Recordati S.p.A

"2014 Third Quarter and First Nine Months Results Conference Call"

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OPERATOR: Good afternoon, this is the Chorus Call conference operator. Welcome and thank you for joining the Recordati 2014 Third Quarter and First Nine Months 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 Ms. Marianne Tatschke, Director of Investor Relations of Recordati. Please go ahead, madam.

MARIANNE TATSCHKE: Yes, hello, good afternoon or good morning to everybody and thank you for attending the Recordati conference call. Fritz Squindo, our CFO will be presenting and commenting upon our first nine months 2014 results. For a better understanding of his presentation, please access the set of slides available on our website www.recordati.com under the Investor Section and presentations tab. At the end of the presentation, we will answer any questions you may have. Please go ahead, Squindo.

FRITZ SQUINDO: Okay, thank you Marianne. Good afternoon or good morning to everyone. We are very pleased to announce our results for the first nine months of 2014 which shows sales growth and significant margin improvement. Let's start with our revenue. Consolidated revenue is €742.1 million, which are up by 5.7% compared to 2013.

Let me comment something regarding our sales evolution, excluding the acquisition of Casen Fleet, and Opalia Pharma that the Company acquired in October 2013, and also excluding the negative currency effect that we have and impacted in the first nine months which amount to €24.5 million, sales growth would have been 1.8% and we continue to have organic development. But as already stated in the first months, I would like to underline that very significant is our margin improvement. EBITDA at 28.7% of sales is €212.9 million, up by 22.4% as we are strongly increasing our EBITDA, but also the same level of increase of operating income at 24.3% of sales. Our operating income in the period is €180.4 million. And here we have an increase of 21.6%. Net income at 16.7% of sales, is €124 million, an increase of 22.2% over the first nine months of 2013. That's very significant and solid improvement of our margin.

Let's also comment our evolution and development of the business in this period. And during the period, we obtained two new products; one is Vitaros which is for the treatment of erectile dysfunction under license from Apricus Biosciences. And the second product, we have announced this agreement in September, PSD502 for the treatment of premature ejaculation under license from Plethora Solutions. Then also, we have also obtained in July our orphan drug Carbaglu…obtained the orphan drug designation from the FDA in the US for the use in organic acidemias.

Then let's move on Slide #3 in which we comment our sales evolution. As usual, we want to start with commenting our main product sales, then Zanidip sales, lercanidipine plain decreased slightly by 0.1%. And this is due to the generic competition mainly in Ireland, Italy and France, and it's also due to a negative currency effect in Turkey, where the product locally is growing, but translated in euro, we had a decrease in our sales of Zanidip in the Turkish business.

Sales grew significantly also in North Africa. Then we continue to develop in new market our lercanidipine plain franchise. Regarding the combination, sales of Zanipress are up by 8.3% and this is mainly due to the performance of the product in Italy and in Turkey. Then the franchise of lercanidipine is continuing in keeping and even growing compared to our expectation.

For the other corporate product, Silodosin, Urorec has been successfully launched in 28 countries with sales of €42.7 million in the first nine months of this year, which are up by 25.3%. And this is mainly due to the performance of our products in Italy, in Spain, in France and by launches in other countries. We have also…we are…Pitavastatin, now we are talking about sales of Livazo, here we have the product launched in some market in Europe and particularly in Spain, Portugal, Ukraine and Greece, and through license agreements Switzerland (Ph) sales of this product are €18.6 million which are up by 10.9% compared to the same period of the preceding year.

Then our specialties which are indicated for the treatment of rare and orphan disease, generated sales of €91.8 million in the first nine months, which are down by 6% and this is due entirely to the termination of the Adagen license in the main countries. We have lost Adagen rights for the main countries at the beginning of this year. Excluding this termination, if we consider all the other parts of our portfolio altogether, the other products in the portfolio grew by 9.1% which is in line with our expectation to have increase in our orphan business in the region of 10%.

Then let's say, overall a good performance of our corporate products. On Slide #4, you can find the graph shows the breakdown of our revenue by type of product…Slide #5, now we can move on the composition of revenue by geography. Let's start with the Italian business; sales of pharmaceuticals in Italy are down by 1.8% compared to those of the same period of the preceding year. And this is due to the termination of Adagen. Adagen was a very important product in our orphan drug portfolio in Italy. And starting from May, also we have been impacted in Italy by the termination of the license of escitalopram, the Italian brand of this product was Entact, but even…but on the other hand, let me say that all the other main products in our portfolio are performing well and are able to not completely, but not completely offset, but partially compensate this important termination that we have in our portfolio in Italy.

Let's move on France, pharmaceuticals sales in France are down by 4.2%, and this is mainly due to here again to the sales decrease of the OTC line products which are indicated for the treatment for ENT disorders, and this is due to seasonal factors, in particular we are talking about winter products, and the season, the winter season was not very acute, very important this year. But also here in France, we had one impact linked to the termination of the Adagen license.

On the other hand, Urorec which is silodosin and a local product which is methadone are performing well. Then we have here again, loss of termination, loss of sale due to the termination of Adagen, which are partially compensated by performance of the other important products in our portfolio.

In Germany, sales are up by 6.4%, thanks to the sales growth of Ortoton, which is a local product in Germany, of Zanipress and of the orthopedic product line.

Let's now move on to Russia, revenue generated in Russia and the other CIS countries is down by 9.1% compared to 2013, mainly due to the negative currency effects which impacted €49 million. Let's comment on sales in Russia, in local currency sales in Russia are up by 4% compared of the same period of the preceding year. Then we have a reduction in Europe, but on local currency, we are growing by 4%.

Another important point to underline regarding our Russian business is that as from January of this year 2014, the distribution of products in the Russian territory is handled directly by our subsidiary [indiscernible] so to speak, and no longer some direct sales to importers. This I think evolved during the first quarter, the setting up of a local inventory and the constant reduction of stocks held by this distributor. In the third quarter sales in local currency grew by 12.4% which has more than compensated to the decrease in the first quarter.

In Spain, sales include €31.4 million generated at the Spanish Pharmaceutical Company Casen Fleet that we have acquired in the fourth quarter of 2013. This Company's main product is CitraFleet, a preparation for colonoscopy which is now part of our corporate product. Let me say that, in Spain, we are doing well with the new acquired portfolio of the Casen Fleet Company, but also our corporate product in particular Livazo and Urorec are also performing well.

Sales in Turkey are up by 0.4%, and are impacted by a negative currency effect of €12.6 million. As usual we prefer to comment the performance in local currency, and in local currency, local sales of our Turkey subsidiary grew by 19.5%, thanks mainly to the good performance of the local, of the corporate product, Procto-Glyvenol, Urorec, lercanidipine, Zanipress, and also to the main local products. Then we have a very significant development of our business in local currency in this area, in this market.

Then the Group financial…the Group business in the USA is only dedicated to the marketing of products for the treatment of rare diseases. And sales in this first nine months are €42.7 million which is up by 6.1%. Then even here we have a negative impact to the currency effect that even if we have this negative currency affect our business in the USA is growing by 6.1%, and I am very pleased by the performance of both Carbaglu and which is the orphan…the product belonging to Orphan

Europe, and also due to…we are very pleased by the performance of the portfolio of product that we have acquired at the end of 2012 in USA.

Sales in North Africa are €29 million and the sales comprised both, the export sales generated by Bouchara Recordati our subsidiary in France in this territory. In particular in Algeria, which were previously shown under other international sales, and this sales include the sales generated by Opalia Pharma; the Tunisian Pharmaceutical Company acquired during the fourth quarter of 2013. In particular, the Company of Opalia, sales are €11.8 million in the first nine months, and we are increasing, developing our presence in this new area which is the North Africa zone.

Sales in Portugal are up by 13.3%, thanks to the good performance of corporate products, Livazo, TransAct and Urorec, as well as the contribution of the products sold by the Portuguese subsidiary of the newly acquired Spanish Company, Casen Fleet, for an amount of €2.5 million. The contribution of Casen Fleet is not just only for Spain, it is also for Portugal, and we are progressively trying to sell directly this product in other territory in Europe.

Let me finish with the other international sales, which grew by 3.2% and comprised mainly sales to our licensees. For our corporate product, the Bouchara Recordati our France subsidiary, export sales excluding those in CIS in North Africa which are, as I said reported separately, and also the Orphan Europe, our Company for the treatment of rare disease [indiscernible] excluding the USA, then overall a good performance in all the basis, with some major issues in Italy and in France, which are mainly linked to the termination of important contract that occurred at the beginning of this year.

On Slide #6; this graph as usual show the geographical breakdown of our pharmaceutical sales. And here it's worth mentioning our growing presence in Spain and in North Africa following our recent acquisition. And let me also underline our presence of around 6% in the USA is our…as I said orphan portfolio treatment for rare disease.

Slide #7, first nine months 2014 results. We have already talked about revenue for the period. Now, just move on the cost structure; gross profit is €497.3 million with a margin of 67% of sales. And this is important to underline, here we have one increase which is in line even better with what we have in the first nine…in first six months. If we compare this number to the results achieved in 2013, and this is due to essentially to a positive mix effect, following the addition to the portfolio of the product belonging to the new Company acquired in 2013. And the sales reduction of Adagen and Entact, which are relatively low margin product, and this is something that is sustainable which is linked to the new composition of our product mix.

Selling expenses as a percentage of sales, they are down compared to the same period the preceding year due to the overall containment in all market and also to the synergies obtained with integration of the newly acquired Company. In Spain, we have merged the two Company effective beginning of October of this year.

R&D expenses are €62 million, which are up by 11.9% and are 8.3%...percentage of revenue. G&A expenses are up by 8.1%, but are substantially stable as a percentage of sales. Thanks in particular to the higher gross margin and to the lower incidence of the selling expenses, EBIT in the first nine months has increased to 24.3% of sales which is a significant improvement compared to the average of EBIT margin achieved in the last period.

Net financial charges are €13.1 million. Here we have an increase compared to 2013 of €2.6 million which are due mainly to the interest accrued on a higher level of investments in particular related to medium long-term loan. We have raised some resources from a financial point of view based on the very favorable financial condition. The effective tax rate during the period is 25.8%, and here we have an improvement…here again, we have an improvement compared to that of the same period, the preceding year mainly due to the mix…Company mix in our Group.

Let me finish with our net income…with net income at 16.7% of sales is €124 million. Here we have an increase of 22.2% over the same period of the preceding year. Then as I said at the beginning of my presentation, very important and significant margin improvement in our first nine months 2014 results, with and an even better performance in the third quarter of this year.

Let's now move on our financial position, which remained very solid. At the end of September, the net financial position show a net debt of €152.5 million with a reduction of €108.5 million compared to the end of last year. Let's just…this is a very important improvement, but during the period let me underline that the residual amount of €2.7 million was paid for the acquisition of the Spanish Company, €1.8 million were paid as upfront to Apricus for the Vitaros license. We have also an initial payment; €4.3 million was paid for the acquisition of a further 23% of the share capital of Opalia. And we have also distributed in April a dividend for a total of €22.4 million. Then we continue to generate free cash flow, and we continue to have a very solid financial position.

Last Slide #11; our outlook for the full year, and then for the full year 2014; let's say despite the two important license termination, and the significant negative currency effect. Our objective, we confirm our objective to achieve sales of slightly below €1 billion. And this is in line with the previous guidelines.

Regarding our profitability, in particular, our EBIT and net income; in view of the results, we have achieved in the first nine month, we have slightly increased our objective for the full year. And we expect our EBIT to be at around €230 million, and our net income to be around €160 million. Then we have slightly improved, as we have also announced in our press release, our objective in term of profitability for the full year 2014.

Here, I am now available for any question you may have.

MARIANNE TATSCHKE: Yes. Can you open the question and answer 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 James Vane-Tempest of Jefferies. Please go ahead, sir.

JAMES VANE-TEMPEST: Hi, good afternoon and thanks for taking my questions. First one, I'm just wondering on looking at the balance sheet whether there is any timing differences because your gross cash balance is around €242 billion is pretty high? And second question, Fritz just…regarding your comment around gross margin is sort of sustainable looking at the mix at the moment? I mean, in the third quarter, your gross margin was 68.5% versus 67% at a nine months stage. So I was just wondering whether there were any differences in the third quarter, and how we should think about that going forward. And third question is just on R&D, I noticed that the percentage of revenues was at the, very upper end of your guidance achieved given an indication of around 9% of revenues. And can you give us a sense in terms of where we are in the cycle of R&D investments, and given your lease…licensing? And then perhaps relating all of that to when we may get an update on your mid-term business plan, you tend to give us a sort of a medium term view every year for the three years ahead. And I am just wondering, when we might get that visibility for 2016. Many thanks?

FRITZ SQUINDO: Okay. First question regarding the balance sheet, let's say that there is a strong generation of cash we have, but nothing extraordinary something which is in line…which is absolutely in line with the normal day-by-day business. Regarding the margin of the third quarter…the margin of the third quarter, then we have a very positive mix in the third quarter which is even better than we have achieved in the first nine months. Let's say, that I believe that, the average achieved in the nine months are absolutely sustainable going forward. The peak achieved in the third quarter is also leading to particular very favorable mix that we have achieved in all (Ph) quarter. As always I said, one quarter doesn't represent a trend, it's something very positive. But for a projection going forward, I would like to use as a projection the gross margin achieved in the first nine month which represent an average which is an improvement, which is link driven by the different product mix, and this in my opinion could be sustainable going forward.

The third question we have 8.3% regarding our R&D cost. The expenditure let me say that, we have in mind in our guidance to have around 9%. Let's say that for the full year 2014, we can expect our R&D cost to be in the region of we have achieved now in the first nine months, a bit less then what we have announced. This is mainly due to some delay in the enrollment in the clinical development of Nymox (Ph) which is just normal. Let me say nothing extraordinary, but a usual delay that you have in the enrollment in obtaining all the approval that this process now…and this processes require in the European….mainly in the European reg (Ph) limitation.

The fourth question was…

MARIANNE TATSCHKE: The mid-term business plan question.

FRITZ SQUINDO: Then we will release…now we are working on our budget process and we expect to release our 2015 result…end of 2015 projection in beginning of February, together with some general indication regarding 2016 and 2017.

JAMES VANE-TEMPEST: That's great. Thanks very much.

OPERATOR: The next question is from Eleanor Fung of Goldman Sachs. Please go ahead.

ELEANOR FUNG: Hi, two question, please if I may. Firstly, based on the first nine months margins, and adjusting for a lower margin fourth quarter that is typical. Your full year guidance seems conservative. Just wondering, if there is any room for upward revisions here 22 to 23 EBIT margin guidance for 2014 and '15. And secondly, just on acquisitions, now that you've made several urology acquisitions this year. Do you think that there are more deals to do in this therapeutic area or you right sized. And can you remind us of your other strategic acquisition priority areas? Thank you.

FRITZ SQUINDO: Okay, then first of all let me talk about the margin expectation, then based on the results and the margin achieved in the first nine months that we think that for the full year 2014, our margin could be in the region of 23%, 24% which is also implicit in our improvement of our guidance. Then this is…and then regarding, and we are very pleased by this margin improvement, and we will see what will be the final number for 2014. But let me underline that now a range between 23-24 could be achieved in 2014, and for sure could be considered as a sustainable margin going forward even we could expect a slight improvement in our margin as always I said for 2015.

Then the second question was…

MARIANNE TATSCHKE: The acquisition…

FRITZ SQUINDO: Regarding the acquisition. Okay, then acquisition we have raised money because we believe that the inorganic growth would remain an important driver for the growth. Let me go back to on our margin as always this improvement of the margin is linked to our organic business and in the organic business we can slightly improve the margin base essentially of this consolidated product mix and the possibility to continue to leverage our sales organization.

At the overall level, I continue to say that, for us the inorganic development is an important driver for the growth, an important pillar for development of the Company. And this is the reason why we have raised money, and we have now cash availability in our balance sheet.

Regarding opportunity, we are working on some opportunity, mainly we are talking about some asset deal, but we continue, this is our usual position. We continue to be very cautious in approaching the price, and as usual we have some deal on our table. We believe to be able to close some deal in the next future. But this is more a commitment, which is not linked to one year or is linked to the development of the Company going forward. Then, I can...

MARIANNE TATSCHKE: Geography or…?

FRITZ SQUINDO: Then for the time being, we are more focused on asset deal, which means to find assets which fit in our existing geography, the opportunity to leverage the existing organization. But it's difficult to say in term of acquisition we confirm that we would like to have both geography consolidation and consolidation of the existing geography with new assets

ELEANOR FUNG: Thank you.

FRITZ SQUINDO: Okay.

OPERATOR: The next question is from Ricardo Luis of Credit Suisse. Please go ahead.

RICARDO LUIS: Yes, hi, good afternoon. Just a quick one, I am not sure if I missed them, but I was still expecting some Phase III data for the Nymox product in the US, which I thought were due in summer time, and do you have any updated timeline for this release? Thank you.

MARIANNE TATSCHKE: Ricardo, the US, the US trials are being conducted by Nymox, and so you will have to ask them.

RICARDO LUIS: Understood. Thank you.

MARIANNE TATSCHKE: Anything else?

OPERATOR: The next question is from Martino De Ambroggi of Equita. Please go ahead.

MARTINO DE AMBROGGI: Good afternoon, everybody. The first question is on the return on sales you mentioned is achievable in the 23, 24 range, also going forward. I was wondering which is the R&D assumption as a percentage of sales considering that this year it was roughly one percentage point lower than initially expected.

FRITZ SQUINDO: Okay, then not 1%, that's 0.7% just to be precise.

MARTINO DE AMBROGGI: Yes, okay, precise.

FRITZ SQUINDO: Then we continue to have R&D in the region of 8 to 10. We consider it based on the current level of R&D as a percentage of sales, the organic development for the full year we can expect 23, 24 and for…and going forward on a organic level, we could also expect a slight improvement which is mainly driven by leverage of the sales organization, which means essentially a further slight reduction of our selling strategy.

MARTINO DE AMBROGGI: Okay, so what was in…?

FRITZ SQUINDO: Within our guidance, it would be clearly announced during the conference call in February when we announce the full year results 2015 and the budget 2015, but as a general indication of on organic base, we could…you could expect a slight improvement in our profitability. We have then a 10% or 11% investments, 11% in R&D which is leading to a new drug for which we have to pay upfront payment will be announced and will be a different story, but based on the current business, based on the current margins, based on the current percentage of R&D, you could expect this trend going forward.

MARTINO DE AMBROGGI: Okay, sorry just to be…because may be I missed the part there was some noise, I hope that was in the region of 8% on sales?

FRITZ SQUINDO: Yes.

MARTINO DE AMBROGGI: Okay, okay sorry. On pricing environment because for instance, in Italy which is still quite important despite being reduced over the past few years as a reference market for you, we saw a lot of discussions regarding cost savings for the entire public authority administration. So I was wondering if there is anything new. It seems nothing specifically for you in Italy, but all around the globe, if there is any intervention that could affect your performance…obviously, based on the current visibility?

FRITZ SQUINDO: Okay, let's start with the Italian situation. In the Italian situation, there is for the time being a very clear cap on maximum expenditure for…to different kind of pharmaceutical expenditure, one is the hospital one for which there is a cap which is exceeded last year and we expect also this year to be exceeded. On the other hand, for the pharmacy level business, this cap which is 12.3% is in line with the expectation. And then as you know, our business is mainly in this area. We have a very minor business in the hospital part, and then we don't expect a significant payback to be paid to the government.

Then overall, we expect the cost, the attitude will remain to try to control the expenditure, but in the part of the business in which we have the part…the big part of our business, here the cap is normally achieved due to the continued launch of generic version of the molecule which allow the government to save money and to achieve what is the objective. Overall, let's say then in 2014, we have seen the usual containment measure, but not as tough as let me say two or three years ago, and this is our expectation also for 2015. Then you could expect some measure in France, in Spain and as usual, in our projection, we considered some more price reduction, but not to the extent that we have seen let me say in 2012.

MARTINO DE AMBROGGI: Okay. And if I may, your assumption on the 23%, 24% return on sale is based on what assumption of top line growth like-for-like, obviously without including any acquisition?

FRITZ SQUINDO: Okay, let me…first of all, I am talking about 23%, 24% for the full year 2014. This year in which we expect…we have now for the first nine months a growth in term of sales by 5%, 6% and for the full year, we expect to be in line also in the fourth quarter with this projection. I don't want today to disclose 2015 numbers. I would just give a general indication that this margin is in someway sustainable going forward. It's not linked to specific items, specific opportunity that we have in 2014, it's mainly linked to two major point, one is the improvement of the gross margin, which is based on the different mix and we expect this different mix to remain essentially the same in 2015, and leverage of our sales organization and we expect it to continue in this direction. Then I don't want today to disclose our number and projection for 2014-2015, just to confirm that this is sustainable going forward.

MARTINO DE AMBROGGI: Okay. Thank you.

OPERATOR: Mr. Squindo, Mrs. Tatschke, there are no more questions registered at this time.

FRITZ SQUINDO: Okay, thank you. Bye-bye.

MARIANNE TATSCHKE: Okay, then bye-bye. Thank you for listening. Bye to everybody.

FRITZ SQUINDO: Bye to everybody.