



Full Year 2017 Results

20th February 2018



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



ROVI – Full Year 2017 Financial Results

ROVI reports an operating revenue growth of 4% and records first sales of its Enoxaparin biosimilar

- **Operating revenue increased by 4% to 275.6 million euros in 2017, driven by the strength of the toll manufacturing business, where sales rose 8%, and by the specialty pharmaceutical business, which grew by 3%, slightly outperforming the market. Total revenue increased by 4% to 277.4 million euros in 2017.**
- **In September 2017, ROVI announced the commencement of marketing of the Enoxaparin biosimilar in Germany, the first European country where ROVI launches its biosimilar.**
- **By 31st December 2017, the countries with the national registration approved of the Enoxaparin biosimilar are Germany, France, United Kingdom, Italy, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia and Bulgaria.**
- **Sales of the Enoxaparin biosimilar amounted to 1.5 million euros in 2017, of which 1.0 million euros were registered in December.**
- **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 24th 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 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 Enoxaparin biosimilar, 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.**
- **Sales of Bemiparin increased 5% in 2017 to 83.9 million euros; this growth came from sales in Spain (7%) and from international sales (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.



- **Sales of Vytorin[®], Orvatez[®] and Absorcol[®], had an outstanding performance with an increase of 18% to 39.4 million euros in 2017. In 2018, the active principle ezetimibe goes out of patent and a price reduction is expected in Absorcol[®].**
- **Sales of Volutsa[®], increased by 30% to 9.0 million euros, and sales of Hirobriz[®] Breezhaler[®] and Ulunar[®] Breezhaler[®] increased by 17% to 14.3 million euros in 2017, compared to 2016. Sales of Neparvis[®], launched in December 2016, reached 4.7 million euros in 2017.**
- **EBITDA of the “on-going business”, calculated excluding R&D expenses in 2017 and 2016 and the impact of the non-recurring revenue in 2016, increased by 11%, from 52.8 million euros in 2016 to 58.7 million euros in 2017, reflecting a 1.4 percentage point rise in the EBITDA margin to 21.3% in 2017. Likewise, recognising the same amount of R&D expenses in 2017 as in 2016 and excluding the impact of the non-recurring revenue in 2016, EBITDA would have increased by 17% to 41.2 million euros, reflecting a 1.6 percentage point rise in the EBITDA margin to 15.0% in 2017.**
- **Net profit of the “on-going business”, calculated excluding R&D expenses in 2017 and 2016 and the impact of the non-recurring revenue in 2016, increased by 16%, from 38.7 million euros in 2016 to 45.0 million euros in 2017. Likewise, recognising the same amount of R&D expenses in 2017 as in 2016 and excluding the impact of the non-recurring revenue in 2016, net profit would have increased by 25% to 27.8 million euros.**
- **ROVI will propose to the Shareholders General Meeting a dividend of 0.1207 euros per share with dividend rights on 2017 earnings. This proposed dividend represents a 35% pay out.**

Madrid (Spain), 20th February 2018, 8:00 AM CET - ROVI released today its financial results for the fiscal year ending on 31 December 2017.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that “Juan López-Belmonte Encina, ROVI’s Chief Executive Officer, said that “*in 2017, we reached 4% operating revenue growth mainly driven by the strength of the toll manufacturing business, where sales rose by 8%, and by the specialty pharmaceutical business, which grew by 3%. According to QuintilesIMS, the Spanish innovative product market increased by 2% in 2017. We forecast continued growth thanks to, among other factors, our flagship product, Bemiparin, which is contributing to our growth, especially in the domestic market, with a sales increase of 7%. Furthermore, we expect a number of factors to contribute to our growth in forthcoming years: (i) the reinforcement of the cardiovascular franchise as a result of the launch of Neparvis[®], a*



product with high strategic value from Novartis, in Spain in December 2016; (ii) our entry into the respiratory market through Hirobriz[®] Breezhaler[®] and Ulunar[®] Breezhaler[®] from Novartis, launched in Spain in December 2014; (iii) our entry into the urology field through the launch of Volutsa[®], from Astellas Pharma, in Spain in February 2015; and (iv) the strengthening of the hypercholesterolaemia franchise through the launch of Orvatez[®], from Merck Sharp and Dohme (MSD), in Spain in June 2015. These recent launches cover growing demand needs and we expect them to provide us with a sustainable and profitable growth opportunity in the future. Our toll manufacturing business' sales increased 8% in 2017 mainly because of the good performance of the injectable business, where revenue increased by 13% as a result of higher volumes manufactured for some customers and a 2% increase 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, since we trust they will be the company's growth engine in the future. We have high hopes of the potential of our long-acting injectable technology (ISM[®]); we 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 shared the project update with the market. We also started a new Phase I study for another candidate, Letrozole, in November. Likewise, we continue the national phase of the registration process of our Enoxaparin biosimilar in Europe, with its approval in Germany, France, UK, Italy, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia and Bulgaria before 31st December 2017. At the same time, we have started marketing it in Germany, one of the top Enoxaparin markets in Europe (in terms of volume and value), with good sales prospects, as reflected in December 2017, when sales were 1 million euros. The Enoxaparin biosimilar represents an excellent growth opportunity for us considering the size of the European Enoxaparin market, which totals more than 1 billion euros. In 2017, ROVI started its internationalisation process, setting up subsidiaries in the main European countries: Germany, United Kingdom, France and Italy. We are very excited about this new phase, in which we aim to become one of the leaders in the low-molecular-weight heparin field worldwide".



1. Financial highlights

<i>€ million</i>	2017	2016	Growth	% Growth
Operating revenue	275.6	265.2	10.5	4%
Other income	1.8	1.6	0.2	13%
Total revenue	277.4	266.7	10.7	4%
Cost of sales	-110.2	-112.0	1.8	-2%
Gross profit	167.2	154.7	12.5	8%
<i>% margin</i>	<i>60.7%</i>	<i>58.3%</i>		<i>2.3pp</i>
R&D expenses	-28.3	-17.5	-10.8	62%
Other SG&A	-108.5	-101.9	-6.6	6%
Other income	-	4.0	-4.0	n.a.
EBITDA	30.5	39.3	-8.8	-22%
<i>% margin</i>	<i>11.1%</i>	<i>14.8%</i>		<i>-3.8pp</i>
EBIT	19.0	28.3	-9.3	-33%
<i>% margin</i>	<i>6.9%</i>	<i>10.7%</i>		<i>-3.8pp</i>
Net profit	17.2	26.1	-8.8	-34%

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 2017 and the comparative information for 2016 are attached to this report (see Appendix 1).

2. Performance of the Group

Operating revenue increased by 4% to 275.6 million euros in 2017, driven by the strength of the toll manufacturing business, where sales rose 8%, and by the specialty pharmaceutical business, which grew by 3%, slightly outperforming the market. Total revenue increased by 4% to 277.4 million euros in 2017.

<i>€ million</i>	2017	2016	% Growth
Specialty pharmaceutical business	214.3	208.4	3%
Toll manufacturing business	61.1	56.6	8%
Royalties	0.2	0.2	43%
Total operating revenue	275.6	265.2	4%



Sales of **prescription-based pharmaceutical** products rose 3% to 183.2 million euros in 2017.

<i>€ million</i>	2017	2016	% Growth
Prescription-based pharmaceutical products	183.2	177.3	3%
Bemiparin (Hibor)	83.9	79.7	5%
Sales in Spain	58.8	54.7	7%
International sales	25.1	24.9	1%
Enoxaparin biosimilar (Enoxaparin Becat)	1.5	-	n.a.
Vytorin & Absorcol & Orvatez	39.4	33.5	18%
Ulunar & Hirobriz	14.3	12.2	17%
Volutsa	9.0	6.9	30%
Medikinet & Medicebran	7.5	7.6	0%
Neparvis	4.7	0.2	n.a.
Corlantor	2.5	13.8	-82%
Exxiv	3.6	5.4	-34%
Thymanax	3.9	5.4	-27%
Other	12.8	12.5	2%
Contrast agents and other hospital products	28.5	27.9	2%
Non prescription pharmaceutical products ("OTC") and Other	2.6	3.2	-19%
Total specialty pharmaceutical business	214.3	208.4	3%

ROVI's low molecular weight heparin (LMWH), **Bemiparin**, had a positive performance in 2017, with sales up 5% to 83.9 million euros. Sales of Bemiparin in Spain (**Hibor**[®]) increased by 7% to 58.8 million euros, while international sales increased by 1% to 25.1 million euros.

Sales of the **Enoxaparin biosimilar**, launched in Germany in September 2017, amounted to 1.5 million euros in 2017, of which 1.0 million euros were registered in December.

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 18% to 39.4 million euros in 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 17% to 14.3 million euros in 2017, compared to 2016.



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 30% to 9.0 million euros in 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 at 7.5 million euros in 2017.

Sales of **Corlentor**[®], a specialty product for stable angina and chronic heart failure from Laboratoires Servier, decreased 82% to 2.5 million euros in 2017. This product was 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 4.7 million euros in 2017.

Sales of **Exxiv**[®], a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD), decreased by 34% to 3.6 million euros in 2017, mainly due to a continued deceleration of the COX-2 market.

Sales of **Thymanax**[®], an innovative antidepressant from Laboratoires Servier, decreased by 27% to 3.9 million euros in 2017. This co-marketing agreement has not been renewed and the product was no longer marketed by ROVI after November 2017.

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

For 2018, a new reduction in healthcare expenditure from 6.0% to 5.8% of GDP is expected (the lowest health spending forecast since 2007), 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 above the growth estimates of the pharmaceutical expenditure.

Sales of **contrast imaging agents** and other hospital products increased by 2% to 28.5 million euros in 2017.

Sales of **over-the-counter pharmaceutical products** ("OTC") and other decreased by 19% to 2.6 million euros in 2017 compared to the previous year. In 2017, OTC sales did not include

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.



Enerzone product sales, while 0.5 million euro sales were included in 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 8% to 61.1 million euros in 2017, compared to the previous year, mainly because of the good performance of the injectable business, where revenue increased 13% as a result of higher volumes manufactured for some customers, and the Frosst Ibérica plant, where revenue increased 2%.

<i>€ million</i>	2017	2016	% Growth
Injectable business	34.9	30.8	13%
Oral forms business (Frosst Ibérica)	26.2	25.8	2%
Total toll manufacturing business	61.1	56.6	8%

Sales outside Spain increased by 5% to 79.9 million euros in 2017 compared to the previous year mainly due to (i) the toll manufacturing business international sale increase; and (ii) the registration of Enoxaparin biosimilar sales. Sales outside Spain represented 29% of operating revenue in 2017 as in 2016.

Other income (subsidies) increased by 13% to 1.8 million euros in 2017 from 1.6 million euros in 2016.

Gross profit increased by 8% to 167.2 million euros in 2017, reflecting an increase of 2.3 percentage points in the gross margin to 60.7% from 58.3% in 2016, mainly due to (i) the increase of toll manufacturing sales, specially of the injectable business which added higher margins; and (ii) the rise of Bemiparin sales.

Research and development expenses (R&D) rose 62% to 28.3 million euros in 2017 mainly due to the preparation and beginning of the Risperidone-ISM[®] Phase III trial and the Letrozole-ISM[®] Phase I trial.

Selling, general and administrative expenses (SG&A) rose 6% to 108.5 million euros in 2017, compared to 2016, mainly due to (i) Neparvis[®] and Mysimba[®] launches, which added expenses of 4.5 million euros, (ii) international subsidiaries expenses, which amounted to 1.6 million euros, and (iii) the start of the activity in the San Sebastián de los Reyes plant.



<i>€ million</i>	2017	2016	% Growth
Personnel expenses	64.0	60.5	6%
Other operating expenses (exc. R&D)	44.5	41.4	7%
Total SG&A expenses	108.5	101.9	6%
<i>Expenses related to new launches</i>	<i>4.5</i>	<i>3.3</i>	<i>36%</i>
<i>Expenses related to intern. subsidiaries</i>	<i>1.6</i>	<i>0.1</i>	<i>n.a.</i>

In 2016, EBITDA was affected by non-recurring 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 to 30.5 million euros in 2017, a drop of 22% compared to the previous year, reflecting a 3.8 percentage point fall in the EBITDA margin, which was down to 11.1% in 2017 from 14.8% in 2016. However, EBITDA of the "on-going business", calculated excluding R&D expenses in 2017 and 2016 and the impact of the non-recurring revenue in 2016, increased by 11%, from 52.8 million euros in 2016 to 58.7 million euros in 2017, reflecting a 1.4 percentage point rise in the EBITDA margin to 21.3% in 2017 (see "w/o R&D costs and one-off" columns of the table below). Likewise, recognising the same amount of R&D expenses in 2017 as in 2016 and excluding the impact of the non-recurring revenue in 2016, EBITDA would have increased by 17% to 41.2 million euros, reflecting a 1.6 percentage point rise in the EBITDA margin to 15.0% in 2017, up from 13.3% in 2016 (see "Flat R&D costs and w/o one-off" columns of the table below).

<i>€ million</i>	Reported		w/o R&D costs and one-off			Flat R&D costs and w/o one-off		
	2017	2016	2017	2016	Chang	2017	2016	Chang
Operat. revenue	275.6	265.2	275.6	265.2	4%	275.6	265.2	4%
Other income	1.8	1.6	1.8	1.6	13%	1.8	1.6	13%
Total revenue	277.4	266.7	277.4	266.7	4%	277.4	266.7	4%
Cost of sales	-110.2	-112.0	-110.2	-112.0	-2%	-110.2	-112.0	-2%
Gross profit	167.2	154.7	167.2	154.7	8%	167.2	154.7	8%
<i>% margin</i>	<i>60.7%</i>	<i>58.3%</i>	<i>60.7%</i>	<i>58.3%</i>	<i>2.3pp</i>	<i>60.7%</i>	<i>58.3%</i>	<i>2.3pp</i>
R&D expenses	-28.3	-17.5	0.0	0.0	n.a.	-17.5	-17.5	n.a.
Other SG&A	-108.5	-101.9	-108.5	-101.9	6%	-108.5	-101.9	6%
Other income	0.0	4.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	30.5	39.3	58.7	52.8	11%	41.2	35.3	17%
<i>% margin</i>	<i>11.1%</i>	<i>14.8%</i>	<i>21.3%</i>	<i>19.9%</i>	<i>1.4pp</i>	<i>15.0%</i>	<i>13.3%</i>	<i>1.6pp</i>

Depreciation and amortisation expenses increased by 4% to 11.5 million euros in 2017, mainly due to the new property, plant and equipment and intangible assets purchases made during the last twelve months.



EBIT decreased to 19.0 million euros in 2017, a drop of 33% compared to the previous year, reflecting a 3.8 percentage point fall in the EBIT margin, which was down to 6.9% in 2017 from 10.7% in 2016. However, EBIT of the “on-going business”, calculated excluding R&D expenses in 2017 and 2016 and the impact of the non-recurring revenue in 2016, increased by 13%, from 41.8 million euros in 2016 to 47.3 million euros in 2017, reflecting a 1.4 percentage point rise in the EBIT margin to 17.1% in 2017 (see “w/o R&D costs and one-off” columns of the table below). Likewise, recognising the same amount of R&D expenses in 2017 as in 2016 and excluding the impact of the non-recurring revenue in 2016, EBIT would have increased by 23% to 29.8 million euros, reflecting a 1.6 percentage point rise in the EBIT margin to 10.8% in 2017, up from 9.2% in 2016 (see “Flat R&D costs and w/o one-off” columns of the table below).

€ million	Reported		w/o R&D costs and one-off			Flat R&D costs and w/o one-off		
	2017	2016	2017	2016	Chang	2017	2016	Chang
Operat. revenue	275.6	265.2	275.6	265.2	4%	275.6	265.2	4%
Other income	1.8	1.6	1.8	1.6	13%	1.8	1.6	13%
Total revenue	277.4	266.7	277.4	266.7	4%	277.4	266.7	4%
Cost of sales	-110.2	-112.0	-110.2	-112.0	-2%	-110.2	-112.0	-2%
Gross profit	167.2	154.7	167.2	154.7	8%	167.2	154.7	8%
<i>% margin</i>	<i>60.7%</i>	<i>58.3%</i>	<i>60.7%</i>	<i>58.3%</i>	<i>2.3pp</i>	<i>60.7%</i>	<i>58.3%</i>	<i>2.3pp</i>
R&D expenses	-28.3	-17.5	0.0	0.0	n.a.	-17.5	-17.5	n.a.
Other SG&A	-108.5	-101.9	-108.5	-101.9	6%	-108.5	-101.9	6%
Other income	0.0	4.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	30.5	39.3	58.7	52.8	11%	41.2	35.3	17%
<i>% margin</i>	<i>11.1%</i>	<i>14.8%</i>	<i>21.3%</i>	<i>19.9%</i>	<i>1.4pp</i>	<i>15.0%</i>	<i>13.3%</i>	<i>1.6pp</i>
EBIT	19.0	28.3	47.3	41.8	13%	29.8	24.3	23%
<i>% margin</i>	<i>6.9%</i>	<i>10.7%</i>	<i>17.1%</i>	<i>15.8%</i>	<i>1.4pp</i>	<i>10.8%</i>	<i>9.2%</i>	<i>1.6pp</i>

Financial expense increased by 11% in 2017, compared to the previous year, due to the increase in banking debt through a 20-million-euro new loan in 2017.

Financial income decreased by 78% in 2017, compared to 2016, due to the reduction of delay interests from Court decisions related to pending invoices due for collection from Public Administration in 2017.

The **effective tax rate** was 1.6% in 2017 compared to 6.4% in 2016. This favourable effective tax rate is due to the deduction of existing research and development expenses and the capitalisation of negative tax bases from Frosst Ibérica, S.A. As of 31 December 2017, Frosst Ibérica negative tax bases amounted to 35.1 million euros, of which 1.5 million euros will be used in the 2017 income tax.

However, ROVI expects to maintain a mid-single-digit effective tax rate for the foreseeable future.



Net profit decreased to 17.2 million euros in 2017, a 34% fall compared to the previous year. However, net profit of the "on-going business", calculated excluding R&D expenses in 2017 and 2016 and the impact of the non-recurring revenue in 2016, increased by 16%, from 38.7 million euros in 2016 to 45.0 million euros in 2017 (see "w/o R&D costs and one-off" columns of the table below). Likewise, recognising the same amount of R&D expenses in 2017 as in 2016 and excluding the impact of the non-recurring revenue in 2016, net profit would have increased by 25% to 27.8 million euros (see "w/o impacts" columns of the table below).

€ million	Reported		w/o R&D costs and one-off			Flat R&D costs and w/o one-off		
	2017	2016	2017	2016	Chang	2017	2016	Chang
Operat. revenue	275.6	265.2	275.6	265.2	4%	275.6	265.2	4%
Other income	1.8	1.6	1.8	1.6	13%	1.8	1.6	13%
Total revenue	277.4	266.7	277.4	266.7	4%	277.4	266.7	4%
Cost of sales	-110.2	-112.0	-110.2	-112.0	-2%	-110.2	-112.0	-2%
Gross profit	167.2	154.7	167.2	154.7	8%	167.2	154.7	8%
% margin	60.7%	58.3%	60.7%	58.3%	2.3pp	60.7%	58.3%	2.3pp
R&D expenses	-28.3	-17.5	0.0	0.0	n.a.	-17.5	-17.5	n.a.
Other SG&A	-108.5	-101.9	-108.5	-101.9	6%	-108.5	-101.9	6%
Other income	0.0	4.0	0.0	0.0	n.a.	0.0	0.0	n.a.
EBITDA	30.5	39.3	58.7	52.8	11%	41.2	35.3	17%
% margin	11.1%	14.8%	21.3%	19.9%	1.4pp	15.0%	13.3%	1.6pp
EBIT	19.0	28.3	47.3	41.8	13%	29.8	24.3	23%
% margin	6.9%	10.7%	17.1%	15.8%	1.4pp	10.8%	9.2%	1.6pp
Net profit	17,2	26,1	45,0	38,7	16%	27,8	22,3	25%
% margin	6.3%	9.8%	16.3%	14.6%	1.7pp	10.1%	8.4%	1.7pp

ROVI will pay a **dividend** of 0.1207 euros per share with dividend rights on 2017 earnings if the Shareholders General Meeting approves the application of the 2017 profit, under proposal of ROVI's Board of Directors. This proposed dividend represents a 35% pay out.

Javier López-Belmonte Encina, Chief Financial Officer of ROVI, said that "we are happy with the results of 2017. Total revenue increased by 4% thanks to the strength of our leading products, which continue to enjoy good sales prospects, as well as of our injectable toll manufacturing business. The commencement of the Risperidone ISM® phase III, as well as the opening of subsidiaries for the marketing of our Enoxaparin biosimilar in the main European markets, required a significant investment effort from us, which was reflected in the 2017 EBITDA figure. However, the EBITDA of the "on-going business" increased by 11% reflecting the good performance of the traditional business. We expect the commercialisation of our Enoxaparin biosimilar to allow us to increase our profit margins in the near future. We continue to have a strong balance sheet and an excellent cash-generating capacity, which allow us to finance organic growth through the launch of new products, such as Neparvis®, Volutsa®, Ulunar® and Orvatez®, and to be in a strong position to benefit in the current operating environment, as we



will pay special 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 19.9 million euros in 2017, compared to 18.1 million euros in 2016. Of this amount:

- 2.9 million euros corresponds to investment capex related to the injectable facility, versus 2.6 million euros in 2016;
- 4.8 million euros relates to investment capex regarding the San Sebastián de los Reyes plant, versus 3.2 million euros in 2016;
- 1.6 million euros were invested in the Granada facility, versus 0.6 million euros in 2016;
- 3.8 million euros were invested in the Alcalá de Henares (Frosst Ibérica) facility, versus 2.6 million euros in 2016; and
- 6.8 million euros relates to expenditure on maintenance and other capex (including capitalized expenses related to the Enoxaparin biosimilar which amounted to 4.5 million euros), versus 9.1 million euros in 2016 (including capex invested for the distribution agreements regarding Neparvis and Mysimba).

	2017	2016	% Growth
Injectable plant	2.9	2.6	11%
San Sebastián de los Reyes plant	4.8	3.2	49%
Granada plant	1.6	0.6	n.a.
Alcalá de Henares plant (Frosst Ibérica)	3.8	2.6	45%
Expenditure on maintenance and other capex	6.8	9.1	-25%
Total Capex	19.9	18.1	10%

3.2 Debt

As of 31 December 2017, ROVI had total debt of 43.2 million euros. Debt with public administration, which is 0% interest rate debt, represented 28% of total debt as of 31 December 2017.

<i>In thousand euros</i>	31 December 17	31 December 16
Bank borrowings	30,938	20,931
Debt with public administration	12,299	12,863
Total	43,237	33,794

As of 31 December 2017, bank borrowings increased by 10 million euros. In 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.

Likewise, in December 2017, ROVI announced the European Investment Bank (EIB) granted it a loan to support its investments in Research, Development and Innovation. The loan is for 45 million euros. ROVI may draw down this amount during a period of 24 months as from signature of the contract and the loan will mature in 2029. The loan provides for a three-year grace period and financial conditions (i.e. applicable interest rates, repayment periods, etc.) favourable to ROVI (see section 6.1).

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 -1.6 million euros in 2017 compared to an increase of 28.2 million euros in 2016 mainly due to (i) the increase of 8.1 million euros in the "inventories" line in 2017, compared to the increase of 3.5 million euros in 2016; (ii) the decrease of 6.9 million euros in the "trade and other payables" item in 2017, compared to an increase of 14.1 million euros in 2016; and (iii) the increase of 1.9 million euros in Capex.

3.4 Gross cash position and net debt

As of 31 December 2017, ROVI had gross cash position of 42.1 million euros, compared to 42.8 million euros as of 31 December 2016, and net debt of 1.1 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 2017 was mainly due to (i) an increase in the "inventories" line of 8.1 million euros mainly due to higher heparin stock levels in 2017; (ii) a decrease in the "trade and other payables" line of 6.9 million euros; (iii) a decrease in the "trade and other receivables" line of 4.1 million euros; and (iv) a decrease in the "cash and cash equivalents" item of 0.7 million euros.

As of 31 December 2017, Social Security and Public Administrations total debt with ROVI amounted to 5.7 million euros, of which 4.0 million euros in Spain and the other 1.7 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 Enoxaparin biosimilar**, despite (i) a new reduction in health expenditure from 6.0% to 5.8% of GDP expected for 2018 (the lowest health spending forecast since 2007), according to the 2018 Draft Budget Plan¹, and (ii) 1-4% growth rate in spending on medicine in Spain to 2021 forecast by QuintilesIMS².

ROVI expects its growth drivers to be Bemiparin, the latest license agreements (Neparvis[®], Volutsa[®], Orvatez[®] and Ulunar[®]), the Enoxaparin biosimilar, 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[®].

Likewise, ROVI expects to stop distributing Merus Labs products (Sintrom[®], Salagen[®], Cordiplast[®] and Estraderm[®]) as of the fourth quarter of 2018.

5. Research and Development update

ISM[®]

As previously informed, ROVI has progressed in the development of DORIA[®], 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 & II program^{3,4} of DORIA[®], ROVI started the pivotal phase III trial "PRISMA-3"⁵ with the recruitment of the first patient on May 2017. An update of the project with details of the design and cost of Phase III was released, together with a presentation to analysts on 24th October 2017 (see section 6.3).

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.

³ Llaudó 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.

⁴ Carabias LA, et al. A phase II study to evaluate the pharmacokinetics, safety, and tolerability of Risperidone ISM multiple intramuscular injections once every 4 weeks in patients with schizophrenia. *Int Clin Psychopharmacol.* 2017 Nov 3. doi: 10.1097/YIC.000000000000203. [Epub ahead of print]

⁵ Study to Evaluate the Efficacy and Safety of Risperidone In Situ Microparticles[®] (ISM[®]) in Patients With Acute Schizophrenia (PRISMA-3). *Clinicaltrials.gov#NCT03160521* [<https://clinicaltrials.gov/show/NCT03160521>].



On the other hand, ROVI has initiated the first Phase I clinical trial¹ of Letrozol ISM® in November 2017. Letrozol ISM® is a long-acting injectable aromatase inhibitor intended for the treatment of hormone-dependent breast cancer.

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 (Enoxaparin biosimilar) 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 (Enoxaparin biosimilar) was approved in Germany by local authorities and its marketing has begun (see section 6.2).

By 31st December 2017, the countries with the national registration approved of the Enoxaparin biosimilar are Germany, France, United Kingdom, Italy, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia and Bulgaria.

6. Key operating and financial events

6.1 ROVI and the EIB agree to sign a loan to boost research into drug administration and prolonged-release technologies

On 21st of December 2017, the market was informed by publication of a relevant fact (number 259847) that the European Investment Bank (EIB) granted ROVI a loan to support its investments in Research, Development and Innovation (R&D&i), which concentrate on technologies for the administration and prolonged release of drugs, including preclinical and clinical trials, that allow the development of future treatments for cancer and central nervous system diseases.

The loan is for 45,000,000 euros. ROVI may draw down this amount during a period of 24 months as from signature of the contract and the loan will mature in 2029. The loan provides for a three-year grace period and financial conditions (i.e. applicable interest rates, repayment periods, etc.) favourable to ROVI.

For the Company, the EIB loan represents an additional financing channel for its R&D&i projects, for which it likewise uses significant amounts of its own equity.

¹ *Evaluation of IM Letrozole ISM® Pharmacokinetics, Safety, and Tolerability in Healthy Post-menopausal Women (LISA-1).* [<https://clinicaltrials.gov/ct2/show/NCT03401320?term=letrozole&rank=4>].



In the year 2016, ROVI's R&D&i expenditure was 17.5 million euros, 6% up on the preceding year. Likewise, the Company expects average R&D&i expenditure in the period 2017-2019 to be approximately 32 million euros per year.

This financing operation is supported by the European Union under the European Fund for Strategic Investments (EFSI), within the framework of what is known as the "Juncker Plan". The research activities associated to this agreement reinforce ROVI's innovation capacity and help the company to maintain a competitive edge and expand its international presence.

6.2 ROVI has commenced the marketing of the Enoxaparin biosimilar 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 (Enoxaparin biosimilar) 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 continued during the rest of the year.

By 31st December 2017, the countries with the registration national phase approved are Germany, France, UK, Italy, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia and Bulgaria.

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.

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

On 24th of 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 on 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 pharmacoeconomic 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 31 DECEMBER 2017 AND 31 DECEMBER 2016

(Thousands of euros)

	31 December 2017	31 December 2016
ASSETS		
Non-current assets		
Property, Plant and Equipment	89,056	82,822
Intangible assets	27,078	24,872
Investment in a joint venture	2,054	2,571
Deferred income tax assets	11,893	10,252
Available-for-sale financial assets	69	70
Financial receivables	65	189
	130,215	120,776
Current assets		
Inventories	75,492	67,386
Trade and other receivables	49,747	53,842
Current income tax assets	2,228	4,466
Cash and cash equivalents	40,700	41,378
	168,167	167,072
Total assets	298,382	287,848



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

(Thousands of euros)

	31 December 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	(8,407)	(8,701)
Retained earnings and voluntary reserves	179,255	162,421
Profit for the year	17,241	26,089
Reserve for available-for-sale assets	(2)	(3)
Total equity	191,687	183,406
LIABILITIES		
Non-current liabilities		
Financial debt	27,029	20,828
Deferred income tax liabilities	1,438	1,640
Deferred revenues	5,005	5,532
	33,472	28,000
Current liabilities		
Financial debt	16,208	12,966
Trade and other payables	52,942	59,852
Deferred revenues	565	746
Provisions for other liabilities and charges	3,508	2,878
	73,223	76,442
Total liabilities	106,695	104,442
Total equity and liabilities	298,382	287,848



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS FOR THE FULL YEARS 2017 AND 2016

(Thousands of euros)

	Full Year	
	2017	2016
Revenue	275,649	265,166
Cost of sales	(110,192)	(112,024)
Employee benefit expenses	(63,990)	(60,465)
Work performed by the Company on its assets	2,057	-
Other operating expenses	(74,809)	(58,916)
Amortisation	(11,479)	(11,023)
Recognition of government grants on non financial non-current assets and other	1,773	1,565
Other income	-	3,997
OPERATING PROFIT	19,009	28,300
Finance income	93	426
Finance costs	(1,013)	(915)
FINANCE COSTS - NET	(920)	(489)
Share of profit of a joint venture	(567)	71
PROFIT BEFORE INCOME TAX	17,522	27,882
Income tax	(281)	(1,793)
PROFIT FOR THE YEAR	17,241	26,089



LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES
CONSOLIDATED CASH FLOW STATEMENTS FOR THE FULL YEARS 2017 AND 2016

(Thousands of euros)

	Full Year	
	2017	2016
Cash flows from operating activities		
Profit before income tax	17,522	27,882
Adjustments for non-monetary transactions:		
Amortisation	11,479	11,023
Interest income	(93)	(426)
Impairment	(1,437)	1,864
Interest expense	1,013	915
Net changes in provisions	630	381
Grant for non-financial fixed assets and income from distribution	(2,012)	(1,847)
Profit from creation of joint venture	-	(3,997)
Share of profit of a joint venture	567	(71)
Changes in working capital:		
Trade and other receivables	3,534	4,131
Inventories	(6,454)	(4,940)
Trade and other payables	(6,910)	13,505
Other collections and payments:		
Proceeds from distribution licenses	87	505
Income tax cash flow	113	(3,399)
Net cash generated (used) from operating activities	18,039	45,526
Cash flows from investing activities		
Purchases of intangible assets	(5,012)	(8,396)
Purchases of property, plant and equipment	(14,932)	(9,680)
Proceeds from sale of property, plant and equipment	25	43
Investment in a joint venture	-	(3)
Proceeds from sale of shares in joint venture	450	1,000
Interest received	285	738
Net cash generated (used) in investing activities	(19,184)	(16,298)
Cash flows from financing activities		
Repayments of financial debt	(13,084)	(10,274)
Proceeds from financial debt	22,350	797
Interest paid	(253)	(230)
Purchase of treasury shares	(532)	(987)
Reissue of treasury shares	1,011	446
Dividends paid	(9,025)	(6,853)
Net cash generated (used) in financing activities	467	(17,101)
Net (decrease)/increase in cash and cash equivalents	(678)	12,127
Cash and cash equivalents at beginning of the year	41,378	29,251
Cash and cash equivalents at end of the year	40,700	41,378