

# **DiaSorin SpA**

## **“Full Year 2016 Results Conference Call”**

**Wednesday, March 08, 2017, 15:00 CET**

MODERATORS: CARLO ROSA, CHIEF EXECUTIVE OFFICER  
PIERGIORGIO PEDRON, CHIEF FINANCIAL OFFICER

OPERATOR: Good afternoon. This is the Chorus Call Conference operator. Welcome and thank you for joining the DiaSorin Full-Year 2016 Results Conference Call. After the presentation, there will be an opportunity to ask questions.

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

CARLO ROSA: Yes, thank you, operator. Ladies and gentlemen, good afternoon. I will make a few comments on the results that we achieved in 2016 and then our CFO, Mr. Pedron will take you through the numbers.

Well, first let me comment the fact that results were extraordinary in terms of revenue growth and profitability and the revised guidance, and improved guidance that was provided in the media in 2016 was actually met both in terms of sales growth and EBITDA.

As far as profitability at €130 million and cash flow of over €130 million, these established a new record for the Company and in that consideration the Board of Director has proposed a dividend of €0.80 which is a 23% increase over the dividend that was paid by the Company last year.

Now, before we talk about the business, I would like to make a comment regarding the three years plan which is...we'll do...the Company will schedule a three years plan presentation for the last week of June, and in that meeting we are going to give lots of color about our Molecular strategy and our Immunoassay strategy for the next say three years. So everybody is going to receive a saved date for one of the days in the last week of June.

Now, if I may start commenting the business, I would like to start Molecular, let me remind you that the Molecular business they does

represent roughly 75% of the total revenues that provided by the focus business that I remind you was both from Quest in May last year. The Molecular business is growing in North American...which is mainly today in North America, is growing double-digit as expected, and we continue the expansion of the business in the hospital setting in the US.

If you remember when we discussed about this acquisition, we saw two strategic elements of this, one was to allow DiaSorin to better penetrate the hospital market in the US, allowing Molecular and Immunoassay to grow together, because we believe that our platform also for Immunoassay in the US can benefit from this success. And the other opportunity that was provided was the fact that the focus business was mainly US driven, whereas DiaSorin having a commercial network throughout the world can really take this business and expand it outside the US.

To that regard, we have initiated and I think we are halfway in transferring the business from the current ex-US distributors that were used by Focus to the DiaSorin subsidiaries. We have completed actually in last year the acquisition of the Australian business that was fairly relevant in Australia, and was transferred to us with some of their personnel from the distributor, so starting January this year, we are direct in Australia. And we are concluding similar deals in Europe and in Israel with the intent by June of this year to have pretty much under control the distribution on Molecular throughout all the main geographies.

As far as new product development is concerned, we are clearly investing in research and development. Let me remind you that when it comes to our Molecular franchisee, the R&D investment is close to 15% of total revenues, whereas traditionally our Immunoassay franchise we have spent between 4%, 5%, 6% depending on the years in supporting the business.

So clearly, the different scale or by the same token is a different reward vis-à-vis the growth.

And in that regard, we launched the first product which is a C. Difficile SA. We launched in Europe in Q4 and it was recently approved by the FDA in February. So, we also launched it in the US market, and so we'll continue. I would say the success in research and development that has been the history of this Company, one of the reasons why we decided to buy, invest and get this technology from Quest.

As far as the rest of the business, there are two opportunities, I would like to underline the first one is Zika. As you know, we have been awarded with financial support and political support by BARDA in the US to develop a Zika [ph] kit for LIAISON for the US market, we have submitted as IUO the product. And we expect that the product is going to be approved in quarter one this year, so we expect that after quarter one, we will be able to introduce Zika to US customers.

Let me remind you that today in the US, there is only one LIAISON product approved for Zika and there is a Molecular product approved for Zika. And so, there is a high demand by labs in the US driven automated solution, because there are some volumes are developing and certainly there is volume concentration in some of the big labs, because from the peripheries of small hospitals and from the smaller labs, everything is funded through the very large labs, where DiaSorin is traditionally present. So, we expect that Zika will provide DiaSorin with a growth opportunity starting from 2017.

The second point I would like to discuss has do with the Beckman Alliance which has been a great success for us in China, it's an operating relationship with Beckman, allowing us to cover the segment...the

growing segment of the very large Class 3 hospitals in China, which require automation. And by the same token, we have announced that the same relationship has been established for the US with the core investment to take the DiaSorin products through the FDA. And we are in the process of preparing the clinical studies and conducting clinical studies in order to file for the FDA...to the FDA for approval of the full hepatitis line.

So I...to me this is a strategic move because, it would have been difficult for DiaSorin to reach the US market, or the opportunity of the US market for hepatitis which I remind all of you excluding the blood bank business segment, which is fairly unique is close to \$500 million. So the fact that we do have an alliance with Beckman will allow us to certainly a faster penetration to that market.

Now, if we go back to what happened in 2017 and...sorry 2016, and how things are developing in Q4 last year for...in terms of different geographies, I think that we continue to experience trends that we have seen in the past with some good new elements of growth.

As far as Europe, notwithstanding the fact that we discussed that Italy continue also in Q4 to be weak, we experienced a 4% decline in revenues in Italy. Notwithstanding that, Europe continues to grow 5% per year, which is in my opinion a tremendous result considering the level of consolidation that is happening in Europe.

France, after we took a hit on Vitamin D in 2015 and in 2016, the business stabilized. And I remind you that the hit in Vitamin D was related to a change in reimbursement in France. And now, we...France is a net contributor to growth again for the Group, in part supporting the decline of the Italian market.

As far as the US is concerned, we see overall relatively small growth, plus 1% year-on-year. And as, you know, is a combination of strong double-digit growth of the CLIA xD business. And decline of the Vitamin D franchise for reason we have been historically discussing and they are all with the same, it pretty much has to do with continuous price erosion, which we continue to see.

Overall, our Vitamin D franchise globally has declined around 4% in Q4 and this is in line with our expectations we discussed this in previous calls and in line with the three years plan that we presented in 2016. So no surprises, as far as, Vitamin D is concerned.

As far as xD, so all the other products with our CLIA LIAISON technology where we registered a growth overall of 13% in Q4, 11.5% back to double-digit growth. We have some...certainly we do see strong growth coming from some of the emerging countries, including China which today represents close to 10% of our overall revenue with gross of 30% year-on-year, so it's phenomenal results.

But by the same token, all these products are really today are becoming relevant also in the US, because of the success we had with strong alliances in the past with the very large labs. And I think we are progressing quite fast in developing our CLIA xD business also in some of the very large US laboratories that we are missing to our list. And we believe that in 2017, there will be an opportunity in the US to consolidate this CLIA xD business also in one of the largest accounts that...to that we are not serving in the US. So I can see a lot of traction for the xD business in US.

As far as Asia...Asia Pacific, with overall growth of 13%, with a phenomenal results that come from China, we are now close to 1,000

systems installed. I think last year for China was a record year, we installed almost 200 systems as a combination of the LIAISON and LIAISON XL.

And we see now, the LIAISON XL being extremely successful not only in the Class 3 hospital, but also in the Class 2 and some in the Class 1. And this is fundamentally due to the fact that volume is being increasing, so dramatically in this...even in the periphery, in the smaller hospitals that the business is big enough now to sustain [ph] placement for LIAISON XL, and this clearly increase the base of potential customers by 5,000 hospitals which we plan to attack in the next years.

Last but not least, we have been discussing in the past about the poor performance of Brazil. And interestingly enough, Brazil is back to growth...into double-digit growth, and this is...it has to do with the fact that we retrench...we limited our business to private accounts, so accounts that today are not dependent from the public system. And as on net result we are developing a very healthy business with a very healthy DSO.

So we also collect the money. And this clearly is making our South America now growth engine again. We I think commented already about Mexico. Mexico even for us is a relatively small business, although we were awarded by a very large vendor that has allowed the company to penetrate the blood bank business, and we believe that Mexico very soon can reach finally a size of around €10 million for us, so it becomes a significant business comparable to some of the European subsidiaries we have, but with the growth rate, it is clear...that working what we see in the more consolidated European market.

Last but not least, when it comes to the result placements, we placed net of 520 systems last year with an excess of 570 LIAISON XL, and clearly we

had...that we are withdrawing some or we say substituting some of the LIAISON that are coming to obsolescence. Where we are not actively promoting any longer the LIAISON business, but everything we have a chance and the system are obsolete.

We do introduce the LIAISON XL in waiting for the launch of the LIAISON XS, that, you know, is a small platform that we envision to be available to the market in 2019. As far as the LIAISON XS, we are today working with the prototypes we have received from Stratec, so we feel that the project is in line to our expectation and again, we expect to see marking and launch in 2019.

And last, but not least, new guidance for 2017. We expect the business to grow at constant exchange rate at 11% both for EBITDA, as far as revenues.

So now, I will leave the podium to Mr. Pedron, and he is going to take you more carefully through the numbers. Thank you.

PIERGIORGIO PEDRON: Thank you, Carol. Ladies and gentlemen, good afternoon, in the next few minutes, I am going to walk you through the financial performance of DiaSorin during 2016. As usual, I would also make some remarks on the contribution of the fourth quarter, and on the impact of the Focus Business was acquisition is being completed in mid-May 2016.

Let me please start with what I believe are the main highlights of the period. As we saw, DiaSorin has closed the year meeting its guidance with the growth in revenues like-for-like with constant exchange rate of 6.4%, the guidance being between 6% and 7%. So very close to the midpoint, and with the growth in EBITDA like-for-like at constant



exchange rate of 9.7%, again the guidance at around 9%, so it's slightly better.

We have delivered at a quarter...full-year EBITDA of €217 million, with an EBITDA margin of 38.2% which is 110 basis points better than 2015. To me, this has been the results, mainly of two factors. On one side, our ability to offset the price pressure such some...on some mainstream products with more sales of high specialty...high value specialty products, such as Vitamin D 125 and the stool panel [ph] test.

On the other, our constant efforts aimed at delivering manufacturing efficiencies and operational leverage through a tight cost control. Lastly, DiaSorin has confirmed its ability to generate predictable and strong free cash flow, €132 million in the year with a growth of 22% compared to 2015 which allow the growth to close 2016 with a positive net financial position of €71 million, after having completed the acquisition of the Focus Business for about €260 million.

Let's now move to the P&L; 2016 revenues as reported at almost €570 million driven by 14% and the 6.4% at constant exchange rate and scope of consolidation. Focus contribution to this growth was €44 million, differently from the first nine months of the year in quarter four we didn't experience any material FX headwind. The appreciation of the US dollar and Brazilian real against the euro almost completely offset the depreciation of the Chinese yuan, the British pound and the Mexican pesos.

Moving now to the full year 2016, we have recorded a negative FX headwind for about €6 million, mainly driven by CNY so the Chinese currency, GBP Mexican pesos, where as the US dollar which is the main foreign currency to which the Group is exposed has been overall flat year-

on-year. Let me remind you also to better understand the guidance that after the Focus acquisition an appreciation of the US dollar of \$0.01 [ph] against the euro means for the Group on an yearly basis about €2 million more sales.

Gross profit adjusted tax below €390 million in the full-year grew by almost 14% or €47 million compared to 2015, closing the year with the ratio of our revenues at 68.4%, in line with 2015, in spite of the slightly dilutive effect of the Focus business.

To me this is the result of higher sales of specialty products on one side and some positive effects of manufacturing efficiencies on the other, which completely offset some price pressure on CLIA [ph] mainstream products. As we said, Vitamin D which is anyway in line with our expectations, and which also offset the higher one off [indiscernible] rework costs we discussed about in quarter three.

2016 total operating expenses at about €207 million or 36.4% of revenues have increased by about 15% at current exchange rate compared to 2015, whereas the growth at constant exchange rate and scope of consolidation is in line with our expectations and very close to 4%.

Let me please remind you that about €8 million of the reported OPEX growth has been driven by the depreciation of the intangible assets, mainly knowhow and customer list, coming from the Focus business acquisition. Net of this depreciation the reported 2016 OPEX ratio on revenues would have been 35% against 36% of 2015. This is the result mainly of the operating leverage on the like-for-like business and the lower OPEX ratio coming from the Focus business.

Finally, as said in the previous quarter, the increase in R&D expenses, which grew in the year by almost 44% has mainly been driven by the depreciation of intangible we just commented and the change in perimeter.

Year-to-date, other operating expenses at €9.3 million has been negatively impacted by €5.4 million of known recurring expenses, mostly driven by costs associated to the Focus business acquisition and to some one-off consultancy costs aimed at streamlining our supply chain processes. Beside Q4 2016 has been hit by a one-off cost of about €1 million related to a reorganization carried out in our Italian Company whose positive effect is expected from 2017 on onwards.

2016 EBIT at €172.6 million or 30.3% of revenues has increased compared to 2015 by 13.6% or about €20 million, with the ratio of the revenues a touch north of 30%. Full-year EBIT ratio of the revenues excluding the mentioned depreciation of the Focus intangible would have been 31.7% compared to the 30.5% of 2015, so an increase in profitability.

Coming now to the tax rate, 2016 tax rate at 33% is in line with how we closed 2015. However, it is worth underlying that 2016 has been negatively affected by a tax settlement reached in Italy related to some tax claim recorded in the years between 2011-2014, and by the reduction of the deferred tax assets coming from the lower tax rate that will be applied in Italy starting from 2017 when corporate income tax rate will move from 27.5% to 24%.

So net of these settlements, 2016 normalized tax rate would have been 31.9% against the 33% of last year, which means 110 basis points less than 2015. This variance is mainly driven by the different contribution to the taxable profit of the Group on the geographies in which we do business.

2016 net results at €112.6 million or almost 20% of revenues is higher than previous year by €12 million or 12%. As expected, the Focus business has positively contributed to the absolute value of the net result of the period. Lastly, year-to-date EBITDA at €217 million with a ratio of revenues of 38.2% is better than last year by €32 million or 17.5%. The variance at constant exchange rate and scope of consolidation is positive by 9.7%, as we said.

Quarter four 2016 EBITDA at €59 million has increased compared to last year by 21.4%, whereas the increase at constant exchange rate and scope of consolidation has been positive by 6.5%. It is worth mentioning though that this quarterly variance has been affected, as we said, by the €1 million non-recurring expenses booked in the Italian subsidiary.

Now moving to the net financial position and the free cash flow, we see that in spite of the acquisition of the Focus business completed in May 2016 for about €262 million and the conclusion in June of the treasury shares buyback plan for almost €14 million, DiaSorin closed the period with the positive net financial position of €71 million, and €130 million in cash.

This is confirming again what we discussed in the previous quarters about the ability of DiaSorin to generate predictable and strong cash flow. During 2016, the Group has generated as we saw €132 million of free cash flow compared to €108 million of 2015 with an increase of €25 million or 22%. And once again, the Focus business continues to contribute in a positive way to this growth.

This is all on my side. Now, let me please turn the line to the operator to open the Q&A session. Thank you.

## Q&A

OPERATOR: Excuse me; this is the Chorus Call conference operator. We will now begin the question and answer session. The first question is from Massimo Vecchio, Mediobanca. Please go ahead.

MASSIMO VECCHIO: Good afternoon, everybody. I have a question for Carlo on the growth of the CLIA business, if you can detail between Vitamin D and ex-Vitamin D, so by going through the drivers, just trying to understand whether...where the growth will come from in 2017? Thanks.

CARLO ROSA: Yes, thank you, Massimo. The growth in 2017 in my opinion will come from a geographical point of view, will come from two geographies. One is the US and this is because as I stated previously, we feel very comfortable with the fact that in the US in 2017 we will be able to expand our business in CLIA xD with one of the largest labs in the US. We are working with this lab for a long-time with our flagship product, Vitamin D, and I think this is paying off in terms of reputation, that's why the LIAISON XL is a very good platform for them as we saw also with other very large labs in the US. And so I expect that in the US there is going to be an acceleration for the xD because of this.

I also expect that we will see...we will continue to see success from China. And mainly driven by the fact that in the Chinese market, there is a very large pool of business today being still in Infectious Disease and Hepatitis which is still conducted using ELISA, and this is one of the...is a very unique situation compared to all the rest of the world where there has been a cannibalization of this technology long time ago. And the reason why ELISA is still standing there, but does have a short life is the fact that there use to be local manufacturer making ELISA. These local

manufacturers, some of these small ones, these appeared and that business has been consolidated in few remaining ELISA companies, but the labs, because of the volume growth cannot use this technology any longer.

And so just to give you an estimate, we believe that as far as Hepatitis and towards infectious diseases which is our bread and butter in the US, almost 70% of the market is still ELISA and it is very rapidly converting, and that to us is a great opportunity because we discussed many times in infectious diseases arena, we do have a reputation in China to give the reference technology and because of that we were able to pretty much install our...install base of LIAISON first then and LIAISON XL.

And I continue...I see the trend honestly to continue. On top of that, what I think is very interesting, as far as China is concerned, is the fact that there is an emerging segment of the market which did not exist before, which has to do with private labs.

If you remember, we have always been discussing about the opportunity in the hospital segment, but it is certainly true that the Chinese government is pushing the development of private labs and this has to do with the fact that private labs would alleviate smaller hospitals that today see the surge in volumes to take care of these volume using the opportunity to send some of the assays [ph] that they need to do directly with the private lab standard.

Traditionally DiaSorin does have, as we have proven in Europe and Australia with Sonic, and in the US with LabCorp and Quest. We do have the platform, the service, which can feed that market, so that makes me comfortable with the fact that with our CLIA xD business in China, we can continue to see growth.

Last but not least, I did comment before on Brazil which you know, Brazil is a hit and loss situation. I think we went through couple of years where we headed the place, because it was complicated, and because of devaluation of currency, and because of the fact that the government was not paying. But at the end, I think we are back into a positive cycle from what we see, and this is because of the fact that we shifted our attention from the public to the private, and there is a hefty private business to go after, and again, the success there has to do with our infectious disease franchise.

So all in all, I believe that there is room for growth in all geographies when it comes to the CLIA xD, and particularly as said in the US, where we do see tremendous opportunities with this product. Thank you.

MASSIMO VECCHIO: A follow-up, if I may. In the context of what you said on ELISA, is the same product that you get through the Focus acquisition helping you meaningfully or is not that well along?

CARLO ROSA: No what we bought from Focus, again for us ELISA is a target typically, what we bought from Focus which is a very specialistic [ph] ELISA, because they have some funny bugs like West Nile, like Cross River, like Dengue. We do see some of the...some opportunity in the remote areas, especially in East Asia and some in Australia. However, we do see...we are pursuing today a strategy to very rapidly cannibalize the business...ELISA business that we can cannibalize from Focus using our XL and CLIA technology, before somebody else does it, and this is especially true in the US.

MASSIMO VECCHIO: Thank you very much.

OPERATOR: The next question is from Scott Bardo of Berenberg. Please go ahead.

SCOTT BARDO: Yes, thank very much for taking my questions. And so first question, please, relates to North America, I am more pleased with the abnormal relatively pedestrian growth in that region. I think you talked a little bit about Vitamin D pressures in that region. So could you please be a little bit more explicit for us and help us understand of your total North American business today. What is Vitamin D actually? And are you still seeing volume growth in Vitamin D in North America or we in overall sort of decline situation now in North America? I am just extending upon the sort of board of Vitamin D comment, I think in your Capital Markets Day, if I am not mistaken, you highlighted the expectations of some revenue stability, I think you are expecting a couple of percentage points growth over the forecast period. Obviously, we are in a situation where we are now declining on a quarterly basis. So I just wonder if you could give us some sense as to where you see the sort of revenue impact...volume revenue impact of Vitamin D that we should be modeling. So that's the first question, please.

And the second question, it is actually a little bit more of a financial one, I would like to ask Mr. Pedron. And I wonder if you could comment a little bit more on the margin expectation for 2017, it appears that you are baking some sort of margin stability, rather than any progression. And so I wonder if you could talk a little bit more about to how you see that, whether it would appear to me that given your expectations for broader menu in North America, specialty tests and some molecular tests, there might be some room for further gross margin expansion. I don't know if you see that to be the case. And also given that you have maybe €9 million in one-off costs impacting your EBITDA this year, it seems to me that in the absence of those next year, we should be able to grow slightly higher than revenues and [indiscernible]. So if you could just give us



some sense of what's baked into your margin expectation, please? Thank you.

CARLO ROSA:

Scott, I will take the Vitamin D question and then Piergiorgio is going to cover the margin expansion in 2017. Look, we always stated, including the capital when we were in the Capital Markets Day that Vitamin D at constant exchange rate, so the business would have slightly declined and what we explained back then, the net effect that we were seeing which was a fictitiously stabilization was related to the assumption that was made at the time on the exchange rate, and Piergiorgio is going to elaborate on this. If you want to understand from a business perspective how Vitamin D is doing in the US.

Well, volume interestingly enough, the volume we see is still increasing and is increasing you know, low-double digits, the true volume increase. We would see more increase and this would be artificial related to the fact that the big...the two very large accounts we have Quest and LabCorp are buying businesses. And so, every time they buy business for us, it can be a good news or it can be some of a good news. It is a good news, if the business that they buy was actually a run...was running their Vitamin D on a completely different platform, and this would be overall an increased revenue contribution and an increased volume contribution.

It would be kind of a good news, if they buy a business that is using our own technology, because when they buy that lab, yes, we pretty much use you know, it's neutral from a volume point of view, but it is detrimental from price point of view, because as you can imagine the price that we provide Vitamin D to Quest or LabCorp is not necessarily the same price that we provide to smaller labs or hospital labs around the country. So it is...moving parts and is a complicated puzzle. But overall, if I may, I believe that Vitamin D in the US, notwithstanding the fact that is a highly

penetrated...very highly penetrated market continues to grow single-digit, and this is to do with the fact that more and more Vitamin D is associated with physical testing, wellbeing...I mean you can open newspapers left and right, and continuously they talk about how good is Vitamin D for you, okay.

As far as what percentage they represent, for our US business we will never disclose it. And I am not going to disclose it because for competition reasons, right. Everybody really wants to understand that, and we've been hiding that as a secret, is a good portion of the business, but is getting diluted more and more by the day, by the fact that the CLIA xD business has been growing 20% in the last few years. And as said, we expect strong growth in 2017 because of this opportunity that we believe will present early this year for our US Company.

Now, I'm going to leave then the margin discussion to Piergiorgio and also please, if you can comment on the Vitamin D artificial affect?

PIERGIORGIO PEDRON: Sure. Hello, Scott. So, for 2017 gross margin, we don't provide a specific guidance on gross margin obviously. Nevertheless, I'm expecting to see some pressure on gross margin in 2017 coming from three main elements. On one side, again we see an underlying price pressure on mainstream products. If you remember, we quoted in the last three years plan, we said the Vitamin D 3% to 5% and the CLIA xD 2%, so that is going to hit our margins.

On the other side the counter mix, we said China is growing very, very good for us. We said that we are going to see some material growth in CLIA xD in North America coming from big labs, which usually have a price which is lower compared to our average selling price, and so this is somehow going to you know, put our gross margin under pressure. And

last but not least, we are going to see in 2017, one full-year contribution of the solid Molecular sales with gross margin ratio of revenues, as I said in the previous quarters, is slightly below the one of the Immuno business. So as a combination of these three elements, we are going to see some pressure. At the same time, I'm also expecting some of this pressure to be offset by manufacturing efficiencies that we've been able to deliver so far material-wise, as happened in 2016, and by a more operating leverage coming from our tight cost control with the net-net result of delivering an EBITDA ratio of revenue in 2017, which I believe is going to be very close to what we achieved in 2016.

So to summarize, EBITDA ratio over revenues in 2017, very close to 2016 as per our guidance, still with some pressure on gross margin for the elements I told you, which is going to be offset the EBITDA level by operating leverage and manufacturing efficiencies.

Going to the Vitamin D and to our three years plan, we were in a situation when we released the plan when the US dollar was if I well remember, 1.33. So it would have been kind of goofy for us to do a plan at constant exchange rate, since such a material part of our revenues is determined in US dollar, we would have projected very funny numbers. So we said, we made an assumption about the exchange rate and we incorporated in the guidance...in the three years guidance the impact, the positive impact from...coming from the exchange rate, but at the same time, we said the underlying business of Vitamin D as I said, also because of the price pressure of 3% to 5% was slightly flattish or slightly negative. What we are going to do for the next plan is to put the plan at constant exchange rate, so that it will be easier for everybody to understand the three years' guidance, so taking out of the table the FX effect.

SCOTT BARDO: That's very clear. Thank you. And maybe just one quick follow-up if I may, all of the reasons you mentioned for gross margin pressure in 2017, they sound a little more structural than one-off, and so I wonder do you see this as a sort of a new trend as to sort of continue the ongoing gross margin pressure from the sort of high levels or is there some sort of compensatory effects with volume and mix that you've enjoyed in the past. Last part of the question, please, I don't think you provided any tax guidance or tax rate guidance this year and I appreciate there is a lot of moving parts with the Italian Patent box, but please, can you share some thoughts actually as to that the potential benefits to your bottom line resulting from tax? Thank you.

CARLO ROSA: Yes, absolutely. So talking about the gross margin, you will actually know more when we will do our Investor Day with a three years' guidance. Said that, yes, there is an underlying price pressure, but at the same time, we are helped by the volume mix effects you were talking about. We sell more and more of our specialty products, high value specialty products, prices of Vitamin D 125, H.pylori, and calprotectin is much, much higher than mainstream products, and there is that kind of helping us to offset the price pressure on the mainstream product.

Talking about the tax rate, we don't provide guidance about tax rate, but what I can tell you is that by all means, we are going to have a positive effect coming from the reduction of total income tax in Italy. As I said, you know, we have two main countries when it goes down to you know, to how much we are paying taxes across the globe. And those countries obviously are the countries where we have our manufacturing sites, the biggest manufacturing sites, which is Italy and US. If we think about Italy, I mentioned that the corporate income tax rate has been reduced by 27.5% to 24%. At the same time, [indiscernible] deduction which had been granted until 2016 has been reduced, but the net-net effect for us in

2017 is I would say a saving in terms of taxes of about €2 million. So again, I'm expecting a saving from Italy of about €2 million.

On top of that, as I believe I mentioned in previous call, we also applied in Italy for the Patent Box, the Patent Box is an elective tax regime that grants us a 50% tax exemption on income derived for a direct exploitation of qualified IP. We applied in 2015; we just have to discuss with the Italian tax authorities about that. We will have a roll back, if we will be able to finalize the discussion by 2017, so in this year as we hope, we are doing our best, but it's not...it doesn't depend completely on us, we will see this year in 2017 a nice step back, because we will be able to book in our accounts the positive effects coming from 2015, 2016 and 2017 Patent Box.

And this without considering you know, the potential tax reform in the US, give or take Italy's 1% tax reduction...in the US tax rate reduction, that means for us again or ballpark number \$1 million less of tax bill. So if you combine the potential tax reform in the US, the Patent Box that we applied for in Italy and the reduction of the tax rate that it's giving you, it's a law in Italy, I'm expecting in 2017, the tax bill to be you know, materially lower than what we had in 2016.

SCOTT BARDO: Very clear answer. And maybe just very quickly, so, if I understand all going well, if you manage to leverage all of these tax...potential tax benefits, is a sustainable high '20s rather than low '30s tax rates a sort of ballpark. Can you at least give us some flavor to where you see the potential that would be helpful?

CARLO ROSA: In 2017, we are going to get one-off effects, right, because we are going to get the Patent Box effect of 2015, 2016 and 2017 all hit in one single year. So if you take out that off the table, otherwise you really don't have a you

know, a sensible benchmark. I would say around 30%, let me say, give or take.

SCOTT BARDO: I will drop down in the queue, thanks for answering my questions.

CARLO ROSA: Thank you.

OPERATOR: The next question is from Alex Cogut at Kempen. Please go ahead.

ALEX COGUT: Hi, thanks for taking my question. Just a quick one on the LIAISON XS could you give a quick update on development and expected launch? Thank you.

CARLO ROSA: Yes, as we have discussed when it comes to the XS, we are now in the phase where Stratec has delivered the prototypes to us. So we have them in the research center, we are conducting testing and validation and we expect, the LIAISON XS to be CE Marked with an initial menu of products in infectious disease for 2019.

ALEX COGUT: And if I can follow-up on that. I believe the previous guidance was launched 2018, if I am not mistaken what is causing the delay?

CARLO ROSA: I think that what we said is end of 2018. So yes, we can say if you prefer end of 2018 beginning of 2019, what I am saying is that we don't expect this system to have an impact in 2018, but to start to have an impact in 2019.

ALEX COGUT: Got it. Thank you.

CARLO ROSA: Thank you.

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

MAJA PATAKI: Yes, thanks for taking my question. Most of it has actually been answered already. But I was just wondering, if you could give us a bit of a breakdown or a bit granularity on the top-line guidance for 2017? Are you expecting to see apart from the full-year consolidation of Focus, but are you expecting to see a significant exploration in Focus sales or should we expect a bit of a slowdown in the DiaSorin, ex-Focus business. Just to get a bit of a feeling what we are looking for? And then the second question was, if you could give us just an indication of where you see FX moving right now? Thank you.

CARLO ROSA: Okay. Okay, I will take the business question. As far as, if I can't break it down for you give or take, we expect to continue to see the historical trend of growth of the Immunoassay or what all we said before in the range of 6%-7%. And we expect to see the Molecular business to grow around 14%-15% in light with what we have been seeing in 2016. We expect that this year in 2017 towards the second part of the year, we may see an impact coming from the European business. I am saying, we may see an impact simply because from a legal point of view, we are still negotiating with some of the distributors...ex-distributors of Focus the takeover of the business.

And so depending on this legal negotiation, we may be able to start promotion or not around the summer, and therefore having or not having an impact in 2017, vis-à-vis the European business. As you can imagine, you know, all the Focus distributor are frozen, they are not developing the business, maintaining the business simply trying to understand what to do with it and trying to establish a value for DiaSorin. But as far as the total

franchise, again I said we expect 15% growth mainly driven by the US business.

MAJA PATAKI: Thank you.

CARLO ROSA: And I believe...the other part of your question was about our view on FX, if I got it right?

MAJA PATAKI: Yes, right now, the impact that you are seeing at current authorized test which you see on FX coming through?

CARLO ROSA: So the impact we are seeing, now you know...the impact we saw in 2016 is negatively impact on the revenues by €6 million as we said, mainly driven by the depreciation of the Chinese currency against the euro and the pound...the British pound. What I believe is important to understand is that about, as I believe we said in the past, the 30%-35% of our sales are denominated in US dollars, and it is the biggest currency for us. So we provided the guidance at 1.11 [ph], which is constant exchange rate over 2016. Now, if I well remember the US dollar is running at 1.05, 1.06, which means [indiscernible] equal 12 million give or take, euro denominated sales more for us. And if you want to go down to EBITDA just ballpark number say, you know, for every dollar cent ballpark €1 million, so €2 million in revenues, €1 million in EBITDA.

MAJA PATAKI: Thank you.

CARLO ROSA: Thank you.

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



LUIGI DE BELLIS: Hey, good afternoon to everybody. Three questions from me on Focus Diagnostic. Could you give us an indication of the pipeline test that you should expect to launch in 2017? And could you provide a feeling on customer retention and new customer win rates for Focus as of today. And lastly, what are you seeing in the competitive environment for Focus? Thank you.

CARLO ROSA: As far as the pipeline, I am afraid that you will need to wait for the Capital Market Day. But traditionally, the Company has had two areas in which it did operate, one which is flu which is as you know our business per se. We have very limited menu and the company does have all the assays which are necessary to operate in that market. And then the infectious disease transplant products. So we expect, honestly to continue to develop the business in the respiratory side. And so, there will be...we expect to launch products like the Bordetella, the parapertussis, and we also expect to continue to develop in the area of infectious disease for women health.

So Group B is spread which is in the US is on the contract to Europe is a tremendous opportunity. Also and not to forget, there is a sizable part of the business which has to do with the use of ASR on the platform by certain customers, so they are buying our platform as open platforms and then they develop their own applications, Quest, for example, is a very large users of these assays. And we will continue to develop the ASR catalog, today, there are almost 40 assays available in the US in ASR, and the target of the Company is to launch every year four new products, because of the situation of the US market and the fact that customers are able and used to develop LDT, this side of the business will certainly continue with us.

As far as the competition, look, this business, this Company, this platform is one main competitor/reference business, which is Safed [ph], because as

we have seen in our Immunoassay business, all the very larger companies Roche, for example, they are going toward consolidation, full automation, very large platforms, mainly driven by the fact that there is an opportunity in this market for blood bank screening. There is today consolidation of blood banking and they need to provide very large platform for blood screening. So [indiscernible] is an example with large platforms, Roche, Beckman with their own platforms. So at the end of the story, when it comes to the rest of the segment you have completely different players, who have Safed, which is the other front, and then you have [indiscernible]. And so, we will continue to play in that segment, we will...which is not that crowded.

We are not going to plan to pay, to play in the other extreme segment which is CLIA waived, you know, there is a big...big movement in the US, these days for certain molecular application, especially for influenza following decentralization of testing then to move from the CLIA certified to CLIA Waived Labs, and we are certainly not going after that path because we don't believe that the platform phase is suitable for that market.

So today, the...for us target and...the target for is Safed, their business model which is very similar to ours. And Safed you know, has been bought by Beckman, we really don't know how this is going to pen out. What we see is that there is a viability of talent on the market because of this, and because there is uncertainty and we are, we plan to kind of use the opportunity of these changes on the market to exploit that market with our platform.

LUIGI DE BELLIS: Thank you. Thank you very much.

OPERATOR: As a reminder, if you wish to register for a question, please press “\*” and “1” on your telephone. The next question is a follow-up from Scott Bardo of Berenberg.

SCOTT BARDO: Yes, thanks very much for taking my follow-up question. And so, excellent cash conversion once again from the Company and de-levering if you like, absorbing the \$300 million Focus business very quickly. I think when you had a similar net cash position a couple of years ago, you highlighted potential for around a €1 billion in fire power and to consolidate. I wonder if you could make some comments as to firstly, do you still see that potential fire power within the organization? And secondly, your broader views on consolidation, is there any requirement or hunger to still consolidate, perhaps you could share some thoughts as to where you would benefit or is there enough for the new organization to internally invest now to drive a principally organic growth story going forward? Thank you.

CARLO ROSA: Scott, I think that the answer is yes and yes. Yes, means that we do have, you are right, we are de-levering fast, actually I think it was quite remarkable the fact that we paid €300 million in cash and we never had a negative net financial position. And yes, in fact the new...the Company we bought is a very...it does contribute to our cash generation and because it's a very profitable business. And on top of that, we also need to consider that because of the structure of the acquisition, we do have created a tax shield in the range of \$6 million per year, which is increasing our cash generation.

So all in all, there is a commitment by the management certainly, but also by the main shareholder to continue to look at opportunities out there, which we believe there are of different nature, either from opportunity to buy customer list and market position. With non-traditional or the safe in-

segments, which are necessary not traditional today DiaSorin, but still they can benefit from a conversion of ELISA to CLIA, then our technologies and content if it is made available at the price that makes sense. And as you said, yes, we do have cash to support this kind of acquisition, but more than cash, I think we have appetite and support by the main shareholder to do so, which is fairly...which I would say is quite unique.

As far as...yes, we do need to invest internally for organic growth, because I believe through this acquisition, we bought tremendous platform, the technology that we bought, which was developed by 3M, which is solid reputable US company, is a very powerful technology and under Quest and Quest when it was managed certainly as a profitable technology, but not strategically as something that they knew how to develop, because it was non-core business for them. And therefore, we now are clearly in a learning phase, vis-à-vis the technology, we are transferring the manufacturing or some of these technologies to our own suppliers, and we are in the process of completing this by the summer.

And then certainly, we see endless opportunities in terms of menu development vis-à-vis this technology. We will need to strengthen our internal organization; clear to us we need to invest in seniority and talent, because we expect growth coming from this in terms of ideas, products and revenues. And that, yes, maybe a challenge for DiaSorin, but we have seen this in the past, we have done this with LIAISON and we feel...we believe the Company is well-equipped you know, to take upon ourselves this next challenge.

SCOTT BARDO:

Very good. Thank you. And why have you sort of doing some strategic thinking. One other question I get off the lot is about the upcoming kind of regulations and potential impact to DiaSorin's business. And I guess now that you've had some experience with Focus and particularly given

that it has this exposure to lab developed test that you mentioned, which is in part included in these sort of time of regulations, I mean what are your overriding thoughts here, do you think that this is going to be an acceleration in pressure or are you relatively sanguine about the future environment in North America? Thank you.

CARLO ROSA:

If I had a clear idea of what's happening in North America, I think, I could run for political office to be honest with you. What we see today in North America is that, yes, there is one fact and the fact is that reimbursement has been cut and that's on the table. But by the same token, reimbursement has been cut, we do have a business which is very skewed toward the larger labs and if you listen to the way the larger labs look at PAMA, they are somehow shielded by this because of the percentage of the business that they do, which is associated with Medicare is low double-digit, right.

Price pressure in our business does come more from competition. We have seen that with what happen to Vitamin D, so do I believe PAMA or anything that will happen in the US is going to dramatically change the [indiscernible] and then go north, what is going to pay in 10 years, but in the next two, three years I don't honestly see things changing trajectory vis-à-vis what we have been experiencing. And by the way, if you think about it, when Obamacare was announcement and then everybody was excited by the fact that 20 million, 30 million more Americans would have been, all of a sudden available as potential customers and we said, well, who knows what we will see eventually.

We didn't see a significant increase in volume go and funnel through the big labs. What we saw is that we saw volume in business increase whenever we...and we were lucky to be able to participate to that because...simply because of the difficulties or the increased pressure in

labs in the US, Quest and LabCorp are buying more and more. So consolidation of labs is supporting our business, because we are today inside LabCorp, we are inside Quest, and when they grow we grow.

SCOTT BARDO: Very good, thanks for your time, thank you very much for the answers.

CARLO ROSA: Yes, thank you.

OPERATOR: The next question is from Bruno Permutti at Banca IMI. Please go ahead.

BRUNO PERMUTTI: Good afternoon. A question related to the Vitamin D in Japan. I would like to understand if it is the introduction and the first data you probably have on the sales there, so are they in line with your expectation or if you are already got a feeling of the market, the acceptance of the market of the Vitamin D there? Second question regarding Roche, if you can give us an update on the agreement and on developments...on the recent developments. And lastly, if I may, if you can on the first months...the first two, three months of this year, I want to understand if it is going...it is all going as expected or if you are seeing something discontinue with this during...I mean, during the year, I mean or you believe that you are...in the first two months of the year are substantially in line with the guidance and with the idea you have for the full-year?

CARLO ROSA: Okay. As you can imagine, I will not comment on how we are doing January and February, you need to wait until the quarter results will be published and I'm not going to make any comment vis-à-vis January and February.

As far as Japan Vitamin D, I think we discussed it already last year, the adoption of Vitamin D in Japan is a toss of a coin and this is why we disclosed that expectations in the budget are fairly limited. Yes, there is

plenty of clinical need of Vitamin D testing or by the same token Japan is a fairly conservative society from a medical point of view. There has been approval of another company that got Vitamin D approval in Japan, which is a Japanese company that does have an installed base in the hospital setting, whereas as we said, since the beginning, we do have our LIAISON XLs business in the bigger reference labs. So far, we didn't see a significant pickup of the business, but honestly, we don't know and just wait and see and see what will happen.

As far as Roche is concerned, yes, we continue, we started seeing placements with Roche, there are close to 20 existing projects, mainly in Europe of significant size, some of which have been awarded, installed, some of which are under discussion. So we see the Roche alliance delivering what we expected in the very large labs because Roche is certainly a dominating parting that space.

BRUNO PERMUTTI: Thank you.

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

CARLO ROSA: Thank you, operator.

PIERGIORGIO PEDRON: Goodbye.