

# **Recordati S.p.A**

## **“First Half 2017 Results Conference Call”**

**Thursday, July 27, 2017, 16:00 CEST**

MODERATORS:     FRITZ SQUINDO, CHIEF FINANCIAL OFFICER  
                      MARIANNE TATSCHKE, DIRECTOR OF INVESTOR RELATIONS AND  
                      CORPORATE COMMUNICATIONS

OPERATOR: Good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Recordati First Half 2017 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 and Corporate Communications of Recordati. Please go ahead, madam.

MARIANNE TATSCHKE: Good afternoon or good morning to everyone and thank you for attending the Recordati conference call today. Fritz Squindo, our CFO will be presenting and commenting upon our first half 2017 results and our objectives for the full year. For a better understanding of his presentation, please access the set of slides available on our website [www.recordati.com](http://www.recordati.com) under the Investor Relations section and presentations tab. At the end of the presentation we will answer any questions you may have. Please go ahead, Fritz.

FRITZ SQUINDO: Okay, thank you Marianne. Good afternoon or good morning to everyone. We can start from our Slide # 2 and let me say that we are very pleased with our first half 2017 results, which continue to show sales and margin growth.

Consolidating revenue in the period is €50.9 million, which are up by 10.7% compared to last year. Let me underline that sales in the period include €25.2 million from the consolidation of Italchimici and Pro Farma the Italian and the Swiss company acquired in 2016 and consolidated respectively as from 1<sup>st</sup> of June and 1<sup>st</sup> of July.

Like-for-like sales growth is 6.4%, which means that we continue with a solid and strong organic growth, and this excellent sales performance

which as I said is mainly due to the organic development of our portfolio and driven a further improvement of our market. EBITDA at 34.4% as a percentage of sales is in absolute value €224 million up by 19.1% compared to last year.

Operating income at 31.2% of sales is €203.2 million, an increase of 19.4% and net income at 22.6% of sales is €147 million, an increase of 19.8% over the same period of preceding year. Let me underline again that we continue to increase and further expand our margins.

Regarding the financial position, net debt at the end of the period is €356.3 million, here we had an increase of €157.5 million, but let me underline that in the period we have distributed dividend and we pay the acquisition of the product from AstraZeneca for an overall disbursement of €325 million. We continue to have solid and strong financial free cash flow generation. Solid financial results but in the period also important development initiatives for the further growth of the company were undertaken.

Let's start with Cystadrops an orphan drug which is indicated for the focular manifestations of cystinosis was approved by [indiscernible] in January and we are starting to sell the product during the period. An important agreement was signed with Meyer Pediatric Hospital in Florence in Italy for the development of the treatment of ROP which is retinopathy of prematurity.

In May we acquired the European rights to AstraZeneca and metoprolol based product which would contribute to a significant enforcement of our presence in this market. More recently we signed an agreement with MimeTech for the development subsequent group of marketing of the new compound for treatment of neuroparalytic keratitis and in July Reagila the

cariprazine product in license which is a novel antipsychotic and the license from Gedeon Richter was approved by the European medicine Agency and we expect to start launches of this drug in '18. Then in the period where both [indiscernible] in the orphan arena and we have also signed agreement for the further development also in the primary and specialty care business.

Slide # 3 here we comment our main product of sales. So let's start with Zanidip, overall we are very satisfied with the positive performance of our corporate product during the first half. Zanidip sales continue to show a one increase by 8% which means that we continue to keep our sales and we had a slight increase of our sales in lercanidipine plain.

Regarding the combination Zanipress sales, Zanipress is the combination of lercanidipine and enalapril. These are up in the period by 3.9%, and the entry of the generic version in the main European market which were expected at the beginning of the year we have had some delays and now the assumption for the entry of the generic of the combination we expect to be in the second half.

Let me underline that in the first half we had only seen some initial sales in Germany. Then we expected generic to enter the beginning of the year, now the assumption is we enter in the second part of the year. The overall sales of the [indiscernible] franchise also thanks to this delay and we are into the generic version of the combination in the first half of 2017 are €105.5 million, very solid performance of our important franchise which is the franchise of the lercanidipine product. Other corporate product let's start with Urorec silodosin [ph] generated sales of €46.5 million during the first half up 8.9%, mainly due to the good performance of the product in Italy, France and Russia.

Sales of Livazo in Spain, Portugal, Ukraine, Greece, Switzerland, Russia and Turkey are €19.4 million up by 9.5% and this is due to the good performance of the product in Spain, Greece and Switzerland also to the launch of [indiscernible] in Turkey. That's a selective market but in this selective market Livazo pitavastatina is growing, is doing very well.

Other product, other corporate product growth overall by 21.6% and these comprise 21 products sold in multiple territory, each of which are OTC products. Major contributors to growth in the period and anti infective [ph] sold in Russia because we had a very strong performance in Russia of all our performance including these other corporate products and the performance also...this performance increase is also due to the inclusion in the OTC portfolio of a line of gastroenterology products based on lactobacillus reuteri mainly sold in Italy by the [indiscernible] but overall this a group of products driven by very solid brand which are growing let me say in all our territories.

Our specialties indicated for the treatment of rare and orphan diseases generated in the period sales of €104.1 million and with an increase of 9.2% due to good performance of the business in all aspects. All our product, corporate product are growing.

In term of product portfolio in Slide #4, the graph shows the breakdown of our revenue by type of product, no major changes compared to the...our presentation in the last quarter. There is a continuity [ph] in the business, Slide #5, composition of sales of revenue by geography, sales in our main markets continue growth, that the difficult phase in Italy include that the consolidation of revenues generated by the activity the Italian company we bought last year consolidated as I said it's from 1<sup>st</sup> of July, 2016 for a total of 20.4 million.

In pharmaceutical sales in France are up by 5% due mainly to the Group performance of Urorec, silodosin, Methadone and also a good performance of Zenata [ph] our combination because as I said, we have not been impacted by generic competition for our combination in France. In addition also to the sale of Lercan [ph], Lercan is the second brand of Lercanidipine which is now sold directly by our subsidiary following the termination of the license agreement with the previous licensees which was Biopharma. The treatment for rare diseases also are growing strongly in France.

Revenue generated in Russia, Ukraine and the other CIS market is 56.4 million which are up by 58% compared to the same period last year and include also a positive...positive exchange gain of 9.3 million. Excluding this positive contribution, sales in Russia in local currency are up by 26.6%. Then a very important contribution to the Group result but also very solid performance in local currency in...for our Russian portfolio.

The Group's pharmaceutical business in the USA is only dedicated for the treatment of...product...for the marketing of product for the treatment for rare diseases sales in the first half are up by 3.5%.

In Germany sales are up by 13.1 million thanks to the significant sales growth of Zanipress, Ortoton, Lercanidipine and other product local product.

Sales in Turkey are up by 1.3% and include here a negative estimated currency exchange effect of 8.5 million due to the depreciation of the Turkish lira...but in local currency our Turkish business is continuing doing well and sales in Turkey in local currency are...grow by 22.3%.

Sales in other western European countries include direct sales in recent months following the acquisition of Pro Farma again in 2016 and we are very pleased by the performance of our new subsidiary [technical difficulty].

Slide #6, here we have a geographical breakdown of pharmaceutical revenue and here again there is no major changes in this breakdown with Italian business which represent 22% and other group of business in Europe, marketing Europe which are a bit less than 10%, but no major changes compared to our breakdown achieved last year.

Slide #7, here we have our P&L analysis. Sales we have already analyzed our revenue for the period, gross profit is 454.1 million with a margin of 69.8% of sales and let me say that we continue to improve our gross profit thanks to a better product mix that we continue to add.

Selling expenses increased less than sales and are therefore down as a percentage of revenue...from revenue compared to the preceding year thanks to the increased efficiency of our Group commercialization, we have fully integrated the portfolio acquired by Italchimici and we continue to leverage our organization thanks to the efficiency that we have achieved in our commercialization.

R&D expenses are 47.2 million up by 13.3% compared to those in the first half of 2016 and this is due to the initiation of the new development program in particular in the orphan diseases but also to the agreement that we have signed in June with [indiscernible] for the development and subsequent marketing for a new compound for the treatment of neurotrophic keratitis for which we had paid an amount of €7 million as an upfront payment which has been fully charged through the P&L in the second quarter. We've been able to achieve this very solid result and

improvement in our market even if we have charged the €7 million upfront payment in the second quarter of this year.

G&A expenses are up by 6.8% but are down as a percentage of sales. Net other expenses significantly reduced as compared to that of the same period of preceding year due to the extraordinary costs incurred in the first half of last year following the acquisition and the reorganization of the Italian company Italchimici.

Net financial charges are 7 million an increase of 1 million compared to the same period of the preceding year and this is due mainly to higher currency exchange rate losses.

The effective tax rate during the period is 25.1% substantially in line with that of the same period of 2016. And net income at 22.6% as a percentage of sales is 147 million and we have in the period an increase as I said at the beginning of the presentation of 19.8% in our net income declared a 20% increase in our net income.

Slide #8, this slide shows the split of revenues and EBIT between our two business segments, EBIT margin are 43.1 million for the rare disease segment a bit lower than what we have recorded in the first quarter because due essentially to the inclusion in the R&D costs of the 7 million paid for the MimeTech development agreement while for the Primary & Specialty care the margin remains at 28.9%.

Financial position, Slide #9. At June the net financial position increase assured that a net debt of 357.3 million which is...which compared to the negative debt that we had at the beginning of the year which was 198.8 million. But this increase let's say is only due to the payment of the dividend as I said at the beginning and also through the payment for the



acquisition of the product of AstraZeneca we had in the period an overall extraordinary disbursement of €325 million then excluding this, we continue to have a solid generation of free cash flow with cash flows also which is even more than one to one with the net income.

Slide #9, the conclusion of my presentation, the financial projection and the target for the full year and Group continue to perform very well also during July and for the full year 2017 also including the consolidation as from this month of the sales of the Metoprolol base product acquired from AstraZeneca, expectation for the full year is to achieve sales of between 1 billion 290 million and 1 billion 300 million to achieve an EBITDA of between 450 million and 460 million, EBIT of between 400 million and 410 million and net income of between 290 million to 295 million then we expect to have a further improvement in our business also thanks to the acquisition of the product of AstraZeneca.

We signed a contract in May and we closed Brazil at the end of June and we will start the consolidation of this new business 1<sup>st</sup> of July of this year. Here I conclude my presentation and I am available for any question you may have. Thank you for your time.

MARIANNE TATSCHKE: Operator, could you please open the question and answer session.

Q&A

OPERATOR: Excuse me. This is the Chorus Call Conference operator. We will now begin the question and answer session. The first question is from KC Arikatla of Goldman Sachs. Please go ahead.

KC ARIKATLA: Thank you for taking my question. Actually, I have one question on your US rare disease segment. In the quarter, they are down by around 1% and

also it looks the list prices of your top three products have gone up by 5% to 10% on April 1<sup>st</sup>. I understand that the net price increase could be very different from this price increase but it would be great if you could provide us some detail on the dynamics in the quarter and if you are seeing any volume decline for your products there? Thank you.

FRITZ SQUINDO: Okay. First of all, we continue to underline that a quarter is not very significant regarding the trend of the business. Having said that, we have our orphan business which is overall as I said in the presentation in half the period growing by 9.2%. Then we continue to have the Orphan business to be essentially in line which is our expectation to have our business to grow double digit. Regarding the business, we have a solid double digit growth in our business of the Orphan Europe which means a group of products that we have acquired in France and we are now developing on a global basis which is growing double digit. Regarding our US portfolio, the visualization is stable. You will see that on a local base our business in the US in the period increased by 1.3%.

Also because last year we increased significantly this business with new patient for the Carbaglu. This was also into the identification of the patient. Now, we have a stable business. We have identified new patient part of this under the patient assistant program in the US but we expect also for this part of the business for the full year to have this high single digit growth in the business but we are not concerned. There are some the cooler situation for the business but the Orphan one, the portfolio belonging to the Orphan Group Company is growing double digit. The US is stable but for the full year, we expect to continue to grow also in the US business. Overall, we confirm our objective to have a double digit growth in the Orphan business.

KC ARIKATLA: Thank you.

OPERATOR: Then next question is from James Wallace of Credit Suisse. Please go ahead.

JAMES WALLACE: Thanks for taking my questions, three if I may. Firstly, how big was the FX impact on the net financial charge? Secondly, can you give you give a bit more clarity on the timeline for your [technical difficulty] launches. Presumably, you have to undergo negotiations with the individual countries to get reimbursement. Do you have any strong health economic studies in place to achieve good prices and then thirdly if you could give any clarity of the GRASPA mission in the EU that would be great.

FRITZ SQUINDO: Three or two questions?

MARIANNE TATSCHKE: Three, FX and the net financial charges. It was...

FRITZ SQUINDO: Okay then in our net financial charges, which are €1 million higher than last year, the negative exchange rate is around 1.4 million then excluding this net financial changes in the Group is a bit less than €6 million then we will...and given losses are mainly due to depreciation linked to the depreciation of the ruble for some inter-company deal between our subsidiaries.

Because at the beginning in March and in April, the ruble was around 60-59 now in particular in June, there was depreciation and now the ruble is in the region of 65-67. Second question was regarding cariprazine. Then first all let me say that we are very pleased by the approval. Now, we expect to start to launch in 2018 the product and we expect the launch throughout to be during 2018. Now, the focus of our effort is for sure in the market access and we have some for cariprazine some...which show positive result for the negative symptom in the use of cariprazine which

we expect to be an important element in our market access activity. But here we are in the initial phase. We will now follow the process and we will update you progressively on the rollout and on the result of our market access activity.

Regarding graph, I will like again to underline that the profits for the submission...resubmission of the file of GRASPA is in the hand of ERYTECH [ph] and no news, they expect to re-file the dossier in the second half of the year but this is mainly driven by the activity of ERYTECH is not in our hand. We are partner, but we are not directly managing the filing of GRASPA for the ALL indication.

JAMES WALLACE: Okay. Thank you very much.

COMPANY REPRESENTATIVE: Bye.

OPERATOR: The next question is from James Vane-Tempest of Jeffries. Please go ahead.

JAMES VANE-TEMPEST: Yes, hi. Good afternoon. Thanks for taking my questions [indiscernible] if I can. Can you just remind us when were Vitaros or Fortacin launched or when will they be launched? Second question is just on your guidance and how much of the upgrade is Metoprolol and is there any underlying organic upgrades within the guidance? My third question is you know, given kind of about your previous question, given the flat second quarter in the U.S. for rare diseases, yes the overall rare diseases business perform very strongly, which markets have driven the growth and by how much. And then, my final question is on North African, just wondering when we may see our business turnaround? Thank you.

MARIANNE TATSCHKE: James what was the first question? Vitaros? Sorry.

JAMES VANE-TEMPEST: Yeah on Fortacin have they been launched or when are they expected to launch?

MARIANNE TATSCHKE: They are focusing okay.

FRITZ SQUINDO: Okay, then.

MARIANNE TATSCHKE: Perfect launch.

FRITZ SQUINDO: Vitaros has been already launched. Now is commercialized mainly in Spain and in Portugal and recently launched also in Ireland, Portugal and Czech Republic and we expect also a launch in Greece. Regarding the Fortacin Plethora, we expect the launch of the drug at the beginning of 2010 and we are now preparing the organization for this launch. Regarding Metoprolol, then regarding Metoprolol in our guidance let's say that at the beginning, we are now starting managing directly, the product is a complex activity because to manage directly Metoprolol means to be able to manage the distribution in all our countries that we had the services from [indiscernible] and essentially in our guidance for 2017. The assumption is to keep Metoprolol say essentially flat, slightly decreasing because the real impact of our activity in terms of selecting, promotion country-by-country we expect to be mainly in 2018 then in 2017 the assumption is to continue with the previous trend also because we expect to start managing and retaining the product only in the...at the end of the year.

Regarding Africa...

COMPANY REPRESENTATIVE: [Foreign language].

FRITZ SQUINDO: Regarding Africa, we have these decreases mainly driven but some limitation in importation in Algeria and then we expect in 2017 probably not to be able to increase our sales because unfortunately if there is a generic version of some drug in Algeria, then there are some limitation in the importation and that is happening for our Zanidip product.

Regarding going back to our guidance, let's say that in our organic Metoprolol has been included with this assumption. Regarding the business, we expect essentially to be in line with our guidance that we have announced in May. Having said that in our guidance now, we have also included this excel cost, which is the upfront payment of €7 million into the upfront payment for the signature of the MimeTech contract. No major changes, but a good performance and the capacity of our business also to absorb this cost, which is not normal days to the clinical development but is upfront paid for having rights for this new interesting compound and we can keep our guidance even if in the R&D we have charged in the first quarter and obviously also on the full year guidance is €7 million. Then there is good performance of the organic business plus the contribution of Metoprolol considering that we have not yet managing directly the business and we expect Metoprolol to become fully managed by our subsidiaries mainly in 2018.

MARIANNE TATSCHKE: The US, I think last.

FRITZ SQUINDO: Okay. US being [technical difficulty] what can I say then excluding U.S. in which we have this flat situation but I would like to underline that for the full year we expect at least high double-digit growth for our US market, all the other business in growing without any particular geography doing well overall all our business and all our main products are growing then solid and well distributed performance of the rare disease business.

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

OPERATOR: The next question is a follow-up from James Wallace of Credit Suisse. Please go ahead.

JAMES WALLACE: Thanks for taking my follow-up. Can you give us some more help on how to think of the AstraZeneca Seloken deal, are there any countries where you have got this? Where you don't have much infrastructure, where you will need to add additional infrastructure and the product in AstraZeneca hands was declining around 5% a year allowing that you expect this the fall...do you expect this to fall in 2016 and do you expect to be able to grow the drug in 2018 or just to essentially hold the drug flat. And then, finally can you give us some more details on the market in Turkey. You are growing about 20%. How long can you continue at this rate?

FRITZ SQUINDO: Okay. Then regarding Metoprolol, I agree Metoprolol was slightly decreasing in the hand of AstraZeneca. For sure we don't want to keep this trend because we expected to promote and to detail the drug essentially where we have already our subsidiary, we don't expect significant increase in our infrastructure, we could also thinking on a slight Slide increase in some Central European markets in which Metoprolol the Astra brand as a very good market share and then we can on someday also rely on this Metoprolol sales for an enlargement of our sales for benefiting also the other products in our portfolio, but essentially we don't expect major changes in our infrastructure for the promotion of the product acquired from AstraZeneca. We expect to use the current infrastructure, we expect it to promote in a selective way and in a different way country-by-country as user that the value in this in managing this brand is not to have a similar strategy but to be selective as we have identified different strategy country by country. And we expect for sure to stop this slight decrease, to stabilize sales and in some market we could also expect to

generate slight increase. And this will be an important objective in 2018, but then we want to for sure to promote, to manage the drug and we expect in some market in particular to generate a slight increase.

Then, we have also the sales in some European market in which we have not a direct presence, this is the case of Scandinavian of Baltic and Hungary and Bulgaria and in Benelux [ph] then today the objective is to identify opportunity based on Metoprolol size of sales based on our current portfolios sales and in the future in some of this market, we could decide to enter directly. But, not only based on the current Metoprolol sales but also linked to other opportunity linked to our corporate product already sold in this market.

Regarding Turkey, this question has been asked also last year 2016-2017 we are growing 22.17% percent last year 22.17%, okay, we know it's a tough market we have been strongly impacted by the devaluation, but locally the pharmaceutical business is growing. And we have a very solid brand and we expect to continue probably not at 20% or more, but at least our expectation is continue to have a double-digit growth in local currency in Turkey.

JAMES WALLACE: Okay. Thank you very much.

FRITZ SQUINDO: Okay.

OPERATOR: The next question is a follow up from Vane-Tempest James of Jeffries. Please go ahead.

VANE-TEMPEST JAMES: Yes, hi, thanks for taking my follow up question. If I can just come back to rare diseases business again, what I understand you are saying that there is perhaps no one individual market outside of the US



which is driving the performance. But, if I just look at the rare diseases business in the second quarter and exclude the US, just on the quarter it's up by about 40%, so I am just trying to understand that all the markets doing that level is that something particular about the second quarter obviously kind of be aware of? And how should we think about that for the full year?

FRITZ SQUINDO: Okay. Then, as I said, the quarter sometimes is not so significant in terms of trend; frankly speaking I prefer to comment on the performance on a larger period in particular in the six-month period. And then we are essentially is doing in sometime for the...or some business there are some tendering, some Middle East market which could be in one quarter in one year and the other quarter in the other year then, let's say that I confirm what I have already said that good performance in all our market and then we are pleased by the performance of our main product.

VANE-TEMPEST JAMES: Okay. So, [multiple speakers] it's up 15% in the first half, is that the type of level you think is sustainable for the full year with high single digit in the US?

FRITZ SQUINDO: We expect to be able to release double-digit growth in line with our assumption for the rare diseases, which means for sure to continue a double-digit growth in the European and on the other part of the world and to recover to a high single digit or even double-digit in the business in the USA. But, we are frankly speaking we are not concerned and worried about this, because the business is growing really well.

VANE-TEMPEST JAMES: Okay. Thank you.

FRITZ SQUINDO: Right.

OPERATOR: The next question is a follow up from KC Arikatla of Goldman Sachs. Please go ahead.

KC ARIKATLA: Thank you for taking up my follow up question. I am sorry to go back to rare diseases, but if I heard you correctly you mentioned that there was a 7 million R&D expense in the quarter, which I presume all of it went to rare disease segment, right? So, if I added back that implies that your EBIT margin for rare diseases was almost 54% that's a bit unusually high. Was there anything that helped during the quarter or was that 7 million not entirely in rare diseases? Thank you.

COMPANY REPRESENTATIVE: Entirely...

FRITZ SQUINDO: Entirely in the rare diseases. Then, are you talk about the quarter, as I said, quarter sometime is not I prefer not to comment in the quarter, what is important is the trend for the...in the first half and what we expected for the full year. Regarding your specific question yes we have charged 7 million and this has been fully charged in the rare diseases.

KC ARIKATLA: Thank you.

FRITZ SQUINDO: That is because...on the other hand the other cost of rare diseases, the R&D of rare disease could be lower than expected and then is the mix is not...you cannot just to leave some 7 million and to have because it's a dynamic, if we have managed this, we have signed this agreement the other end there are some delay in some cost development for some clinical development of rare disease. But, let me again underline we prefer comment the full, the six months and not only the quarter because quarter is not always so significant in terms of plants.

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

MARIANNE TATSCHKE:       Okay.

FRITZ SQUINDO:       Okay. Thank you, bye.