points of erosion were related to a different weight of instrument sales on total revenues.

Just for you to understand, this is especially true in quarter four, where instruments revenue grew 40% versus previous year and represented 12.5% of revenues versus 10.5% in the previous three quarters.

For your reference, in Q4 last year, instrument revenues were only 9% in the quarter. So, this has been an outstanding quarter in terms of instrument revenues. Again, this is related to the fact that we launched the LIAISON XL in similar geographies – strategic geographies covered by third-party distributors so there is an initial outflow of LIAISON XL to the distributor but very clearly this will start to contribute positively to reagent sales starting from quarter one.

However, as far as Q4 is concerned, there is a further element which has affected our EBITDA margin. This has to do with the fact that in quarter four, we now have the full commercial sales force which is dedicated to the launch of our molecular product line. So, it is the first quarter where we see full impact of – on the operating expenses level for our molecular assay.

Clearly, in 2013, these expenses will be offset by the fact that revenues would be generated for this product line. For the time being, we'll just see the cost associated with the start-up.

Now, I will move now to the financials and will allow our CFO to comment on it. And then, we'll discuss guidance, and then we will open up the Q&A. Pier?

Pier Luigi de Angelis

Chief Financial Officer & Senior Corporate VP, DiaSorin SpA

Thank you, Carlo. Ladies and gentlemen, good afternoon. Let me focus your attention on some key relevant points of 2012.

Looking at the profit and loss figure, it is worth mentioning our capability to achieve good results in terms of revenue. Despite the difficult worldwide economy, especially in Europe, which, combined with Vitamin D pricing pressure already commented by Carlo, affected our capability in growing double-digit across all the rest of the CLIA menu ex-Vitamin D.

2012 was confirmed a transitional year, where double-digit growth across all the CLIA menu and the Vitamin D decrease offset respectfully each other.

I also would like to stress the fact that today DiaSorin is the company with the largest menu of CLIA technology all around the world, having achieved the target of 100 assays on the LIAISON platform. The completeness of our product offering across the main clinical areas served in the immunodiagnostic market is positioning DiaSorin as a diagnostic specialist company, also able to serve the mainstream product demand from big lab chains and laboratories.

Another relevant driver of 2012 was certainly our LIAISON XL, which is gaining more and more importance also as we speak. As an example of the success, let me remind you that we had successfully launched the LIAISON XL last December in Shanghai, setting the base for a great success of reagent sales in such a relevant country.

And in Q4 2012, we also have achieved the approval for LIAISON XL in Brazil, where we are showing the market to get more relevant reagents revenues, thanks to the new analyzer installed. All these things highly correspond in the revenue achieved in 2012, which have totaled €434 million.

As far as the marginality of the group and on our capability to keep our margin high, Carlo already deeply commented on them. So, let me still only stress again the fact that we are comfortable in keeping an important marginality going forward, thanks to the fact that all our CLIA products enjoyed a stand up margin in line with

Vitamin D and that their revenue trend grew above 14% during the year, which had also in the last quarter of 2012 with growth of more than 19%.

I would like to also like to point out our capability in containing our operating expenses. If we consider 2012, the increase of 5.7% would have been 130 basis points lower when considering this expense at cost [indiscernible] (12:04) excluding the staff cost for the launch of the new molecular business, namely R&D, sales and marketing, operating and manufacturing cost.

We're also really comfortable on our capability in generating a substantial amount of cash during the year. Also, thanks to a wiser management of our networking capital, where we have been able to reduce the timing in cashing our receivable while keeping under control our inventory level, only up about €2 million negative vis-à-vis the end of 2011.

Last, but not least, let me focus on some other relevant figures of the company. Our net financial position was equal to €92.2 million before the distribution of a special dividend of €0.83 per share, equal to €45.1 million based on January 3, 2013. After the payment, the net financial position is still €5.5 million higher than the end of 2011.

In 2012, we have been able to generate again a consistent amount of cash. Our free cash flow was in fact equaled to €82.6 million, comparable to €82.7 million generated in 2011.

Our net result was still and again relevant to allow the board of directors to motion to the next shareholder meeting the approval of the distribution of dividend of €27.2 million, equal to €0.50 on each share outstanding, ex-treasury share, which is to be paid on May 23, 2013.

Carlo Rosa

CEO, Executive Director & General Manager, DiaSorin SpA

Thank you, Pier. Listen, let me just cover the guidance for the 2013, and then we move on to the Q&A session.

As far as revenues is concerned, we feel comfortable with a growth between 2% and 4% at constant exchange rate, and we expect molecular revenues to represent at least €5 million of the total revenues.

As far as EBITDA is concerned, we expect the EBITDA to stay flat in absolute value at constant exchange rate versus what we achieved in 2012, with an absorption from the molecular business equal to €6 million, and this is a result of the investments which are necessary to develop this business.

Very clearly, these finances are start-up. We have a lot of costs which are associated with sales, marketing activity, more research and development and, therefore, we still expect that in 2013, the molecular business will not be a positive contributor to our EBITDA.

As far as guidance for new system installation of LIAISON and LIAISON XL, we believe that we would exceed 550 in place in 2013.

So, I would now open the session for Q&A. Thank you.

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 Romain Zana of Exane BNP Paribas. Please go ahead.

Romain Zana
Analyst, Exane BNP Paribas SA

Q

Yes. Good afternoon, gentlemen. Thanks for taking my questions. I have two, actually. The first one on Vitamin D. You detailed in the press that Vitamin D in the U.S. was down around 21% in the full year 2012. Could you tell us what was the underlying volume market growth in the U.S. on Vitamin D? And also, the same question for Europe.

And second question is rather a big picture question on margin. Your 2015 guidance suggests that the EBITDA margin will return to the level above 42%, so in the long term. Do you still believe that it is realistic and, if yes, what should – why should we see a reversing trend at some point of time? Thank you.

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

A

Yes. Romain, I'll take the Vitamin D first. The Vitamin D growth in the U.S. was simply not there. We – in terms of volume, we estimate that the volume – that the volume has been quite flat vis-à-vis the previous year. The best way for us to judge what the market does is to look at our largest customer. It does represent a significant share of the U.S. market and in fact those volumes were flat. We reached – the U.S. market has reached now a very high level of penetration and Vitamin D has become a routine parameter there, also for the annual physical checks. So I don't expect to see any positive volume contribution going forward.

As far as Europe is concerned, as we have discussed many times, I think that it is very different from country to country. There are countries like Italy and Germany, for example, where we still have growth between 15% and 30%. Other countries like France, where it's more flattish as far as volume is concerned. Very clearly, the appearance of more and more competitor has affected the pricing compared to what you had seen, for example, two years ago, not to the same extent of the U.S. but marginally there has been a price effect in Europe as well.

Other geographies, I think in Australia, still you see a single-digit growth, which is outstanding seeing the level of penetration. And another very large market, which is Israel, I think with the only exception that I've seen in the world so far where a conscientious effort has been made to educate certain physicians not to test Vitamin D and we have seen decline of volume in Israel between 10% and 15%.

Now, as far as margins for long-term vision, when we have prepared the plan in 2010 – yes, 2010 was presented in 2011 – very clearly, it was a different world in two ways. I think it was a different world from a financial point of view because we have seen that the things have changed significantly, especially in Europe, after that date. And second, we made an assumption of the kind that Vitamin D would have been flat so we were expecting – we were expecting volume to become flat.

In competition, clearly, we did not foresee the effects of some limited-time crazy pricing that some competitors have applied especially in the U.S. So [ph] we owned (20:24) to ourselves a plan that will be issued by the second part of this year. And I just want to understand how stable is the European market and how can we rely on that and, based on that, we can put together a forecast that we issue to the market for sure by the end of the year.

Romain Zana
Analyst, Exane BNP Paribas SA
Q

Just two follow-up question on that, if I may. For the guidance, am I right to understand that a nice target for you now would be sustain the level of margin looking forward?

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

I think so. I think so, but there is one thing that we are doing internally and I will try to – let me say, to find a way at least to give you an indication how to model the business.

Very clearly, today, we have two businesses within DiaSorin. One is our immunoassay business, which is a business that is following a certain dynamic. And then, there is a start-up business, which is the molecular business that is absorbing investments, being a start-up, and is clearly growing at a different pace.

We will try to provide you with elements where we tell you how much out of the profitability of the – let me say, of the overall business is being eroded by the investments that we are making on the molecular because it becomes significant. It does clearly affect the profitability today, and I want to make sure that everybody that understands that some of the erosion not necessarily related to the Vitamin D, but is related to conscientious investments that this company is making to develop a molecular franchise.

Romain Zana
Analyst, Exane BNP Paribas SA
Q

Okay. And very quickly on retaining the pricing. So you said that in the U.S., you expect a roughly flat volume. And on the pricing side, I mean, is the bulk of the pricing pressure is now behind us, or what would be the magnitude of the pricing pressure do you expect over the next couple of years?

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

I feel the – I believe that the bulk of the pricing pressure is behind, meaning that the repositioning of the direct business that we have – has been throughout as we discussed in the last call, so in 2012, very clearly. Unfortunately, just mathematically, we will feel still some of the effect in 2013 because we will have the full year effect of pricing renegotiation. But the last call – or actually the contracts that we have signed today in the U.S. have a pricing which is in line with what we sell in all the major markets worldwide.

Romain Zana
Analyst, Exane BNP Paribas SA
Q

Thank you very much. And sorry for having been a little bit long.

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

[indiscernible] (23:26).

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. I have three questions. The first on CLIA ex-Vitamin D products, if is it possible to have an indication regarding the expected growth rate for this kind of product for 2013 and the main test expected to contribute on 2013.

The second question on Vitamin D, could you provide an update regarding the timing of the Vitamin D test approval in Japan and expected the contribution in 2013? And the last question on U.S. market, could you elaborate on your growth strategies for the U.S. market, both organically and, potentially, via acquisition? Thank you.

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

A

Yes. CLIA ex-Vitamin D, as you have seen, the growth is spectacular, I would say, with a 19%. And also, it's accelerating throughout the year. I believe – with, and without really giving any specific number, I believe the certainability of high double-digit growth for this product line is realistic.

Keep in mind that in 2013, we have the launch of the XL in two key strategic areas, one – which happened, by the way, already at the end of last year – one is China and the other one is Brazil. And these markets are clearly known Vitamin D markets. Plus, what has been really re-assuring for me, at least in the last two quarters, is the fact that in Europe we have seen a recovery. Let's hope it will last. But at least a stabilization, so we don't see erosion of volume any longer and, therefore, all the platforms – all the new business which is non-Vitamin D business that we added throughout 2012 is now able to show the contribution. There was a contribution also before, unfortunately it was taken out by the volume erosion that we have seen in Q1 and Q2. So high double-digit is something, I would feel comfortable with.

As far as the U.S. market strategy, very clearly, what we have been trying to do since the availability of this early is to rush and reposition our effort into non-Vitamin D sales. And the non-vitamin D products, although not be shown in the chart, but it grew over 30% versus previous year. We sold more than €10 million of non-Vitamin D products in the U.S. Unfortunately, the different scales still compared to the Vitamin D, so the ability to offset the Vitamin D loss in price is not there yet.

However, in order to increase the growth of sales development, as you know, we've started last year with a project to increase mainly in the U.S. We have a target of reaching 50 new assays available on the LIAISON XL starting from the current 25. We have – these products that we are bringing today, U.S. have divided into exempt products and in registered products. So, we're clearly focusing on the one that required the 510(k) approval. We got three so far. And I expect that in quarter one, we should get a way of – I'm just going by memory, I would say, between 6 and 10 additional that should be able to be either approved or being exempt – distributed in the U.S. market.

So, the strategy is clearly there. The products have been brought to the market, the XL. We now have, I think, more than 100 XLs installed in the U.S., and all the new placements, early on XL. Again, it takes a little time because of the size of the business of Vitamin D in the U.S.

Sorry, there was another question which was on Vitamin D, what was that?

Luigi de Bellis
Analyst, Equita SIM SpA

Q

Yes. It is...

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

Japan, Japan, Japan.

Luigi de Bellis
Analyst, Equita SIM SpA
Q

Yes.

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

I am as frustrated, I believe, as everybody else. I expected – I hope I could be the good news by this conference call because we are just waiting for the Ministry to signal the approval. Unfortunately, we didn't get it. Our expectation in 2012 is that – in 2013, sorry, for Vitamin D in Japan is that once launched, we should get a contribution in, let say, between €500,000 to €1 million of revenues because of the relatively rapid adoption of these tests and because of the fact that we already have system installed in the big lab that's waiting for the orders to come in the reimbursement. It is Japanese bureaucracy. All we had to do was done, we're just waiting for Ministry to approve.

Luigi de Bellis
Analyst, Equita SIM SpA
Q

Thank you very much.

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

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

Hi. Good afternoon. So I just got a quick clarification on your guidance, first of all. Now, you're talking about 2% to 4% constant exchange rate for annual revenue growth. Is that including or excluding the €5 million from molecular diagnostics? And a similar some question on EBITDA, when you're talking about flat EBITDA, is that including or excluding the €6 million loss?

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

Martin, it's both yes and yes. Yes, it does include €5 million of molecular. Yes, the flat EBITDA includes the €6 million erosion which is related to the negative contribution or absorption of the start-up Molecular business.

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

Okay. And in terms of Vitamin D pressure still to come in 2013, I know – I appreciate [indiscernible] (30:16) could be there's an effect from the fact you didn't lock in all the prices at the beginning of 2012. How much of a headwind is that 2013 to the extent you're prepared to quantify?

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

The line is not very clear.

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

Q

Sorry. I'm trying to ask you to quantify the further pressure on revenues from Vitamin D in 2013 given that you've seen the full effect of the last round of price cuts at the end of 2012. Assuming there are no more price cuts for Vitamin D, how do we think about that franchise developing across 2013?

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

A

Listen, ballpark, I expect that the effect in 2013 will be in excess of €10 million.

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

Q

Okay, that's clear. In terms of your molecular diagnostics franchise, does it breakeven in 2014 or is that too early to think about it breaking even?

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

A

I think it will breakeven. But as we speak, to be honest with you, I'm more concerned about sales development. Now, this is – if you think about it, if we had to buy any sort of start-up [ph] training (31:37) to have, let's say, technology for molecular without revenues, one would say in excess of €100 million, that is what the price tag today associated with anybody claiming to have something. Okay, we decided to go different way, we decided to develop it internally with – through R&D efforts and licensing, so there was a cost – there is a cost associated with this, which is in OpEx.

There, I think, that in terms of size and profitability, DiaSorin has enough resources to fund all of this. So I'm not really worried necessarily about breaking even but I'm worried about developing an installed base of LIAISON IAM system and extraction business because I know that the profitability will come. And I know it because the standard cost of manufacturing, which is a very relevant part of this path that we took, is extremely favorable. So today, the effect that you would see is the OpEx effect that you need as a set-up costs on a relatively small business and it's going to diluted further when the business will grow.

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

Q

Okay. Could you give us a little color on how successful your new gastrointestinal infections franchise has been so far and what you now expect from that?

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

A

You mean the [ph] two assay (33:05), right?

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

Q

Yes.

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

A

I think that we spent an awful amount of time in developing awareness; awareness, meaning that going to labs and providing – breaking the news that they can switch over into our platform. Unfortunately, until the beginning of quarter four when we launched the GDH assay, we hadn't a complete panel, because the current guideline, especially for C. diff, requires the use of two assays, GDH as a screening and C. diff as a reflex. And we had the C. diff but we just added the GDH.

So I expect that with lots of successes, so we had installations, we have customers, I expected to see the impact in terms of revenue generation in 2013 because now we have the full panel. Now, also, there is a reason for other customers to implement [ph] routine (34:12) on the assay and switch over from the current assays to full automation. Keep in mind – remember that one of the fundamental assumptions that we had was – has been proven right; the end user price for this product is extremely high. But the profitability of this line is there.

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

So if I read you right, we're about five months into when you had full panel that you needed. Can you give us any color on how you progressed in recent months?

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

I don't think I want to comment on progression, Martin. I think that we will comment on development of the stool assay going forward throughout 2013.

I'm feeling comfortable again for two reasons. Now, the basic menu is there and I think there are three more products which are expected to be launched in 2013. I think that pricing is extremely favorable and extremely well received by customers because they are able to pay for automation, so very high margin contribution even if with big products there is a royalty being associated with it which goes back to, in some cases, to Meridian, as we have disclosed, and there is no competition to the [indiscernible] (35:39). So, we will comment about these in – when the quarters will develop.

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

Okay. And just a final question on your U.S. strategy, following up on previous question. When you – how long do you think it will take you to get from 25 assays to 50 assays and anything you'd particularly highlight as real opportunities in the U.S. that you'll be able to take advantage of from these new product launches?

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

As I said before and originally, we have a target in mind to get to 50 assays reasonably by, I would say, mid next year. I expect that as soon as the 510(k)s, the first three ones already came in, as soon as the 510(k)s will come back and be approved, we will have – we will pick up momentum. As said, there are a bunch of exempted products which are ready because they are related just to internal validation studies, these have all been done and ready to be launch. However, we cannot introduce this to the market until the 510(k) products will not be approved. So I will say Q1 and Q2 are good quarters when we will start to see completion of the panel and moving forward.

Don't forget though that today we have something very interesting in DiaSorin in the U.S., which is now the full migration and the viability of a good portion of the infectious disease assay that we have available under LIAISON now are being migrated to the LIAISON XL. And so, we have -notwithstanding the fact that we are making some

of the new assays, we do have all the existing assays now available on the platform. And then, we can start a strategy clearly to go after the hospital-based business using LIAISON XL.

Okay. One of the problems, as we discussed before, about the U.S. is that the size of the Vitamin D business is so significant that we need to continue to develop our existing sales and revenues associated with non-Vitamin D in order to be able to stabilize and affect and see growth again coming from the U.S. market.

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

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, yes. Thanks for taking the questions. So firstly, just on molecular diagnostics then, if we come back to, I guess, Martin's question on the €6 million loss. I mean that suggests from the comments you've made sort of operating spend on this business is about €10 million, I think, this year. That €10 million, if you like, on sales and marketing, investment and building of this franchise, is that then leverageable or should we see that – is that cost base just the initial sort of infrastructure in place, do we anticipate it to grow in the future too?

And then, secondly, on the sort of overall revenue growth of 2% to 4%, I guess I'm just trying to understand the levers in that outlook in so far as you said obviously now that the non-Vitamin D businesses has surpassed Vitamin D, which suggests therefore that if that's going to continue growing at double-digit, that that business alone should be able to drive some pretty good top line growth. So, I guess I'm wondering what is the headwind, if you like, the business – is going to be the biggest headwind during 2013 to result in an overall sort of potentially 2% growth on the top line. Thank you.

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

A

Okay. Yes. You need to keep in mind that, today, there is a third component to our business, which is the traditional ELISA and the Murex business, which are still represent, I think, altogether, €70 million, €80 million worth of business.

That business have two components. One is to do with Murex, which is, let me say, a relatively steady business. No growth. Very clearly is not a growth contributor, but is a fantastic cash cow and a lot of strategic important, core asset, we discussed many times. But then, there is the remaining business, which is traditional RIA and ELISA, which is declining. Declining then – so there's some headwind that we need to face year-on-year. It is declining simply because the technology is disappearing and some of these RIA technologies are already dying off.

So, when you look at 2% to 4%, you need to take into component three elements of the business: very strong growth of non-CLIA – sorry, CLIA and non-vitamin D, the headwind related to Vitamin-D; then, Murex, which is stable; and the traditional business which is declining, a great cash cow but is declining.

Your second question was on molecular. And I think if I understand correctly, you said are you done – I mean is this the cost that you're going to incur – that you will continue to incur into or this is going to materially increase. Is this the sense of your question?

Peter J. Welford
Analyst, Jefferies International Ltd.
Q

Yes, exactly. I think it's about €10 million by looking at the back of the envelope. If you take – so, I was just trying to work out how that €10 million could evolve over time?

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

Listen, I've seen that there was a – that this is of the top. So we're going from pretty much zero to €10 million, and this is a result of research and development. But I would say, lately, especially starting in quarter four, I think the same is mainly to do with the set up of the commercial organization.

Now, today, we have a commercial organization set up in Europe, U.S. and Australia. It is, in a sense, some countries minimalistic, meaning that we hire people from competition, we put together small teams and we are starting promotion with these people. Very clearly, as soon as the revenues will come – and in order to push revenues up, where we expect them to go, we're willing to invest in – I'm not expecting a big investment in research and development, but I expect that the marketing and sales costs will grow and will continue to grow proportionally to the growth of revenues.

One thing of this molecular business that you need to understand is that salaries, especially associated with sales people, are significantly higher than what you pay for the traditional business. And this is very simple to explain; most these sales people are PhDs, because this is the – this is still a sale which is strongly associated with the content rather than system.

Peter J. Welford
Analyst, Jefferies International Ltd.
Q

That's great, thanks. So, could I just follow up with one other quick one, which is on Murex? We saw a quite a big decline in the fourth quarter. I realize 4Q in 2011 was abnormally strong, if you like. Is that the only effect what we're seeing in Murex with the drop-off in 4Q or was there some other factor? That's it then. Thank you.

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

No, it has to do with two things. As we discussed before, and this is in Brazil, because if you remember, Brazil is big – is a good portion of our Murex business, along with China. And the second thing had to do with shipments that happened in Q4 last year and simply for a matter of seasonality did not happen.

Overall, you have seen the business of Murex have been flattish so – and I expect it to continue to be a very nice opportunistic business, very profitable for us. But again, if you remember, we bought this business for a different reason, which was to give more creditability to our effort on Hepatitis and HIV which clearly does result into growth of the Hepatitis brand under LIAISON XL.

Peter J. Welford
Analyst, Jefferies International Ltd.
Q

Great, thank you.

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

Maura Garbero
Analyst, One Investments Holding SAGL

Q

Good afternoon and thanks for taking my question. The first one is on the instruments. Can you possibly give us an indication of what we should expect in 2013 compared to 2012 in terms of instruments on total revenues?

And the second question, how many of those new placement will be sold rather than only placed, as you traditionally did, as you are growing more into emerging markets?

And the final question, would it be possible to have the breakdown by technology, the top line, as you were used to report? I mean, including Murex, because nowadays it seems that CLIA contributes to 73%, but at the nine-month was around 67%, but then I realized that you changed the performance of that [indiscernible] (45:21)

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

A

Okay. In terms of what should be the weight of instrument sales, so, remember, it has been 10%. And I think that for your modeling, you should continue to use 10%. It could be – it could go up and down, depending on different quarters. And in 2012, it has been more significant simply because we launched the LIAISON XL in certain geographies where we act through distribution. And that is why you've seen spikes, especially as we've discussed in Q4 where, as I said before, instruments EBITDA represent twelve-point – I think – five-percent of total revenues.

What was the second question again? The weight of CLIA versus non-CLIA?

Maura Garbero
Analyst, One Investments Holding SAGL

Q

Yes, yes. If you look at the breakdown of your revenues by technology, you're now netting Murex which is a different contribution than what it used to be?

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

A

I'd say, CLIA is 73.5% versus 10% of ELISA and 4% RIA.

Maura Garbero
Analyst, One Investments Holding SAGL

Q

And that compares – using the same breakdown, that compares to the nine months? Because of the nine months, looking at the same table, the figure was 67%?

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

A

You mean in the quarter, right? You want to know the weight in the quarter?

Maura Garbero
Analyst, One Investments Holding SAGL

Q

Yes.

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

I don't think I have it – I don't think I have it with me. I would...

Maura Garbero
Analyst, One Investments Holding SAGL
Q

It's just because you used to give it including Murex and now it seems that you are taking out Murex.

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

Yes.

Maura Garbero
Analyst, One Investments Holding SAGL
Q

So that leaves a pretty different breakdown between CLIA and ELISA, but it doesn't matter. And then, if you just come back to the final question I had on the instruments, how many of the instruments will be sold and placed of the 500 – or more than 500 new placements you're targeting?

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

I believe, listen, probably, a quarter of those will be sold and the rest will be placed. I'm just going by memory because I don't have the data of the plan in front of me. But I would say that these could be a realistic number.

Maura Garbero
Analyst, One Investments Holding SAGL
Q

Thank you.

Operator: The next question is from Maja Pataki of Kepler. Please go ahead.

Maja S. Pataki
Analyst, Kepler Capital Markets SA (Switzerland)
Q

Yes, good afternoon, gentlemen. I have, actually, only one question left since everything has been asked before. I was just wondering if after the first – initial few weeks, months, on the molecular side, you could give us a bit of an update on the feedback you received from existing clients. And as I recall, you're planning to target new customer and new market segment. I was wondering if you have already some feedback and if you would be willing to share that with us. Thank you.

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

I think that, so far, we have – I would – again, going by memory, I would say between 10 systems and 20 systems which are being installed in different geographies. And installations have been mainly driven by the infectious disease, [ph] which have the total debt – have been (49:29) installed.

Very clearly, being new comer to this field, what it takes now is time for customers to do the evaluation around comparisons to PCR, and we expect to have a publication coming out of these initial evaluation which has

happened, I would say, mainly in England and in – now in Germany and Italy, which are in this sense very sophisticated market.

So today, we are putting the effort in building awareness of the technology and the brand. And so far, I would say, so good.

Maja S. Pataki
Analyst, Kepler Capital Markets SA (Switzerland)
Q

And just a quick follow-up on that. Did you encounter any reaction that you didn't expect? I mean something that had significant impact on your strategy going forward?

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

I don't know what you mean about this. I think, to be honest with you, I'm very pragmatic, so I think it will be very difficult to make a final assessment either on a bad reaction or getting excited on a good reaction. I think that we started the deployment, we are running clinical studies, we are running evaluations.

And as said, I don't see any roadblock in terms of our strategy. What I see – what I see is – clearly, is that this is not a typical sale as it happens with LIAISON XL, where the level of sophistication of the evaluation on the customer is different. In that case, quality and results are given for granted, so it's more – the discussion has more to do with the flow of lab and efficiency. In this case, you're back to where immunoassay was 30 years ago. So, it's more content and analytical results, and this is why it takes time for this customer to run the evaluation.

Keep in mind that the other thing which is relevant is that for lots of these products, you study evaluation from fresh blood and not from frozen blood, which means that in order to evaluate, you need to enroll patients, collect samples. It's a completely different business. It's really more research and development-driven rather than productivity and workflow. So, so far, so good.

Maja S. Pataki
Analyst, Kepler Capital Markets SA (Switzerland)
Q

Thank you.

Operator: The next question is from Sachin Soni of Kempen. Please go ahead.

Sachin Soni
Analyst, Kempen & Co. NV (Broker)
Q

Good afternoon, everyone. My question is regarding new system installed guidance. Looking at what you installed, roughly 125 in Q4, is 500 not a bit too low or – since it's globally? And then, the other thing is, is it the global target or is it just a key countries' target? Thank you.

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

Listen, I think that 500 is a very – is a good number, especially in the current environment. And clearly, this is for global use. We open up more markets than we used to have before, so we have more access to bigger market. But I believe that overall, 500 is a reasonable target for the organization.

Sachin Soni
Analyst, Kempen & Co. NV (Broker)

Q

Okay. Thank you.

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

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

Okay. Thank you, operator. Take care. Bye-bye.

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