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ROVI.MC - Full Year 2018 Laboratorios Farmaceuticos ROVI SA Earnings Call

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PRESENTATION

Operator

Ladies and gentleman, thank you for standing by and welcome to the ROVI Full Year 2018 Financial Results Conference Call. (Operator Instructions) I must advise you that this conference is being recorded today, Tuesday, 26th of February 2019. I would now like to turn the conference over to your first speaker today, Mr. Javier López-Belmonte. Thank you. Please go ahead, sir.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

Thank you, Carl. Thank you very much, and good afternoon to everyone. This is Javier Lopez Belmonte, CFO of ROVI. At this time, I would like to welcome everybody to this full year 2018 results conference call, which we will start in a moment. Let me please first introduce ROVI's attendees today, Juan Lopez Belmonte, CEO; Marta Campos, Investor Relations; and myself. (Operator Instructions). Let me now turn the call over to the CEO, Mr. Juan López-Belmonte for the highlights of these full year 2018 results.

Juan López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - CEO & Director*

Thank you, Javier, and welcome to everybody. I am glad to present our full year 2018 results. Performance this year has been over our expectations. Our 10% operating revenue growth discussed on '18 was driven by the strength of the specialty pharmaceutical business, which grew by 16%, strongly outperforming the market. Data provided by QuintilesIMS indicate that the Neparvis market in Spain increased 2% in 2018. However, sales of pharmaceutical products with prescriptions for ROVI rose 18% in the same period, exceeding the market by 16 percentage points.

We forecast that we will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in 2018, which according to the Ministry of Health consumption and social welfare, show a growth rate of 3%.

Regarding the classification of authorities, using data from QuintilesIMS, ROVI was positioned 20th in terms of value and was the fastest growing innovative company among the 20 top ranked companies in 2018.

In 2018, ROVI ranked (inaudible) in this classification compared to 2017. As a member of Farmaindustria, the Spanish pharmaceutical industry association, ROVI is subject to a collaboration agreement entered between Farmaindustria and the Spanish Government in 2016. Pursuant to the agreement, in the event of public spending on drugs, excluding generics and biosimilars, increases at a rate in excess of the actual rate of growth of the Spanish gross domestic product, the pharmaceutical industry must reimburse the difference to the government through monetary payments. In 2018, the public spending growth rate was higher than the GDP growth rate and therefore, the sales recorded by ROVI were EUR 3.5 million lower than the actual sales. This amount is included in the "Discounts to the National Health System" line.

In 2018, we made an important investment effort in research and development. As we continue to develop a Phase III trial for Risperidone and a Phase I study for Letrozole, both with our ISM technology. Likewise, EBITDA was affected by nonrecurring expenses of EUR 1.1 million linked to a substantial change to Frosst Ibérica employees' working conditions. EBITDA with research and development calculated excluding research and development expenses in 2018 and 2017 and the impact of nonrecurring expenses last year increased by 8% from EUR 58.2 million in 2017 to EUR 63 million in

2018, reflecting a 0.3 percentage point fall in EBITDA margin to 20.8% in 2018.

Net profit through R&D calculated excluding research and development expenses in 2018 and 2017 and the impact of nonrecurring expenses in 2018 increased by 19%, from EUR 45 million in 2017 to EUR 53.8 million last year.

Prescription-based pharmaceutical specialties, which grew by 18% in 2018 on high strategic value products and contribute to give ROVI a wider scope for the coming years. Rovi counts as driving force with its low molecular weight heparin franchise, where sales rose 42% to EUR 121.5 million last year. Low molecular weight heparin sales represented 40% of operating revenue in 2018 compared to 31% in 2017. We aim to become one of the leaders in the low molecular weight heparin field worldwide, which are 2 molecules, Bemiparin and an enoxaparin biosimilar. Bemiparin, which performed very well in 2018, grew by 9% to an amount of EUR 91.3 million. Sales of Bemiparin in Spain increased 15% to EUR 67.4 million last year, while the low molecular weight heparin market increased 4.2%, beating the market by 11.8 percentage points and achieving a market share of 32% in 2018 compared to 28% in the previous year. Bemiparin international sales decreased by 5% to EUR 23.8 million in 2018. Regarding enoxaparin biosimilar pickup, we launched the product in Germany in September 2017, in the U.K., Italy, France, Spain, Austria, Latvia and Estonia in 2018. And we should be launching in all major countries in Europe before end of Q1 2019. For this purpose in the first stage of commercialization strategy, we have established subsidiaries in France, U.K., Germany, Italy and Poland. These 5 countries, plus Spain and Portugal, cover around 75% of the European enoxaparin market and provide a Pan-European infrastructure that is highly leverageable. Besides Europe, we have signed now licensing agreements in 68 countries as part of our second stage of our commercialization strategy. We have signed 2 important licensing agreements to distribute and market our enoxaparin biosimilar. The first with Hikma Pharmaceuticals, who have exclusive rights for 17 Middle East and North Africa countries and the second with Sandoz for 14 countries/regions. We started the commercialization in Q4 2017 in Germany, which sales amounted to EUR 1.5 million and there our sales increased to EUR 30.2 million in 2018.

So let me summarize the opportunity here. This is a EUR 1.5 billion market with high entry barriers where biosimilar strength will reach 50% to 70% of market share with only 2 other players already in the market.

The latest launches were again a strong driver of growth in 2018. Sales of Neparvis from Novartis launched in December 2016 indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction reached EUR 13.6 million compared to EUR 4.7 million last year. Sales of Volutsa from Astellas Pharma increased by 25% to EUR 11.2 million. Sales of Hirobriz Breezhaler and Ulunar Breezhaler, both inhaled bronchodilators from Novartis, increased by 7% to EUR 15.3 million. Sales of Vytorin, Orvatez and Absorcol, the first of the 5 licenses of Merck Sharp & Dohme decreased by 9% to EUR 36 million in 2018. In the second quarter of 2018, the active principle ezetimibe went out of patent and the

price of Absorcol was reduced. Likewise, generics formulated with ezetimibe and simvastatin have recently been marketed, so the price of Vytorin has been reduced to be competitive. All these product launches will lead us to stretch the average life of our product portfolio by several years, and we expect they will provide us with a sustainable and profitable growth opportunity in the coming years. Other products, such as Medikinet and Medicebran from Medice, decreased by 2% to EUR 7.4 million in 2018.

Finally, sales of contrast imaging agents increased by 4% to EUR 29.7 million and ROVI continues being the market leader in this segment. Recovering from manufacturing, sales decreased by 11% to EUR 54.6 million in 2018, mainly because of the reduction of the injectable business compared to 2017 when exceptional high volumes were manufactured for some customers. ROVI has one of the largest solid oral forms manufacturing plants in Europe. Frosst Ibérica plant [takes], decreased 1% percent in 2018 to EUR 21.9 million. The manufacturing plant at San Sebastián de los Reyes acquired in June 2015, they started the syringe filling operations in February 2018, thus expanding the production lines of injectables of the group.

As previously informed, ROVI has progress in the development of risperidone ISM. The first candidate for its leading edge drug delivery technology ISM for a prolonged release of Risperidone, a well-established second-generation antipsychotic medicine. After successfully finishing the Phase I and II programs of Risperidone ISM, we started a pivotal Phase III trial PRISMA III with the recruitment of the first patient in May 2017.

May 2018, we informed that after a prespecified interim analysis on the pivotal PRISMA III study, an independent data monitoring committee recommended to continue the clinical trial and not increasing the currently planned number of randomized patients. After finishing the recruitment in September 2018, all patients completed the double blind, main part of the study in December 2018. Therefore, the company plans to file an NDA, U.S. Registration Dossier for the FDA the second half of 2019.

On the other hand in November 2017, ROVI started the clinical development of Letrozole ISM, the first long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer. The first stage I clinical trial, the LISA-I study, is an open-label dose-escalation study to evaluate the pharmacogenetics, safety and treatability of single intramuscular injections of Letrozole ISM at different strengths in healthy postmenopausal women. The clinical trial is currently ongoing as scheduled.

And finally, let me end with our guidance for 2019. ROVI expects a high single-digit growth rate for the operating revenue. We have stayed on the path of sustained growth. We have increased our sales, strongly outperforming the market. We have expanded our heparin franchise through the launch of our enoxaparin biosimilar in 7 new countries and the signature of 2 important agreements with Hikma and Sandoz for 41 countries, which will reinforce our European presence through the acquisition of 3 new products, Falithrom for German market, and Dexchlorpheniramine for the Spanish and French markets. And we have consolidated our pharmaceutical specialties area thanks to the strength of our leading products, such as Neparvis, Ulunar and Volutsa. Likewise, we are making an effort to heavily invest in research and development focused on our ISM technology, what we see as a new avenue of future growth for ROVI.

To conclude, we believe we are at a growth inflection point with a strong growth opportunity driven by Risperidone and Letrozole, both candidates elevating our leading edge drug delivery technology ISM and our enoxaparin biosimilar, which will allow us to transform our European footprint. These growth levers are firmly underpinned. They are very solid ongoing business that has delivered year-after-year based on our leading specialty pharma franchise on our high-value added toll manufacturing services.

And now I pass on to Javier, who will run you through the financials in more detail. Thank you very much for your attention and for taking the time to participate in this telephone conference.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

We are very happy with our performance in 2018, as Juan already said, our operating revenue increased by 10% this year. Sales of prescription-based products increased by 18%, strongly outperforming the market and 16 percentage points in 2018. Regarding our low molecular weight heparin franchise, we achieved a 42% growth. Sales of Bemiparin, our flagship product, developed in-house grew by 9% and enoxaparin biosimilar sales reached EUR 30.2 million last year. Gross profit increased by 5% to EUR 176.2 million in 2018. The gross margin showing a decrease of 2.6 percentage points from 60.7% in 2017 to 58.1%, mainly due to several factors: first, the drop in the injectable business, which had other higher margins in 2017. Increase Enoxaparin biosimilar sales, which added lower margins in 2018 after the launch of the product in 7 new markets. The commented EUR 3.5 million reduction in sales reported in connection with the agreement entered into between Farmaindustria and the Spanish Government. And finally, then increase in the low molecular weight heparin raw material prices, which in 2018 were running around 30% over 2017 prices. ROVI expects these rising trend to continue during 2019.

ROVI's commitment to innovation has been reflected in the figures for 2018. R&D expenses rose 15% to EUR 32.4 million. These figures are mainly the result of a focused investment in the ISM Risperidone project. Our investment effort in R&D is motivated by our firm commitment to market, owned quality and successful products in the immediate future. Selling, general and administrative expenses, SG&A, rose 4% percent to EUR 113.2 million in 2018 mainly due to international subsidiaries expenses, which amounted to EUR 6.6 million compared to EUR 1.6 million in 2017. Excluding expenses related to these international subsidiaries, SG&A would have decreased by 0.2% in 2008.

For this year, 2019, expenses related to international subsidiaries are expected to be around, or close to, EUR 10 million. In 2018, EBITDA was affected by nonrecurring expenses of EUR 1.1 million, leading to a substantial change in Frosst Ibérica employees' working conditions. This change in these working condition was mainly related to the removal of the catering service for which the employees were compensated with a sum similar to the cost that ROVI would have incurred in the following 5-year period. EBITDA decreased to EUR 25.9 million in 2018, a fall of 1% compared to the previous year, reflecting a 1.1 percentage point decrease in the EBITDA margin, which was down to 9.7% in 2018 from 10.9% the previous year.

However, EBITDA, pre-R&D, calculated excluding R&D expenses in 2018 and '17 and the impact of nonrecurring expenses in 2018, increased by 8% from EUR 58.2 million in 2017 to EUR 63 million in 2018, reflecting only a 0.3 percentage point fall in the EBITDA margin to 20.8% in 2018. EBIT performance followed the same trend as EBITDA in 2018. It decreased by 5% to EUR 17.5 million, reflecting a 0.9 percentage point fall in the EBIT margin. EBIT, pre-R&D, are calculated in the same way excluding R&D expenses in 2018 and' 17 and the impact of nonrecurring expenses in 2018 increased by 9% from EUR 46.7 million in 2017 to EUR 51 million last year, reflecting only a 0.1% percentage point fall in the EBIT margin, to 16.8% in 2018.

Net financial costs decreased by 13% up to EUR 0.8 million in 2018. Net profit increased to EUR 17.9 million last year, a 40% rise compared to 2017. However, net profit pre-R&D, calculated excluding R&D expenses in 2018 and '17, and the impact of nonrecurring expenses in 2018 increased by 19%, from EUR 45 million in 2017 to EUR 53.8 million last year.

The effective tax rate was minus 7.3% in 2018, generating a positive income tax of EUR 1.2 million compared to 1.6% in 2017. This favorable effective tax rate is due to the deduction of existing research and development expenses and the capitalization of negative tax bases. As of the end of last year, negative tax bases of the Group amounted to EUR 36.3 million, of which EUR 1.4 million will be used in the 2018 income tax.

While the Risperidone ISM Phase III trial is ongoing, adding higher R&D expenses, ROVI expects a very beneficial effective tax rate to be applicable, which could cause the income tax item to be positive income as of this year. Notwithstanding, when the R&D expenses are normalized after completion of the Phase III trial, the company expects the effective tax rate to be in mid-single digit numbers in the following years.

ROVI invested EUR 17.4 million in 2018 compared to EUR 15.5 million the previous year. Of this amount, EUR 15.1 million relates to investment CapEx regarding our facilities and EUR 2.3 million relates to maintenance and other CapEx. In addition, in 2018 ROVI invested EUR 9 million for the acquisition of Falithrom.

Meanwhile, free cash flow decreased to minus EUR 17.8 million in 2018 from minus EUR 1.6 million in 2017 mainly due to increasing inventories, receivables and payables and the increase in CapEx. As everybody knows, in 2018, ROVI increased its equity by approximately EUR 80 million. Net expenses related to the transaction amounted to EUR 3.9 million, resulting in a net capital increase of EUR 84.1 million. As of the date of this presentation, ROVI among other uses, has used EUR 22.5 million of these funds to acquire Falithrom and Polaramine.

Regarding our debt as of 31st December 2018, ROVI had total debt of EUR 34.2 million. Of that amount, EUR 22.7 million is debt with banks, representing 66% of total debt, while EUR 11.5 million correspond to debt with public administration, related to the development of R&D projects, which is 0% interest rate debt representing 24% of total debt.

After the completion of the capital increase in October last year, as of 31st December 2018, ROVI had a gross cash position of EUR 97 million compared to EUR 18.9 million as of 30th September 2018, and EUR 42.1 million as of 31st December 2017. And net cash of EUR 62.8 million compared to net debt of EUR 20.6 million as of 30th September 2018, and net debt of EUR 1.1 million as of 31st December 2017.

Finally, ROVI will put a proposal to the general shareholders meeting to allocate the 2018 profit to, firstly, the reserves items on the company's statement of financial position and, secondly, the distribution of a dividend of 0.0798 euros per share entitled to receive it, which would entail the distribution of approximately 25% of the consolidated net profit for 2018.

Finally regarding news proposals in 2019, we expect to announce additional new products to be launched in the specialty pharma area, new contracts in the toll manufacturing division, and new national marketing approval for the enoxaparin biosimilar in 2 EU countries, Greece and Luxembourg. Likewise, we expect to launch our enoxaparin biosimilar in all major countries in Europe before first quarter 2019.

With regards to R&D, we expect to release the Risperidone ISM Phase III data by the second quarter of 2019 and we plan to file an NDA, a new drug application in the U.S. Registration Dossier for the FDA in the second half of 2019. Also, we expect to release the Letrozole ISM Phase I data result by the second quarter of this year.

And that's all regarding our financial results for 2018. We can now start the Q&A session.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of [James Minge Teppit].

Unidentified Analyst

I got 3 if I can, please. Firstly, last year you helpfully gave an indication of expectations of back out. I was just wondering whether you would be happy to do the same for 2019? And also, does your revenue guidance include some of the recent product additions? That is my first question then I'll just ask the other 2.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

Hi James, this is Javier speaking. This year we are not providing a formal guidance to the market. But we are saying to analysts and investors that you can take the sales of the last quarter of the year, have a good visibility to this year by similar sales. And second, with regard to the acquisitions, as we have arranged in the guidance, we now feel more comfortable to be hitting the higher part of the range; however, we are still in February, so it is very early for us to update the guidance, but we feel more confident being in the higher part of the range.

Unidentified Analyst

Thank you, just to clarify your answers. You're saying if you looked at the last quarter, you are saying that is the run rate or you saying that the base in your expecting growth from that? I didn't understand your answer.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

We, as I said, this is early for us for visibility for the year, we are just seeing it as a run rate. This is a good, at least to the people on the ground we have good visibility for the evolution of the sales for the year.

Unidentified Analyst

And then what do you spoke about in terms of the gross margin in terms of lower contract manufacturing revenue and then also high backout revenues and then raw materials, the cost going up, do you expect gross margins to come down again this year and how should we view the evolution of your gross profit line, please?

Juan López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - CEO & Director*

Hi James, this is Juan. I mean, I think gross margins have been coming through capital evolving as we would expect it. As we share with the investor community, we believe that this is at least the way we see the Enoxaparin is in terms of our mid-term, long-term rates where we want to become one of the leading companies in the low molecular with heparin. And really, our marketing and pricing strategy has been decided accordingly to this long-term objective. Right now, we are seeing certain tension in the raw material price, which is logical to understand we, all companies involved in this market, we are building inventories, so we are creating sort of an artificial over-demand in all materials that probably is impacting our current supply chain and is impacting all companies. We do expect still some tensions in 2019, but hopefully, we believe that in 2020 it should stabilize and even start showing some levels of price reduction. But as I said before, I mean this is as we expected, we being in the low molecular weight heparin market for years. Right now, we are already in a race of building inventories and making sure that we launch our products as soon as possible in all accepted markets. And as Javier has mentioned before, we are showing a really very promising platform in the last quarter this year and we really want to make sure that we've capture the right market share in the domestic markets as soon as possible.

Unidentified Analyst

Understood. So it sounds as if gross margins are probably trending down a little bit this year and then hopefully starting to go up in 2020, is that the right way to think about it?

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

Yes, that should be the logical path.

Unidentified Analyst

And then my final question just on SG&A. If I understand correctly, you're saying there is an incremental EUR 10 million in 2019 for subsidiaries. I am just curious, putting all that together, if you'd be happy to give at least an indication of EBIT or EBITDA margin or how we should think about profitability for this year.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

This is Javier speaking again. Let me clarify that this EUR 10 million or pretty close to EUR 10 million SG&A for the international subsidiaries are not incremental, it is the absolute quantity, so we are not talking about another EUR 10 million. We are talking about up to EUR 10 million, so that would mean only from EUR 3 million to 4 million extra for the year, with some of these costs are viable being the evolution of the phase, but of course logistics and warehousing costs. And then EBITDA, the guidance for the company is not to give our guidance, especially since this year we've been very -- we have many variables that are not easy to control.

Operator

Okay, our next question comes from the line of Jose Maria.

Jose Maria Canovas Garcia de Blanes - *JB Capital Markets, Sociedad de Valores, S.A., Research Division - Analyst*

I've got 2. First of all, it is regarding Bemiparin. What would you expect for Bemiparin sales, both in Spain and international? And if you could maybe give some more color on what happened this year with international sales. And I had some problems with my connection, so I don't know if you have already answered this question, but regarding raw material prices, what would you expect for 2019? So I think I heard that you were expecting a similar trend than the one seen in 2018, but just to confirm this point.

Juan López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - CEO & Director*

Hello, this is Juan. Regarding Bemiparin, specifically on Spain, actually the performance last year was extremely good. We don't see any sign that this should be different in 2019, although we expect that growth may slow down slightly, especially after the second, third quarter of this year, but we do expect as well an important growth in Bemiparin section in Spain. Regarding the Bemiparin in international business, the decrease was mainly due to the devaluation of the Turkish currency, which is one of our most important markets in the international landscape and devaluation of the currency has really impacted us in a very important way, showing that 5% decrease, which is mainly due to the sales of that country. Our expectations, we're trying to talk over with the Turkish government to see if we can get some sort of compensation by getting a price increase of Bemiparin in Turkey. Right now, we don't have visibility on that sense, so we should be expecting on international Bemiparin to have a level of sales very similar to what we achieved in 2018. Regarding raw material prices, I cannot share with you what I did before with James. Gross margins and raw material prices are evolving as we expected. I mean, we all companies, we are right now building inventories, trying to make sure that we have product to launch in our countries as soon as possible. So we do believe that we have created a certain level of an artificial bubble in terms of an over-demand on all the materials on the low molecular weight heparin supply chain. That has provided certain price tensions in 2018. We believe that those tensions will continue in an important part throughout 2019, but we believe that will stabilize at the end of the year or beginning of 2020 and we may even see some signals of decrease next year. Again, having said that, that was already in our road map, and it was something that we have already in mind when we are launching the product in different markets. Right now, our focus is to make sure that we launch the product in the most important market and making sure that we capture as much market share as possible in the most profitable low molecular heparin markets.

Operator

Our next question comes from the line of Susie Jana.

Susie Jana - *Edison Investment Research Limited - Analyst*

I just really wanted to follow up on the market dynamics in the bench markets. Firstly, really, can you give us a bit of color on why it did particularly well in Spain this year versus last year, I know we saw some changes there. And also, are you seeing the two biosimilars that you have launched in Europe Enoxaparin, are you seeing any sort of competition there? And then lastly, just in terms of NHS discounts, can you give us a little bit of transparency there, what you might be thinking about in 2019, whether it's skewed to a few products within the portfolio.

Juan López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - CEO & Director*

Hello, Susie, this is Juan. Regarding Bemiparin, the market dynamics in Spain, just let me remind that Bemiparin is a second generation low molecular weight heparin. We have always marketed the product as clinically appreciated profile versus Enoxaparin, in the sense that first it is the only low molecular weight heparin that can be administered before and after surgery, and secondly it is the only low molecular weight heparin that provides 24-hour coverage to all patients regardless their risks with 1 dose per day. That means that basically what has happened, at least for this addition, the fact as soon as we were launching in Spain or the fact that as soon as we have already been launched in Europe, again our commercial awareness has increased significantly in the last 8 months and that's why we believe that our share of voice and our share of science compared to Sanofi's commercial profile has increased significantly and we believe that those are the rationale, the facts, that has provoked this tremendous performance of Bemiparin in the Spanish market last year. And that's why we believe that to some extent, obviously it would be difficult to maintain this growth rate to continue in 2019, but again we have been marketing Bemiparin for the last 10 years on a completely differentiated pumps. Once biosimilars has been launched, it is also logical that Sanofi may have reduced their promotional budget, and that includes the number of reps and sales to be taken abroad, and we believe that is the reason why Bemiparin has performed with such successful rates last year. Regarding the biosimilars in Europe, actually there is little information I can share with you, in the sense, first to the best of our knowledge, has just started marketing the products in Germany and I believe possibly in Italy and we don't have that margin for really to share. Regarding our Chinese colleagues, again we have not seen that much competition from them. But again, we are still in the very early stages in most of the market. Bear in mind that we are only selling EUR 40 million in the market in Europe that accounts for almost a billion. So again, still our market share is pretty small and we are the leading company in terms of sales, so that's why we are still very optimistic of the potential sales that we can make out with this product. Let me remind as well that we believe, as we have always shared, that this is an industrial product, what counts is the supply chain, what counts is investor capabilities and we really think that sense really have got a unique completed features in terms of global capacity, vertical integration from raw material to finish. And that is why as I mentioned in the last 2 questions, the way this would have target this market between mid-term and long-term basis, and ROVI is fully committed to become one of the leading low molecular weight heparin companies in this market. Regarding discounts, they are in line, which we previously share with you at different events, I mean discounts are between 20% to 30%, depending on their market. Hospital prices were already low and they were lowered significantly initially by Sanofi, and they more of less have remained in the same level in terms of prices, and with sale prices the average discounts depending on the companies between 20% to 30%, which again is pretty much in line with the trend followed by other biosimilars launched before.

Operator

Our next question comes from the line of [Alvaro Arisagi].

Unidentified Analyst

I'm sorry to say that most of my doubts have been already clarified yet. Just to make sure, because I couldn't listen to it, but you promised that you recently acquired a (inaudible) in the data that you provide as well.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

Hello, this is Javier. Our guidance was originally released to the market last November when we haven't acquired those calls yet. What I said is that those acquisitions are small, they only account around EUR 9 million, from ballpark. What I can say right now is that we feel more comfortable to achieve the higher part of the range. However, it is still early for us, it's only February, to change or update the guidance.

Operator

Our next question comes from the line of [Isabelle Carvallo].

Unidentified Analyst

Three questions, if I may. The first one is regarding Bemiparin during the Q4. A side note from -- I think there has been a slowdown in the last quarter of the year in Spain. If you can please clarify if this is correct. Second question is regarding the CapEx. Your CapEx expectation for this new year, 2019. Finally, if you can comment a little bit on your M&A plans given your strong cash flow, net cash position.

Juan López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - CEO & Director*

Hello [Isabelle], this is Juan. Regarding Bemiparin, the first quarter 2018 is very much in line with other quarters. It has -- maybe it is a little bit flattish compared to Q4 2017, but again don't forget that low molecular weight heparins are very much related to surgery procedures, but depending on the holidays and depending on the date that surgery theaters are closed, you have certain level of impact. But let me say as a recap, we don't see any dynamic today that should change the performance that we have shown in 2017. It may slow down a little bit as I mentioned before, because obviously we are also marketing the biosimilar Enoxaparin in Spain, and there has been certain level of reduction as well, coming from that side. But we are marketing that product as a completely differentiated compound and low molecular weight heparins, they have to be prescribed by law by trade mark. We do believe that at least, I mean, that the performance Bemiparin, again should be very much in line with last year. Maybe with certain level of slowdown in the second part, but the product is showing a lot of energy. Our share of these for the data that we are getting from the all this, our share of voice has been increasing substantially in a very sustainable way for the last 3 quarters, and I think those unique value propositions regardless to the therapeutic window, pre and post surgery administration, and the one that is still very important and competitive differentiations for Enoxaparin. Again, we are also reaching a market share, which is already 32%. We still believe that we have room to grow, and it will depend very much on the next quarters how far we can go on our market share, but to some extent, we don't see in Q4 any signal that it should dramatically slow down because of the process.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

This is Javier. With regards to your second question about CapEx. Let me tell you that our forecast for the year, not taking into account any M&A activity could be similar to last year figure. Our maintenance CapEx, however, could be around EUR 12 million to EUR 15 million. And finally, your last question with regards to our M&A activities. As we share with our investors in the capital race transaction we estimated at that point that around

EUR 40 million to EUR 60 million could be used through M&A. So far in these 3 months, I believe, we have already used around EUR 22 million and we will be -- we are actively looking for new potential acquisitions that could enlarge our operations, especially in Europe with our new subsidiaries, or that would add operation leverage to our domestic operations here in Spain. So yes, we are very active, but always looking for something that is small, but could be seen as a big plus.

Operator

Our next question comes from the line of Samir Devani.

Samir Devani - *Rx Securities Limited, Research Division - Research Analyst*

Just got a couple. EUR 3.5 million rebates and I just want to understand how you book that, is that all in Q4 or has it been booked throughout the year? And then the second question just on capacity at your injectables plant. If you can just tell us what the outlook there is in terms of expecting any potential new business.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

Hi Samir, this is Javier, good afternoon. The rebate to the National Health System, as Juan was trying to explain, is quite complex, because it depends on evolution of the GDP, also it depends on the evolution of the pharmaceutical expenditure, both in the hospital channel and the rebate channel. So is not clear, so we did book some amount in the first 9 months; however, the main amount has been booked in the last quarter of the year when -- through Farmaindustria, through the corporation we've been informed about actual quantities. And we could have the visibility to give to auditors and the mechanism is we have accounted as less sales in the P&L. With regards to your second question about the capacity of the injectable business. As you may remember, we bought our second facility in 2015, second injectable facility today, and we have been able to start filling syringes last year, and this year we hope to start also manufacturing there, even our biosimilar. Capacity was, we try also not to market or to commercialize the whole capacity to our customers, as you know trying to reserve or to keep enough room for manufacturing of our own biosimilar. Having said that, I believe that the expectation for growth in '19 are positive in the sense of ongoing manufacturing and in terms of capacity, it is always complex to give you percentage. We do believe that we have enough capacity to get important market share in the Heparin market. And again, we have more capacity in some parts of the manufacturing process in biosimilars. We still feel that we have plenty of capacity to become a leading player in the heparin market and we have to upscale our infrastructure again.

Samir Devani - *Rx Securities Limited, Research Division - Research Analyst*

That's great. And maybe just a follow-up on the rebate. Should we be seeing a similar Q4 effect this year?

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

Again, that's another good question because we have no government right now, but we have a government in progress. Election has been called, so the agreement -- maybe Juan will comment on this with some more information.

Juan López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - CEO & Director*

Hi Samir, this is Juan. I mean officially, the agreement has been renovated for a quarter, that means until end of March. Up to today, we don't have any visibility of whether that can be renovated for the rest of the year, because as Javier has said, we have general elections in the 28th of April, so it will be very difficult to find a comfort back to really discuss the terms of our yearly annual renovation. The Russian agreement was renewed for the first quarter, was to give time to renew a global annual agreement. As elections have been announced, again, they -- we don't have any indication of what could happen with this agreement. We should have more visibility in the second quarter once we have a government already being appointed.

Operator

Okay, we will now take our last question. And our last question comes from the line of [Hermes Falcao de Singleton] .

Unidentified Analyst

(inaudible) from Caixabank BPI. Three from me. First, I would like to start formally the topic. I want to get your view on whether you contributing in the low molecular weight heparin market will start a volatility crisis could impact competition levels in the future. With the completion, if I understand this correctly, the growth slow down, after the second and third quarter in Spain and Bemiparin should be connected with some cannibalization by the enoxaparin biosimilar. If you can quantify your expectations regarding these impacts. And third, if you could quantify the raw material impact from the margin dilution from the Enoxaparin biosimilar growth, so just expectations for what we could see in 2019 at the run rate.

Juan López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - CEO & Director*

Hello, this is Juan. I hope I have understood the right way your first question regarding the trend for low molecular weight heparin. What we believe and we are seeing is that there is no therapeutic alternative for low molecular weight heparin. There is really nothing in the pipelines of any -- at least that we have been able to check in the big Pharma companies in regards to anticoagulant. We believe that with -- oral coagulant, that means Xarelto, apixaban, and Pradaxa. Low molecular weight heparin the anticoagulant, antithrombotic that area is fully covered. This is our view, we believe that low molecular weight heparin is going to be a product clinically is going to be needed for -- at least for the next 10 years. Actually, the figures that we are getting from the RD is that the market is still showing some growth, in terms of units, obviously low single-digit growth and still we are seeing it is really the product of choice in the hospital setting and surgery settings. So in that sense, we are very optimistic in the sense that the market is going to remain a very important market, again, book on the side of ROVI, so we have give you a view without counting the U.S., and enoxaparin sales, accounts for EUR 1.5 billion. If you add up to that the rest of the low molecular weight heparin markets, we may be talking about a market close to EUR 2 billion, so definitely ROVI with the strategy of having 2 different compounds in Enoxaparin plus Bemiparin, plus our industrial capabilities and our know how the low molecular weight heparin market, we believe we have features to really establish ROVI as one of the leading companies in the low molecular weight heparin. Regarding Bemiparin, as I mentioned before, we are already reaching a market share of 42% in 2018, so it is logical that the closer that we get to market shares close to 40%, we're going to suffer a natural slowdown, not only because of the cannibalization of the enoxaparin biosimilar, but as well because we are already reaching sales, which are really, I believe, extraordinary in terms of performance. That's why I would like to be conservative, I mentioned before to some of your colleagues that we don't see any signal today that may change the dynamics of 2019, but being conservative and realistic, it is also difficult to show a similar growth in 2019. We do expect that Q1 and Q2 should be in line, but it would be as well common sense that we show a slowdown in terms of growth of Bemiparin throughout 2019, but again it is not because the product is weakening, it is not because low molecular weight heparin are decreasing, it is actually because we are already reaching a level of market share which is getting 40%. Bemiparin may become in the near future maybe the leading low molecular weight heparin in Spain. So we are actually reaching what it would be a natural ceiling in terms of sales. I'm sorry, but I forgot your third question, if you can just repeat it?

Unidentified Analyst

Yes, it is just related to the gross margin. I would just like to understand what is the impact of the raw material increase this year and the margin dilution from Enoxaparin biosimilar growth, because I think it just seems this will be maintained in 2019, if I understood correctly.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

Yes, regarding gross margin, again as I mentioned before, low molecular weight heparin we treat as an industrial thing. So again, all companies right now, we are building inventories. They are trying to really to buy all materials required to make sure that we have all our drugs available in all markets as soon as possible, and thus creating a sort of a bubble throughout all the different materials throughout the supply chain, not only raw material, but as well the different serums. And don't forget that we have taken up a very sophisticated compound, so raw material that comes from the, of the case then is finishing up with the syringe, which now has to be sterilized, and blister packaged, I am talking about hundreds of multi use, again we are talking about how we accomplish both, we reduced price throughout the markets compared to other different syringes. Again right now, we are all companies trying to fill our capabilities, and that artificial bubble is creating tensions in the raw material prices. We believe that, that's going to continue during 2019. I'm confident of our expectations it will come to an end shortly at the end of this year, beginning of 2020. Anyway, we believe it was in the road map, we knew that was going to happen. The same way it has happened with biosimilars, why it is important for ROVI is the midterm strategy. We want to become one of the leading low molecular weight heparin suppliers. And right now our price and marketing strategy is really focused, not so much obviously, increasing our gross margin, but definitely making sure that we capture leading market shares in both countries where are most suitable in terms of prices and volumes, and this is really right now the focus on the company. Having said that, obviously gross margins will be positively over time, because again as we gain size and volume, we will have, how can I say, an escalating impact on the gross margin. We believe 2019 will be a transition year and we will start seeing much more positive data in 2020.

Operator

(Operator Instructions) There are no further question at this time. Please continue.

Javier López-Belmonte Encina - *Laboratorios Farmaceuticos Rovi, S.A. - Second Deputy Chairman & CFO*

Thank you. As the operator said, there are no more questions at this time. So we finalize this full year results conference call. We appreciate your time and attention, and good-bye and have a good afternoon, thank you. Bye-bye.

Operator

Okay, that does conclude our conference for today. Thank you for participating and you may all disconnect.
