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Operating results
9M 2018 financial results - Highlights

- **Operating revenue** increased by 8% to €218.9Mn in 9M 2018, driven by the strength the specialty pharmaceutical business, where sales rose 15%, strongly outperforming the market. Total revenue increased by 8% to €220.0Mn in 9M 2018.

- **In 2019**, ROVI expects a high-single-digit growth rate for the operating revenue.

- **ROVI is upgrading its operating revenue guidance for 2018**, from mid-single digit growth rate to high-single-digit growth rate. Guidance for Enoxaparin biosimilar sales remains unchanged, within a range of between €20Mn and €30Mn, and is expected to be towards the higher end of the range.

- **ROVI launched its enoxaparin biosimilar in Germany** in September 2017, in the United Kingdom in March 2018, in Italy in April 2018, in Spain in September 2018, in France in September 2018 (pursuant to an agreement with Biogaran), and in Austria and Latvia in October 2018.

- By 30th September 2018, the countries with the national registration approved of the low molecular weight heparin (biosimilar of Enoxaparin) are Germany, France, UK, Italy, Spain, Portugal, Belgium, Finland, Norway, Sweden, Austria, Hungary, Slovenia, Estonia, Latvia, Slovakia, Bulgaria, Romania, Croatia, Czech Republic, Denmark, Poland and Ireland.

- **Sales of the Enoxaparin biosimilar amounted to €16.7Mn** in 9M 2018.

- **Very good performance of Bemiparin**: 11% increase to €68.7Mn with a growth of 21% in Spain.

- Sales of Hirobriz and Ulunar increased by 9% to €11.4Mn; Volutsa increased sales by 25% to €8.2Mn; and Neparvis, launched in December 2016, reached sales of €9.3Mn in 9M 2018 (vs €2.8Mn in 9M 2017).

- In 9M 2018, EBITDA was affected by non-recurring expenses of €1.1Mn, linked to a substantial change to Frosst Ibérica employees working conditions.

- **EBITDA “pre-R&D”** (w/o R&D and non recurring expenses) increased by 13%, from €45.8Mn in 9M 2017 to €51.6Mn in 9M 2018, reflecting a 1.1 pp rise in the EBITDA margin to 23.6% in 9M 2018. Likewise, recognising the same amount of R&D expenses in 9M 2018 as in 9M 2017 and excluding the impact of the non recurring expenses in 9M 2018, EBITDA would have increased by 21% to €32.7Mn, reflecting a 1.7 pp rise in the EBITDA margin to 15.0% in 9M 2018.

- **Net profit “pre-R&D”** (w/o R&D and non recurring expenses) increased by 13%, from €35.5Mn in 9M 2017 to €40.1Mn in 9M 2018.
Growth driven by specialty pharma business...

- **Operating revenue increased by 8%** to €218.9Mn in 9M 2018 driven by the strength of:
  - the specialty pharmaceutical business, where sales rose 15%

- ROVI forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in the first nine months of 2018, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 3%.
...with high profitability

- In 9M 2018, EBITDA was affected by non-recurring expenses €1.1Mn, linked to a substantial change to Frosst Ibérica employees working conditions.
- EBITDA “pre-R&D” (w/o R&D and non recurring expenses) increased by 13%, from €45.8Mn in 9M 2017 to €51.6Mn in 9M 2018, reflecting a 1.1 percentage point rise in the EBITDA margin to 23.6% in 9M 2018.
- Net profit “pre-R&D” (w/o R&D and non recurring expenses) increased by 13%, from €35.5Mn in 9M 2017 to €40.1Mn in 9M 2018.

Note: EBITDA and Net profit “pre-R&D” calculated excluding R&D expenses in 9M 2018 and 9M 2017 and the impact of non recurring expenses in 9M 2018.
Bemiparin, leading the specialty pharmaceutical business

**Prescription-based pharma products sales (€Mn)**

- Sales of **prescription-based pharmaceutical products increased by 17%** to €156.4Mn in 9M 2018.
  - **Bemiparin total sales increased by 11%** to €68.7Mn in 9M 2018:
    - Sales in Spain increased **21%** to €49.5Mn.
    - International sales decreased by **8%** to €19.2Mn.
Strong growth potential of Enoxaparin Biosimilar Becat®

Strong Commercial Launch with a Clear Strategy

- ROVI launched enoxaparin biosimilar Becat® in Germany (first EU market) in September 2017, in UK, Italy, Spain and France in 9M 2018 and in Austria and Latvia in October 2018.
- Enoxaparin biosimilar Becat® expected to launch in key European markets before Q1 2019 through recently established European sales offices.
- Newly-established European sales offices provide pan-European infrastructure that is highly leverageable for further growth of ROVI’s heparin franchise and broader portfolio.

Well-Established Network to Minimize Time-to-Market

Stage I of Commercial Strategy

- ROVI expects to directly market enoxaparin biosimilar Becat® in 7 European countries...
- ...which account for 75% of the European market...
- ...of which only 1 is already in the market

Stage II of Commercial Strategy

- Continue international expansion in other markets with strong growth potential through out-licensing agreements
- Already Signed Out-Licensed Agreements: 63 Countries

ROVI signed a licensing agreement with Sandoz to distribute enoxaparin biosimilar Becat® in 14 countries/regions and with Hikma in 17 Middle East and North African countries.
Strong performance of the product portfolio (1/2)

Absorcol, Vytorin and Orvatez sales (€Mn)

- Sales of Vytorin®, Orvatez® and Absorcol® decreased by 3% to €28.0Mn in 9M 2018. In 2Q 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.

Hirobriz and Ulunar sales (€Mn)

- Sales of Hirobriz and Ulunar®, both products for patients with COPD, launched in Spain in Q4 2014 increased by 9% to €11.4Mn in 9M 2018.

Medicebran and Medikinet sales (€Mn)

- Sales of Medicebran and Medikinet®, products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, decreased 2% to €5.2Mn in 9M 2018.

Vytorin, Orvatez and Absorcol, the first of the five licenses of MSD, are indicated for the treatment of hypercholesterolemia. Hirobriz Breezhaler and Ulunar Breezhaler are both products from Novartis indicated for the treatment of COPD (Chronic Obstructive Pulmonary Disease). Medicebran and Medikinet are specialty products from Medice indicated for the treatment of ADHD in children and teenagers.
Strong performance of the product portfolio (2/2)

Volutsa sales (€Mn)

- Sales of Volutsa, launched in Spain in February 2015, increased by 25% to €8.2Mn in 9M 2018.

Neparvis sales (€Mn)

- Exxiv sales decreased by 39% to €1.8Mn, mainly due to a deceleration of the COX-2 market.
- Contrast imaging agents and other hospital products increased by 4% to €22.2Mn in 9M 2018.

Volutsa is a specialty product from Astellas Pharma indicated for the treatment of moderate to severe storage symptoms and voiding symptoms associated with benign prostatic hyperplasia.

Neparvis is a specialty product from Novartis indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction.

Exxiv is a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD).
Value added toll manufacturing services

- **Toll manufacturing sales** decreased by 16% to €38.5Mn in 9M 2018, compared to 9M 2017, mainly because of the reduction of the injectable business compared to 9M 2017, when exceptional high volumes were manufactured for some customers.
  - Frosst Ibérica plant sales decreased by 1% to €18.8Mn in 9M 2018 compared to 9M 2017.
  - By the end of 2018, a mid-teen decline (from 10-20%) in toll manufacturing is expected.
ISM® Platform Opens Up New Avenues of Growth for ROVI

Overview

• Internally-developed and patented innovative drug-release technology, ISM®, which allows for the sustained release of compounds administered by injection
  • Based on two separate syringes respectively containing (a) the drug and polymer (solid state) and (b) the solvent (liquid state)
  • Potential wide applicability of ISM® technology to new chronic therapeutic areas, including psychiatry and oncology
  • 505(b)(2) path of approval for candidates leveraging ISM® technology

2 Candidates Currently in Clinical Trials

<table>
<thead>
<tr>
<th>Product</th>
<th>Potential Indication</th>
<th>Current Situation</th>
<th>Key Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>DORIA® Risperidone, monthly</td>
<td>Schizophrenia</td>
<td>Pre-Clinical</td>
<td>Phase III started in H1 2017 (interim read out 9 May 2018)</td>
</tr>
<tr>
<td>Letrozole ISM® Long acting Letrozole</td>
<td>Breast Cancer</td>
<td>Pre-Clinical</td>
<td>Phase I started in November 2017</td>
</tr>
</tbody>
</table>

Key Company Highlights of ISM® Platform

1. Predictability
   - Pop PK model & simulations already validated for DORIA® in Phase I & II Clinical Program
   - Expected high success rate in Phase III

2. Usability
   - Improved stability
   - No cold chain needed

3. Flexibility
   - Selecting the most convenient posology depending on clinical needs
   - From 1 to 6-month administration

4. Improved Clinical Management
   - Long acting injection (LAI) (1-6 months) plasma therapeutic levels from day 1
   - Rapid onset & sustained clinical effect

5. Vertical Integration
   - Technological barriers (e.g. power filling)
   - Strong IP
   - Manufacturing capabilities
   - Protected technology
   - Fully integrated manufacturing plants

Concentrated on improving posology for already approved compounds, which benefits risk / reward profile

Multiple FDA / GMP approved facilities to support the platform

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1. ISM® stands for In Situ Microparticles®
2. PK stands for pharmacokinetic.
Guidance 2019

2019 operating revenue growth rate

High-single-digit

The key growth levers in 2019

Specialty Pharma Business

- Bemiparin
- Latest launches such as Neparvis, Orvatez, Volutsa and Ulunar
- Existing portfolio of specialty pharmaceuticals
- New in-licensed products to be launched
- Biosimilar of Enoxaparin

Toll Manufacturing Services

- Spare capacity in the injectable plants and in the oral compounds plant
- New customers to be acquired
Financial results
Good revenue level with outstanding Bemiparin growth

Operating revenue increased by 8% to €218.9Mn, achieved on:
- 17% growth in prescription-based products;
- 4% growth in contrast agents and other hospital products;
- 16% reduction in toll manufacturing; and
- OTC and other revenues decreased by 18% (including revenue from distribution licenses).

Bemiparin, ROVI’s flagship product internally developed, reached sales of €68.7Mn (11% growth vs 9M 2017). Sales grew by 21% in the domestic market and decreased by 8% in the international market.
Gross margin impacted by the decrease of injectable toll manufacturing sales

• **Gross profit increased by 7%** to €130.7Mn in 9M2018, the gross margin showing a decrease of 0.4 pp from 60.1% in 9M 2017 to 59.7%, mainly due to a drop in the injectable business, which added higher margins in 9M 2017.

• However, the good performance of the injectable business in Q3 2018 helped to recover, to a large extent, the margin decrease of 2.5 pp recorded in 1H 2018.

• Sales of the Enoxaparin biosimilar had a positive impact in 9M 2018; nevertheless some gross margin erosion is expected in the future, as the product will be launched in other markets.
Cost control along with commitment to R&D

- **SG&A expenses rose 4%** to €79.1Mn in 9M 2018 mainly due to:
  - international subsidiaries expenses, which amounted to €4.1Mn compared to €1.0Mn in 9M 2017.
  - Excluding expenses related to international subsidiaries, SG&A would have decreased by 0.2% in 9M 2018.
- **R&D expenses increased 30%** to €24.6Mn in 9M 2018 mainly due to the development of the Risperidone-ISM® (Doria®) Phase III trial and the Letrozole-ISM® Phase I trial.
EBITDA

**EBITDA (€Mn) and EBITDA margin (%)**

<table>
<thead>
<tr>
<th></th>
<th>9M 2017</th>
<th>9M 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBITDA</td>
<td>13,2%</td>
<td>11,9%</td>
</tr>
<tr>
<td>EBITDA margin</td>
<td>27,0</td>
<td>25,9</td>
</tr>
</tbody>
</table>

**EBITDA (€Mn) and EBITDA “pre-R&D” (w/o R&D and non recurring expenses) margin (%)**

<table>
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<tr>
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<th>9M 2017</th>
<th>9M 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBITDA “pre-R&amp;D”</td>
<td>22,5%</td>
<td>23,6%</td>
</tr>
<tr>
<td>EBITDA margin “pre-R&amp;D”</td>
<td>45,8</td>
<td>51,6</td>
</tr>
</tbody>
</table>

**EBITDA (€Mn) and EBITDA margin (%) with flat R&D costs and w/o non recurring expenses**

<table>
<thead>
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<th>9M 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBITDA</td>
<td>13,2%</td>
<td>15,0%</td>
</tr>
<tr>
<td>EBITDA margin</td>
<td>27,0</td>
<td>32,7</td>
</tr>
</tbody>
</table>

- In 9M 2018, EBITDA was affected by non-recurring expenses of €1.1Mn linked to a substantial change to Frosst Ibérica employees working conditions.
- **EBITDA** decreased to €25.9Mn in 9M 2018, reflecting a 1.4 pp fall in the EBITDA margin, which was down to 11.9% in 9M 2018 from 13.2% in 9M 2017.
- **EBITDA “pre-R&D”** (w/o R&D and non recurring expenses) increased by 13%, from €45.8Mn in 9M 2017 to €51.6Mn in 9M 2018, reflecting a 1.1 pp rise in the EBITDA margin to 23.6% in 9M 2018. Likewise,
  - recognising the same amount of R&D expenses in 9M 2018 as in 9M 2017 and excluding the impact of the non recurring expenses in 9M 2018, EBITDA would have increased by 21% to €32.7Mn, reflecting a 1.7 pp rise in the EBITDA margin to 15.0% in 9M 2018.

Note: EBITDA “pre-R&D” calculated excluding R&D expenses in 9M 2018 and 9M 2017 and the impact of non recurring expenses in 9M 2018.
EBIT

EBIT (€Mn) and EBIT margin (%) with flat R&D costs and w/o non recurring expenses

- Depreciation and amortisation expenses increased by 0.3% to €8.9Mn in 9M 2018.
- EBIT decreased to €17.1Mn in 9M 2018, reflecting a 1.1 pp fall in the EBIT margin, which was down to 7.8% in 9M 2018 from 8.9% in 9M 2017.
- EBIT “pre-R&D” (w/o R&D and non recurring expenses) increased by 16%, from €37.0Mn in 9M 2017 to €42.8Mn in 9M 2018, reflecting a 1.3 pp rise in the EBIT margin to 19.5% in 9M 2018. Likewise,
  - recognising the same amount of R&D expenses in 9M 2018 as in 9M 2017 and excluding the impact of the non recurring expenses in 9M 2018, EBIT would have increased by 32% to €23.9Mn, reflecting a 2.0 pp rise in the EBIT margin to 10.9% in 9M 2018.

Note: EBIT “pre-R&D” calculated excluding R&D expenses in 9M 2018 and 9M 2017 and the impact of non recurring expenses in 9M 2018.
Net profit

- Net profit decreased to €15.7Mn in 9M 2018, a 8% fall compared to 9M 2017.
- Net profit “pre R&D” (w/o R&D and non recurring expenses) increased by 13%, from €35.5Mn in 9M 2017 to €40.1Mn in 9M 2018. Likewise,
  - recognising the same amount of R&D expenses in 9M 2018 as in 9M 2017 and excluding the impact of the non recurring expenses in 9M 2018, net profit would have increased by 30% to €22.1Mn.
- Effective tax rate of 4.7% in 9M 2018 vs 2.3% in 9M 2017. This favourable effective tax rate is due to:
  - R&D deductions; and
  - negative tax bases from Frosst Ibérica, S.A., Rovi GmbH (the German franchise) and Rovi Biotech, S.R.L. (the Italian franchise).
- As of 30 September 2018, negative tax bases amounted to €35.0Mn, of which €1.0Mn will be used in 9M 2018.
- 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. Notwithstanding, when the R&D expenses are normalised 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.

Note: Net profit “pre-R&D” calculated excluding R&D expenses in 9M 2018 and 9M 2017 and the impact of non recurring expenses in 9M 2018. Same effective tax rate as the reported net profit.
**Capital expenditure and Free Cash Flow**

**Capex evolution (€Mn)**

- 8.1 Mn in 9M 2017
- 9.3 Mn in 9M 2018

**Free Cash Flow (€Mn)**

- -2.1 Mn in 9M 2017
- -13.2 Mn in 9M 2018

**Capex breakdown (%)**

- **Injectables;** 20%
- **Granada & Alcalá facility;** 48%
- **Maintenance capex and other;** 17%
- **San Sebastián de los Reyes facility;** 14%

**FCF decreased to €-13.2Mn mainly due to:**

- €27.1Mn increase in “inventories” in 9M 2018 vs €6.4Mn increase in 9M 2017;
- €10.6Mn increase in “trade and other receivables” in 9M 2018 vs €5.7Mn decrease in 9M 2017;
- €10.5Mn increase in “trade and other payables” in 9M 2018 vs €19.8Mn decrease in 9M 2017;
- €1.5Mn of “prepaid expenses”, related to capital increase, registered in 9M 2018;
- €1.2Mn increase in capex; and

- **€9.3Mn of capex invested in 9M 2018.**
  - €1.9Mn of investment capex related to the injectable plant;
  - €2.2Mn of investment capex related to the Granada facility;
  - €2.3Mn of investment capex related to the Alcalá de Henares facility;
  - €1.3Mn of investment capex related to the San Sebastián de los Reyes facility;
  - €1.6Mn of maintenance capex and other capex.
Debt breakdown by source (%)

- Debt with public administration: 31%
- Loans from banks: 69%

Debt maturities by year (€Mn)

- 2018: 5.5
- 2019: 17.4
- 2020: 3.9
- 2021: 1.7
- 2022 & beyond: 11.0

- **Debt with public administration** represented 31% of total debt, with 0% interest rate.
- **Gross cash position of €18.9Mn** as of 30 September 2018 vs €42.1Mn as of 31 December 2017.
- **Net debt of €20.6Mn** as of 30 September 2018 vs €1.1Mn as of 31 December 2017.
- ROVI paid a gross dividend of 0.1207 euros per share on 2017 earnings and it represented a 35% pay-out.
## News-flow 2018/2019

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<th>Specialty Pharma</th>
<th>Toll manufacturing</th>
<th>ISM® technology platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales of biosimilar of Enoxaparin</td>
<td>New contracts to be announced</td>
<td>Doria® final Phase III data readout at the end of Q2 2019</td>
</tr>
<tr>
<td>Additional new in-licensing products to be launched</td>
<td></td>
<td>ISM-Letrozole® Phase I data readout at the end of Q2 2019</td>
</tr>
<tr>
<td>Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar in 3 EU countries (23 already granted)</td>
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</tbody>
</table>
For further information, please contact:

Juan López-Belmonte  
Chief Executive Officer  
+34 91 3756235  
jlopez-belmonte@rovi.es  
www.rovi.es

Javier López-Belmonte  
Chief Financial Officer  
+34 91 3756266  
javierlbelmonte@rovi.es  
www.rovi.es

Marta Campos  
Investor Relations  
+34 91 2444422  
mcampos@rovi.es  
www.rovi.es