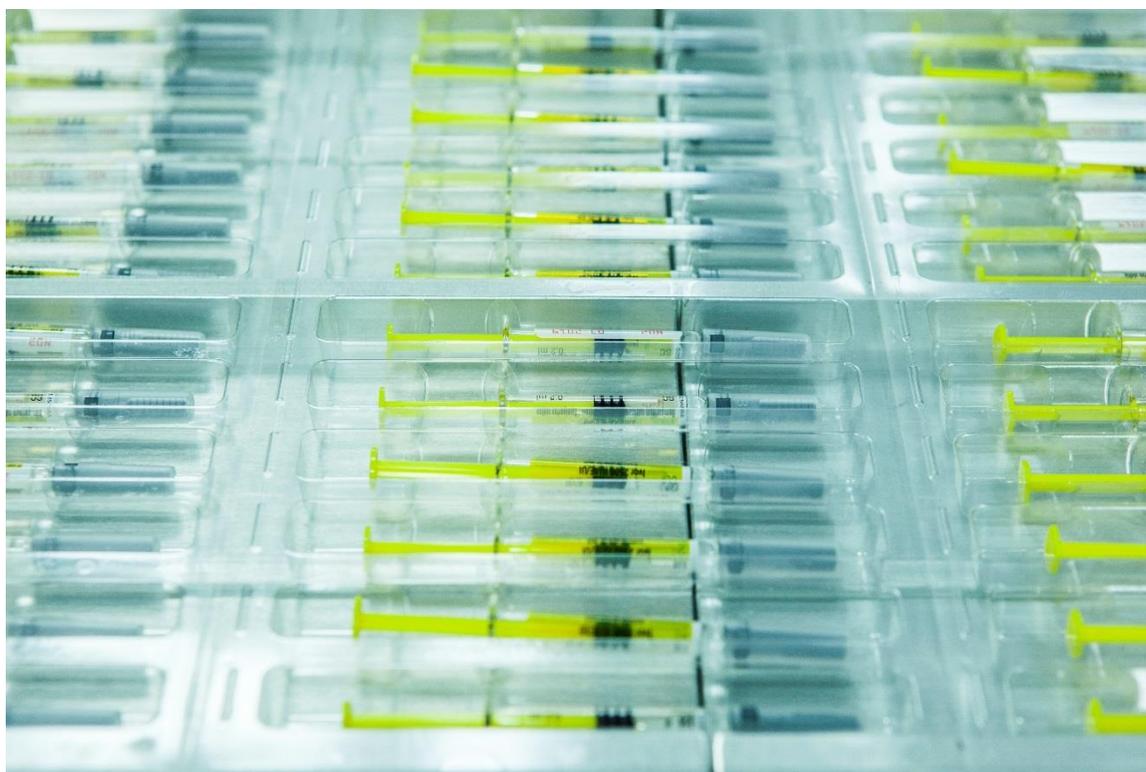




Nine-month period ending 30th September 2017 Results

8th November 2017



Laboratorios Farmacéuticos Rovi, S.A. and Subsidiaries
Investor Relations



ROVI – Nine-month period ending 30th September 2017 Financial Results

ROVI reports operating revenue growth of 6% with stable recurrent EBITDA despite growth in R&D

- **Operating revenue increased by 6% to 203.4 million euros in the first nine months of 2017, driven by the strength of the toll manufacturing business, where sales rose 20%, and by the specialty pharmaceutical business, which grew by 3%, slightly outperforming the market. Total revenue increased by 6% to 204.5 million euros in the first nine months of 2017.**
- **By 30th September 2017, the countries with the national registration approved of the low molecular weight heparin (biosimilar of enoxaparin) are Germany, France, UK, Hungary, Slovenia, Estonia, Latvia and Slovakia.**
- **In September 2017, ROVI announced the commencement of marketing of enoxaparin biosimilar in Germany, the first European country where ROVI launches its biosimilar and one of the top enoxaparin countries in Europe (in terms of volume and value).**
- **In the second quarter of 2017, ROVI started a Phase III trial “PRISMA-3” of DORIA[®] (Risperidona ISM[®]) with the recruitment of the first patient and on 24 October 2017, an update of the project with details of the design and cost of Phase III was released, together with a presentation to analysts.**
- **ROVI has started a Phase I trial “LISA-1” of Letrozole ISM[®] in November 2017.**
- **For 2018, ROVI expects a mid-single digit growth rate for operating revenue with a range of 20-30 million euro sales of biosimilar of enoxaparine, despite (i) a new reduction in sanitary expenditure from 6.0% to 5.8% of GDP expected for 2018, according to the 2018 Draft Budget Plan¹; and (ii) 1-4% growth rate in spending on medicine in Spain to 2021 forecast by QuintilesIMS².**

¹ http://www.minhafp.gob.es/Documentacion/Publico/CDI/EstrategiaPoliticaFiscal/2018/PLAN_PRESUPUESTARIO_2018.pdf

² *Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.*



- **Sales of Bemiparin increased a 4% in the first nine months of 2017 to 61.7 million euros; this growth came from sales in Spain (2%) and from international sales (8%).**
- **Sales of Vytorin[®], Orvatez[®] and Absorcol[®], had an outstanding performance with an increase of 21% to 28.9 million euros in the first nine months of 2017. In 2018, the active principle ezetimibe goes out of patent and a price reduction is expected in Absorcol[®].**
- **Sales of Volutsa[®], increased by 33% to 6.5 million euros in the same period, and sales of Hirobriz[®] Breezhaler[®] and Ulunar[®] Breezhaler[®] increased by 19% to 10.4 million euros in the first nine months of 2017, compared to the first nine months of 2016. Sales of Neparvis[®], launched in December 2016, reached 2.8 million euros in the first nine months of 2017.**
- **EBITDA declined by 13% to 27.2 million euros in the nine-month period ending 30 September 2017, compared to the same period of 2016, reflecting a 2.9 percentage point fall in the EBITDA margin down to 13.4% in the first nine months of 2017 from 16.3% in the same period of 2016. Excluding the impact of the non-recurrent revenue in the first nine months of 2016, EBITDA would have increased by 0.4% in the first nine months of 2017, reflecting a decrease of 0.8 percentage point in the EBITDA margin.**
- **EBITDA of the “on-going business”, namely EBITDA excluding R&D expenses and non-recurrent revenue, would have increased 14.6% in the first nine months of 2017 compared to the same period of 2016.**
- **Net profit decreased to 17.0 million euros in the nine-month period ending 30 September 2017, a 21% fall compared to the same period of the previous year. Excluding the non-recurrent revenue of 4.0 million euros, net profit would have decreased 4%.**
- **ROVI has paid a gross dividend of 0.1830 euros per share on 2016 earnings. This dividend represents a 35% pay out.**

Madrid (Spain), 8th November 2017, 8:00 AM CET - ROVI released today its financial results for the first nine months of 2017 ending 30 September 2017.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that *“in the first nine months 2017, we reached 6% operating revenue growth mainly driven by the strength of the toll manufacturing business, where sales rose 20%, and by the specialty pharmaceutical business,*



which grew by 3%. According to QuintilesIMS, Spanish innovative product market increased by 2% in the first nine months of 2017. We forecast to continue to grow thanks to, among others, our flagship product, Bemiparin, which is contributing to our growth, especially in the international market with 8% growth in sales, and domestic market with 2% growth. Furthermore, we expect (i) the strengthening of the cardiovascular franchise through the launch of Neparvis® in Spain, a product of high strategic value from Novartis, in December 2016; (ii) the launch of Mysimba® in Spain, a new pharmacological alternative for treating obesity from Orexigen, in January 2017; (iii) our entrance in the respiratory market through the launch of Hirobriz® Breezhaler® and Ulunar® Breezhaler®, from Novartis, launched in Spain in December 2014; (iv) our entrance in the urology field through the launch of Volutsa® in Spain, from Astellas Pharma, in February 2015; and (v) the strengthening of the hypercholesterolaemia franchise through the launch of Orvatez® in Spain, from Merck Sharp and Dohme (MSD), in June 2015, to contribute to growth in the coming years. These recent launches cover growing demand needs and we expect they will provide us with a sustainable and profitable growth opportunity in the future. In addition, the MSD agreement will allow us to launch four additional new products until July 2019, underpinning our belief in the sustainability of our long term outlook. All these new product launches will lead us to extend the average life of our product portfolio by several years.

Our toll manufacturing business' sales increased 20% in the first nine months of 2017 mainly because of the good performance of the injectable business, where revenue increased 33% as a result of higher volumes manufactured for some customers, and an increase of 5% in the Frosst Ibérica plant.

At the same time, we are confident of the potential of our current pipeline of R&D projects, making important investment efforts as we trust they will be the company's growth engine in the future. We are excited with the potential of our long acting injectable technology (ISM®); we have started a Phase III trial with our ISM® technology in the second quarter of 2017 with the recruitment of the first patient and we have share with the market the update of the project. We have started a new Phase I study for another candidate in November of this year. Likewise, we continue the national phase of the registration process in Europe of our biosimilar of enoxaparin, with the approval in Germany, France, UK, Hungary, Slovenia, Estonia, Latvia and Slovakia by 30th September 2017. At the same time, we have started marketing in Germany, the first European country where ROVI launches its biosimilar and one of the top enoxaparin countries in Europe (in terms of volume and value). All these represents an excellent growth opportunity for us considering the size of the European enoxaparin market, which amounts to more than 1 billion euros"



1. Financial highlights

| <i>€ million</i> | 9M 2017 | 9M 2016 | Growth | % Growth |
|----------------------|----------------|----------------|---------------|-----------------|
| Operating revenue | 203.4 | 191.5 | 12.0 | 6% |
| Other income | 1.1 | 1.4 | -0.3 | -24% |
| Total revenue | 204.5 | 192.9 | 11.6 | 6% |
| Cost of sales | -82.2 | -80.0 | -2.2 | 3% |
| Gross profit | 122.3 | 112.9 | 9.4 | 8% |
| <i>% margin</i> | <i>60.1%</i> | <i>59.0%</i> | | 1.1pp |
| R&D expenses | -18.9 | -13.1 | -5.8 | 44% |
| Other SG&A | -76.1 | -72.6 | -3.5 | 5% |
| Other income | 0.0 | 4.0 | -4.0 | n.a. |
| EBITDA | 27.2 | 31.1 | -3.9 | -13% |
| <i>% margin</i> | <i>13.4%</i> | <i>16.3%</i> | | -2.9pp |
| EBIT | 18.4 | 23.1 | -4.7 | -20% |
| <i>% margin</i> | <i>9.0%</i> | <i>12.1%</i> | | -3.0pp |
| Net profit | 17.0 | 21.5 | -4.5 | -21% |

Note: certain numerical figures included in this document have been rounded. Therefore, discrepancies in tables between totals and the sums of the amounts listed may occur due to such rounding.

The consolidated financial statements of Grupo ROVI for the first nine months 2017 and the comparative information for 2016 (balance sheet) and for the first nine months of 2016 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 6% to 203.4 million euros in the first nine months of 2017, driven by the strength of the toll manufacturing business, where sales rose 20%, and by the specialty pharmaceutical business, which grew by 3%, slightly outperforming the market. Total revenue increased by 6% to 204.5 million euros in the first nine months of 2017.

Sales of **prescription-based pharmaceutical** products rose 3% to 133.8 million euros in the first nine months of 2017.

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a positive performance in the first nine months of 2017, with sales up 4% to 61.7 million euros. Sales of Bemiparin in Spain (**Hibor**[®]) increased by 2% to 40.8 million euros, while international sales increased by 8% to 20.9 million euros. ROVI expects to maintain international sales stable in 2017.



Sales of **Vytorin**[®], **Orvatez**[®] and **Absorcol**[®], the first of the five licenses of MSD, indicated as adjunctive therapy to diet in patients with hypercholesterolemia, increased by 21% to 28.9 million euros in the first nine months of 2017. In 2018, the active principle ezetimibe goes out of patent and a price reduction is expected in Absorcol[®].

Sales of **Hirobriz**[®] **Breezhaler**[®] and **Ulunar**[®] **Breezhaler**[®], both inhaled bronchodilators from Novartis for patients with respiratory difficulties due to a pulmonary disease known as Chronic Obstructive Pulmonary Disease (COPD), launched in Spain in the fourth quarter of 2014, increased by 19% to 10.4 million euros in the first nine months of 2017, compared to the same period of the previous year.

Sales of **Volutsa**[®], a specialty product from Astellas Pharma indicated for the treatment of moderate to severe storage symptoms and voiding symptoms associated with benign prostatic hyperplasia, launched in Spain in February 2015, increased by 33% to 6.5 million euros in the first nine months of 2017.

Sales of **Medicebran**[®] and **Medikinet**[®], specialty products from Medice indicated for the treatment of ADHD (Attention Deficit and Hyperactivity Disorder) in children and teenagers, launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, remained flat in 5.3 million euros in the first nine months of 2017.

Sales of **Corlontor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, decreased 75% to 2.6 million euros in the first nine months of 2017. This product will be no longer marketed after first half 2017.

Sales of **Neparvis**[®], a specialty product from Novartis, launched in December 2016, indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction, reached 2.8 million euros in the first nine months of 2017.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 28% to 2.9 million euros in the first nine months of 2017, mainly due to a continued deceleration of the COX-2 market.

Sales of **Thymanax**[®], an innovative antidepressant from Laboratoires Servier and for which ROVI has a co-marketing agreement covering Spain, decreased by 23% to 3.2 million euros in the first nine months of 2017.

According to QuintilesIMS, Spanish innovative product market increased by 2% in the first nine months of 2017 compared to the same period the previous year. Nevertheless, ROVI prescription-based pharmaceutical product sales rose 3% in the same period, beating the market by 1,0 percentage points.



Also, prescription-based pharmaceutical market covering the 12-month period ending Sep 2017 increased by 2% compared to the same period of 2016. However, ROVI prescription-based pharmaceutical product sales rose 4% the last year.

For 2018, a new reduction in sanitary expenditure from 6.0% to 5.8% of GDP expected for 2018, according to the 2018 Draft Budget Plan¹, and a 1-4% growth rate in spending on medicine in Spain to 2021, is forecast by QuintilesIMS². Despite the difficult situation, the Spanish pharmaceutical industry continues to go through, ROVI forecasts to continue to grow.

Sales of **contrast imaging agents** and other hospital products increased by 5% to 21.4 million euros in the first nine months of 2017.

Sales of **over-the-counter pharmaceutical products** (“OTC”) **and other** decreased by 25% to 2.1 million euros in the first nine months of 2017 compared to the same period of the previous year. In the first nine months of 2017, OTC sales did not include Enerzone product sales, while 0.5 million euro sales were included in the first nine months of 2016, before the creation of the joint venture of ROVI and Enervit for the distribution of nutritional products in Spain and Portugal.

Toll manufacturing sales increased by 20% to 46.1 million euros in the first nine months of 2017, compared to the same period the previous year, mainly because of the good performance of the injectable business, where revenue increased 33% as a result of higher volumes manufactured for some customers, and the Frosst Ibérica plant, where revenue increased 5%. This increase in the injectable business was specifically linked to the first nine months of 2017 and ROVI expects to achieve a mid-to-high single digit growth rate for this business in 2017. Likewise, ROVI expects to achieve a slight growth for the toll manufacturing area in 2017 compared to a fall of 9% in 2016.

Sales outside Spain increased by 8% to 59.3 million euros in the first nine months of 2017 compared to the same period the previous year mainly due to toll manufacturing business international sale increase. Sales outside Spain represented 29% of operating revenue in the first nine months of 2017 as in the same period of 2016.

Other income (subsidies) has decreased by 24% to 1.1 million euros in the first nine months of 2017 from 1.4 million euros in the same period in 2016, due to lower subsidies granted for R&D projects.

Gross profit increased by 8% to 122.3 million euros in the nine-month period ending 30 September 2017, reflecting an increase of 1.1 percentage points in the gross margin to 60.1%

¹ http://www.minhfp.gob.es/Documentacion/Publico/CDI/EstrategiaPoliticaFiscal/2018/PLAN_PRESUPUESTARIO_2018.pdf

² *Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.*



from 59.0% in the same period of 2016, mainly due to the increase of injectable business' sales, which contributed with higher margins.

Research and development expenses (R&D) rose 44% to 18.9 million euros in the first nine months of 2017 mainly due to (i) the preparation and beginning of Risperidone-ISM[®] Phase III trial and (ii) the performing of development activities for the formulation of the Risperidone-ISM[®] Phase III trial and the Letrozole-ISM[®] Phase I trial.

Selling, general and administrative expenses (SG&A) rose 5% to 76.1 million euros in the nine-month period ending 30 September 2017, compared to the same period of 2016, mainly due to Neparvis[®] and Mysimba[®] launches which added expenses of 2.6 million euros, and international subsidiaries expenses.

In the first nine months of 2016, EBITDA was affected by non-recurrent revenue of 4.0 million euros as a result of the joint venture created by ROVI and Enervit for the distribution of nutritional products in Spain and Portugal.

EBITDA decreased by 13% to 27.2 million euros in the nine-month period ending 30 September 2017, compared to the same period of 2016, reflecting a 2.9 percentage point fall in the EBITDA margin down to 13.4% in the first nine months of 2017 from 16.3% in the same period of 2016. Excluding the impact of the non-recurrent revenue in the first nine months of 2016, EBITDA would have increased by 0.4%, from 27.1 million euros in the first nine months of 2016 to 27.2 million euros in the first nine months of 2017, reflecting a decrease of 0.8 percentage point in the EBITDA margin. EBITDA of the "on-going business", namely EBITDA excluding R&D expenses and non-recurrent revenue, would have increased 14.6% in the first nine months of 2017 compared to the same period of 2016.

Depreciation and amortisation expenses increased by 10% to 8.8 million euros in the first nine months of 2017, mainly due to the new property, plant and equipment and intangible assets purchases made during the last twelve months.

EBIT declined by 20% to 18.4 million euros in the first nine months of 2017, compared to the same period of 2016, reflecting a 3.0 percentage point drop in the EBIT margin to 9.0% in the first nine months of 2017, from 12.1% in the first nine months of 2016. Excluding the impact of the non-recurrent revenue in first nine months of 2016, EBIT would have decreased by 4%, reflecting a decrease of 0.9 percentage point in the EBIT margin.

Financial expense increased by 5% in the first nine months of 2017, compared to the same period of the previous year, due to the increase in banking debt through a 20-million-euro new loan in the first nine months of 2017.



Financial income decreased by 69% in the first nine months of 2017, compared to first nine months of 2016, due to the reduction of delay interests from Court decisions related to pending invoices due for collection from Public Administration in the first nine months of 2017.

The **effective tax rate** was 2.3% in the first nine months of 2017 compared to 5.6% in the same period of 2016. This favourable effective tax rate is due to the deduction of existing research and development expenses, 5.8 million euros higher in this period compared to the same period of 2016, and the capitalisation of negative tax bases from Frosst Ibérica, S.A. As of 31 December 2016, Frosst Ibérica negative tax bases amounted to 36.7 million euros, of which 1.6 million euros were used in the 2016 income tax and 1.0 million euros in the first nine months of 2017. For December 2017, a reduction in effective tax rate compared to 2016 year end is expected (6.4%).

On 3 December 2016, the Official State Gazette published the Royal Decree-Law 3/2016, taking tax measures regarding the consolidation of public finance and other urgent social measures. These tax measures, that came into force on that date, will negatively affect ROVI's income statement and income tax payable rate. Nevertheless, ROVI expects to maintain an effective tax rate from high single digit to low double digit for the foreseeable future.

Among the tax measures that will affect corporate income tax, it should be noted that:

- ✓ the compensation of negative tax bases from previous years is limited to 25%; and
- ✓ R&D tax credit schedule is maintained.

Net profit decreased to 17.0 million euros in the first nine months of 2017, a 21% fall compared to the same period of the previous year. Excluding the impact of the non-recurrent revenue in the first nine months of 2016, net profit would have decreased by 4% in the first nine months of 2017.

ROVI General Shareholders Meeting, on 31 May 2017, approved the payment of a **gross dividend** of 0.1830 euros per share on 2016 earnings. This dividend was paid on 5th July 2017 and it represented a 35% pay-out and an increase of 32% compared to the dividend on 2015 earnings.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that *"we are very happy with the results of the first nine months of 2017. Total revenue increased by 6% thanks to the strength of our leading products, which continue to enjoy good sales prospects, as well as of our injectable toll manufacturing business. Recurrent EBITDA has been flat despite growth in R&D, with a slight increase of 0.4 percentage points, as a result of higher R&D expenses driven by the cost of Phase III-PRISMA 3 project. We expect the commercialisation of our biosimilar of enoxaparin in Germany will allow us to increase our profit margins in the next future. We continue with a strong balance sheet and an excellent capacity to generate cash, which allows us to finance organic growth through the launch of new products, such as Neparvis®, Volutsa®,*



Ulunar[®], Orvatez[®] or Mysimba[®], and to be in a strong position to benefit in the current operating environment as we will pay attention to potential opportunities to expand our sales base and improve the utilisation of our asset base”.

3. Balance Sheet items

3.1 Capital expenditure

ROVI invested 8.1 million euros in the first nine months of 2017, compared to 6.8 million euros in the first nine months of 2016. Of this amount:

- 1.5 million euros corresponds to investment capex related to the injectable facility, versus 1.3 million euros in the first nine months of 2016;
- 1.7 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 2.1 million euros in the first nine months of 2016;
- 1.9 million euros were invested in the Granada and the Alcalá de Henares (Frosst Ibérica) facilities, versus 1.5 million euros in the first nine months of 2016; and
- 3.0 million euros relates to expenditure on maintenance and other capex (including capex related to the biosimilar of enoxaparin), versus 1.9 million euros in the first nine months of 2016.

ROVI expects capital expenditure for 2017 to be below the 2016 figure (18.1 million euros).

3.2 Debt

As of 30 September 2017, ROVI had total debt of 47.1 million euros. Debt with public administration, which is 0% interest rate debt, represented 28% of total debt as of 30 September 2017.

| <i>In thousand euros</i> | 30 September 17 | 31 December 16 |
|---------------------------------|------------------------|-----------------------|
| Bank borrowings | 33,945 | 20,931 |
| Debt with public administration | 13,159 | 12,863 |
| Total | 47,104 | 33,794 |

As of 30 September 2017, bank borrowings increased by 13 million euros. In the first nine months of 2017, ROVI increased its banking debt through a 20-million-euro new loan, with a fixed interest rate of 0.65% and a 3-year amortization period with a grace period of 17 months.



3.3 Free cash flow

Free cash flow (net cash generated (used) from operating activities minus (plus) property, plant and equipment and intangible assets purchases (sales) plus interest received) decreased to -2.1 million euros in the first nine months of 2017 compared to an increase of 23.8 million euros in the first nine months of 2016 mainly due to (i) the increase of 6.4 million euros in the “inventories” line in the first nine months of 2017, compared to the increase of 1.8 million euros in the first nine months of 2016; (ii) the decrease of 19.8 million euros in the “trade and other payables” item in the first nine months of 2017, compared to a decrease of 1.7 million euros in the first nine months of 2016; (iii) the decrease in the “trade and other receivables” line of 5.7 million euros in the first nine months of 2017, compared to a decrease of 5.2 million euros in the first nine months of 2016; and (iv) the increase of 1.3 million euros in Capex.

3.4 Gross cash position and net debt

As of 30 September 2017, ROVI had gross cash position of 45.6 million euros, compared to 42.8 million euros as of 31 December 2016, and net debt of 1.5 million euros (available-for-sale financial assets plus deposits plus cash and cash equivalents minus short term and long term financial debt), compared to net cash of 9.0 million euros as of 31 December 2016.

3.5 Working capital

The increase in working capital in the first nine months of 2017 was mainly due to (i) a decrease in the “trade and other payables” line of 19.8 million euros; (ii) an increase in the “inventories” line of 6.4 million euros mainly due to higher heparin stock levels in the first nine months of 2017; (iii) a decrease in the “trade and other receivables” line of 5.7 million euros; and (iv) an increase in the “cash and cash equivalents” item of 2.8 million euros.

As of 30 September 2017, Social Security and Public Administrations total debt with ROVI amounted to 5.8 million euros, of which 4.2 million euros in Spain and the other 1.6 million euros in Portugal.

4. Guidance for 2018

In 2018, ROVI expects **a mid-single digit growth rate for the operating revenue with a range of 20 to 30 million euro sales of biosimilar of enoxaparine**, despite (i) a new reduction in sanitary expenditure from 6.0% to 5.8% of GDP expected for 2018, according to the 2018 Draft Budget Plan¹, and (ii) 1-4% growth rate in spending on medicine in Spain to 2021 forecast by QuintilesIMS².

¹ http://www.minhfp.gob.es/Documentacion/Publico/CDI/EstrategiaPoliticaFiscal/2018/PLAN_PRESUPUESTARIO_2018.pdf

² Outlook for Global Medicines through 2021. Report by the QuintilesIMS Institute.



ROVI expects its growth drivers to be Bemiparin, the latest license agreements (Neparvis[®], Volutsa[®], Orvatez[®], Ulunar[®] and Mysimba[®]), the biosimilar of enoxaparine, its existing portfolio of specialty pharmaceuticals, new product distribution licenses and new contracts in the toll manufacturing area.

In 2018, the active principle ezetimibe goes out of patent and a price reduction is expected in Absorcol[®].

5. Research and Development update

ISM[®]

As previously informed, ROVI has progressed in the development of the first candidate for its leading-edge drug delivery technology, ISM[®], for a prolonged release of risperidone, a well-established second-generation antipsychotic medicine.

In 2016 the results of the Phase I trial PRISMA-1 were published in the medical journal *International Clinical Psychopharmacology*¹, as well as the results of the Phase II study "PRISMA-2" were presented on the 24th *European Congress of Psychiatry*². Both studies have demonstrated that Risperidone ISM[®] achieves therapeutic levels from the first hours after drug administration, without needing oral risperidone supplementation, and provided a sustained release throughout the 4-weeks dosing period over multiple intramuscular injections, regardless the injection site (gluteus or deltoid muscle).

During December 2016 and first quarter 2017, the study protocol for the Phase III trial "PRISMA-3" was submitted in the participant countries and during second quarter of 2017 patients' recruitment has started (see section 6.2).

On the other hand, Rovi has initiated the first Phase I clinical trial of Letrozol ISM[®] in November 2017. Letrozol ISM[®] is a long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer.

¹Llaudó J, et al. Phase I, open-label, randomized, parallel study to evaluate the pharmacokinetics, safety, and tolerability of one intramuscular injection of risperidone ISM at different dose strengths in patients with schizophrenia or schizoaffective disorder (PRISMA-1). *Int Clin Psychopharmacol.* 2016;31(6):323-31.

²Pharmacokinetics, Safety, and Tolerability of Four 28 Days Cycle Intramuscular Injections for Risperidone-ISM 75 Mg in Patients with Schizophrenia: A Phase-2 Randomized Study (PRISMA-2). 24th European Congress of Psychiatry, March 13, 2016, Madrid (Spain) [<http://epa-abstracts-2016.elsevier.cc/#289/z>]



Enoxaparin biosimilar

ROVI informed (by publication of the relevant fact number 249265 dated 7th of March of 2017) that the decentralised procedure used for the Company to submit, in 26 countries of the European Union, the marketing authorization application of a low molecular weight heparin (biosimilar of enoxaparin) was completed with positive outcome.

In September 2017 (by publication of the relevant fact number 256121 dated 7th of September 2017), ROVI informed that the national marketing authorization phase of the registration process for a low molecular weight heparin (biosimilar of enoxaparin) was approved in Germany by local authorities and its marketing has begun (see section 6.1).

Key operating and financial events

6.1 Rovi has commenced the marketing of the biosimilar of enoxaparin in Germany

On 7th of March 2017, the market was informed by publication of a relevant fact (number 249265) that the decentralised procedure used for the Company to submit, in twenty-six countries of the European Union, the marketing authorization application of a low molecular weight heparin (biosimilar of enoxaparin) was completed with positive outcome.

In the mentioned decentralised procedure, Germany has acted as Reference Member State (RMS). The national phase of the registration process, which is expected to be completed with the granting by the competent local authorities of the marketing authorisation in each concerned country, was initiated in the first quarter 2017, and it continues during the second quarter. This national phase could last from three to ten months.

By 30th September 2017, the countries with the registration national phase approved are Germany, France, UK, Hungary, Slovenia, Estonia, Latvia and Slovakia.

In September 2017, ROVI has informed by publication of a relevant fact (number 256121), the commencement of marketing of enoxaparin biosimilar in Germany, the first European country where ROVI launches its biosimilar and one of the top enoxaparin countries in Europe (in terms of volume and value).

ROVI will regularly update the milestones considered relevant in this process of marketing authorisation as the schedule of the registration of the medicinal product progresses in each country.



6.2 Rovi updates the Phase III-PRISMA 3 project of Risperidone ISM[®], called DORIA[®]

On 24 October 2017, the company released a relevant fact (number 257683) updating the evolution of Phase III-PRISMA 3 of Risperidone ISM[®], called DORIA[®].

As mentioned before, in May 2017, ROVI began a Phase III study for a long-acting injectable (LAI) based in the ISM[®] technology patented by ROVI, to treat schizophrenia called DORIA[®] (previously Risperidone ISM[®]).

Schizophrenia diagnosed disorders affects around 3 million patients (Source IMS) in US and Europe, and although it has no cure, there are effective treatments to control symptoms. These treatments use Second-Generation of Antipsychotics (SGA) medications with a predictable efficacy and safety profile, and risperidone is the most used active principle.

ROVI has developed DORIA[®], and expects a good evolution in Phase III, as the Active Principle is one of the most prescribed for schizophrenic patients (risperidone) and ISM[®] technology has been proved in Phase I&II studies.

Long-acting injectables (LAIs) are becoming the goal standard for schizophrenia compared to oral treatments, and with DORIA[®], ROVI is aiming to play a relevant role in the US and Europe Schizophrenia LAIs market, with an estimated total value in 2021 of 3.4 billion dollars (2.5 billion dollars in US and 930 million dollars in Top-5 Europe) (IMS Source).

The strategic drivers of DORIA[®] are:

- Long acting injectable (LAI) based in the ISM[®] technology developed by ROVI.
- LAI is becoming the goal standard for Schizophrenia.
- A good pharmacological profile providing a rapid onset allowing a once monthly injection without oral supplementation and loading dose.
- One monthly represents a fully medically supervised patient: eradicates all potential issues that may arise with an oral product.
- A monthly injection provides a better control of patients avoiding relapses.
- One monthly ensures a relapse rate improvement which on a pharmaco-economic basis that justifies a cost effective of LAIs.

ROVI will regularly update the milestones considered relevant in this Phase III-PRISMA 3 process.

About ROVI

ROVI is a fully integrated Spanish specialty pharmaceutical company engaged in the research, development, in-licensing, manufacturing and marketing of small molecule and specialty



biologic drugs. The Company has a diversified portfolio of products that it markets in Spain through its specialized sales force, calling on specialist physicians, hospitals and pharmacies. ROVI's portfolio of 30 principal marketed products is currently anchored by the internally-developed, second generation low molecular weight heparin, Bemiparin. ROVI's research and development pipeline is focused primarily on the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products and other glycosaminoglycans and on the development of new controlled release mechanisms based on ISM[®] technology, with the aim of obtaining new pharmaceutical products that enable the regular administration of formulations which are administered daily in chronic and prolonged treatments. ROVI manufactures the active biological ingredient (Bemiparin) for its principal proprietary products and for injectable pharmaceutical products developed by its in-house research team, and utilizes its state-of-the-art filling and packaging capabilities to provide a broad array of toll manufacturing services to leading international pharmaceutical companies, primarily in the area of pre-filled syringes. In addition, ROVI provides contract manufacturing and packaging services of solid oral pharmaceutical dosage forms, using the most enhanced technology, Roller Compaction. Additional information about ROVI is available on the company's website: www.rovi.es

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Forward-looking statements



This news release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this press release.



APPENDIX 1

**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
 CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2017 AND 31 DECEMBER 2016**

(Thousands of euros)

| | 30 September 2017 | 31 December 2016 |
|-------------------------------------|--------------------------|-------------------------|
| ASSETS | | |
| Non-current assets | | |
| Property, Plant and Equipment | 81,724 | 82,822 |
| Intangible assets | 25,212 | 24,872 |
| Investment in a joint venture | 2,279 | 2,571 |
| Deferred income tax assets | 11,781 | 10,252 |
| Available-for-sale financial assets | 69 | 70 |
| Financial receivables | 115 | 189 |
| | 121,180 | 120,776 |
| Current assets | | |
| Inventories | 73,822 | 67,386 |
| Trade and other receivables | 48,123 | 53,842 |
| Current income tax assets | 2,330 | 4,466 |
| Cash and cash equivalents | 44,171 | 41,378 |
| | 168,446 | 167,072 |
| Total assets | 289,626 | 287,848 |



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS AS OF 30 SEPTEMBER 2017 AND 31 DECEMBER 2016

(Thousands of euros)

| | 30 September 2017 | 31 December 2016 |
|---|--------------------------|-------------------------|
| EQUITY | | |
| Capital and reserves attributable to shareholders of the company | | |
| Share capital | 3,000 | 3,000 |
| Legal reserve | 600 | 600 |
| Treasury shares | -8,405 | -8,701 |
| Retained earnings and voluntary reserves | 179,223 | 162,421 |
| Profit for the period | 17,020 | 26,089 |
| Reserve for available-for-sale assets | -2 | -3 |
| Total equity | 191,436 | 183,406 |
| LIABILITIES | | |
| Non-current liabilities | | |
| Financial debt | 32,801 | 20,828 |
| Deferred income tax liabilities | 1,489 | 1,640 |
| Deferred revenues | 5,183 | 5,532 |
| | 39,473 | 28,000 |
| Current liabilities | | |
| Trade and other payables | 40,017 | 59,852 |
| Financial debt | 14,303 | 12,966 |
| Deferred revenues | 706 | 746 |
| Provisions for other liabilities and charges | 3,691 | 2,878 |
| | 58,717 | 76,442 |
| Total liabilities | 98,190 | 104,442 |
| Total equity and liabilities | 289,626 | 287,848 |



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30
SEPTEMBER 2017 AND 2016

(Thousands of euros)

| | Nine-month period ending 30 September | |
|--|--|---------------|
| | 2017 | 2016 |
| Revenue | 203,409 | 191,453 |
| Cost of sales | (82,210) | (79,969) |
| Employee benefit expenses | (47,049) | (45,319) |
| Other operating expenses | (47,975) | (40,435) |
| Amortisation | (8,847) | (8,061) |
| Recognition of government grants on non financial non-current assets and other | 1,068 | 1,409 |
| Other income | - | 3,997 |
| OPERATING PROFIT | 18,396 | 23,075 |
| Finance income | 92 | 296 |
| Finance costs | (771) | (732) |
| FINANCE COSTS - NET | (679) | (436) |
| Share of profit of a joint venture | (292) | 157 |
| PROFIT BEFORE INCOME TAX | 17,425 | 22,796 |
| Income tax | (405) | (1,281) |
| PROFIT FOR THE PERIOD | 17,020 | 21,515 |



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDING 30
SEPTEMBER 2017 AND 2016

(Thousands of euros)

| | Nine-month period ending 30 September | |
|---|--|-----------------|
| | 2017 | 2016 |
| Cash flows from operating activities | | |
| Profit before income tax | 17,425 | 22,796 |
| Adjustments for non-monetary transactions: | | |
| Amortisation | 8,847 | 8,061 |
| Interest income | (92) | (296) |
| Impairment | 1,670 | (221) |
| Interest expense | 771 | 732 |
| Net changes in provisions | 813 | (165) |
| Grant for non-financial fixed assets and income from distribution | (1,189) | (1,536) |
| Profit from creation of joint venture | - | (3,997) |
| Share of profit of a joint venture | 292 | (157) |
| Changes in working capital: | | |
| Trade and other receivables | 5,002 | 5,916 |
| Inventories | (7,980) | (1,279) |
| Trade and other payables | (19,857) | (1,431) |
| Other collections and payments: | | |
| Proceeds from distribution licenses | 87 | 505 |
| Income tax cash flow | 62 | 1,044 |
| Net cash generated (used) from operating activities | 5,851 | 29,972 |
| Cash flows from investing activities | | |
| Purchases of intangible assets | (2,537) | (1,381) |
| Purchases of property, plant and equipment | (5,552) | (5,436) |
| Proceeds from sale of property, plant and equipment | - | 24 |
| Investment in a joint venture | - | (3) |
| Proceeds from sale of shares in joint venture | 450 | 1,000 |
| Interest received | 133 | 575 |
| Net cash generated (used) in investing activities | (7,506) | (5,221) |
| Cash flows from financing activities | | |
| Repayments of financial debt | (8,963) | (6,604) |
| Proceeds from financial debt | 22,190 | 797 |
| Interest paid | (188) | (188) |
| Purchase of treasury shares | (394) | (741) |
| Dividends paid | (9,025) | (6,853) |
| Reissue of treasury shares | 828 | 308 |
| Net cash generated (used) in financing activities | 4,448 | (13,281) |
| Net (decrease)/increase in cash and cash equivalents | 2,793 | 11,470 |
| Cash and cash equivalents at beginning of the period | 41,378 | 29,251 |
| Cash and cash equivalents at end of the period | 44,171 | 40,721 |