



# Rovi

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**Nine-month period ended 30  
September 2015 Financial Results**

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# Operating results



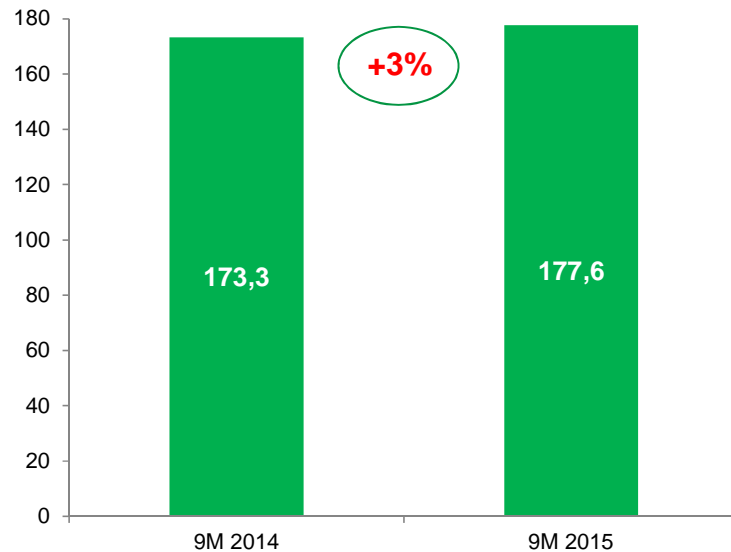
## 9M 2015 financial results - Highlights

- **Operating revenue** increased by 3% to €177.6Mn, mainly driven by the strength of the specialty pharmaceutical business, where sales rose 5%. Total revenue increased by 2% to €178.5Mn in 9M 2015.
- **The clinical trial of Risperidone ISM “PRISMA-2” has successfully finished. Final positive results to be announced before ending the year.**
- **For 2016**, ROVI expects operating revenue to grow from high single digit to low double digit.
- **Outstanding performance of Bemiparin in Spain:** +6% growth to €36.5Mn.
- **Good performance of Absorcol & Vytorin & Orvatez:** sales increase of 10%.
- **Sales of Hirobriz and Ulunar**, both products for patients with COPD launched in Spain in Q4 2014, reached €4.7Mn.
- **Sales of Medicebran and Medikinet**, both products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, increased by 3% to €5.2Mn.
- Sales of **Volutsa**, a product launched in February 2015, reached €1.9Mn in 9M 2015.
- **EBITDA** decreased by 12% to €25.4Mn in 9M 2015, reflecting a 2.4 pp fall in the EBITDA margin to 14.3% in 9M 2015 down from 16.7% in 9M 2014. However, maintaining, in 9M 2015, the same amount of R&D expenses that was registered in 9M 2014 and excluding the impact of (i) Other income, in 9M 2015 and 9M 2014, and (ii) recent product launches, in 9M 2015, EBITDA would increase by 19% to €31.7Mn, reflecting a 2.4 pp rise in the EBITDA margin to 17.8% in 9M 2015 up from 15.4% in 9M 2014.
- **Net profit** declined by 17% to €16.5Mn in 9M 2015. However, maintaining, in 9M 2015, the same amount of R&D expenses that was registered in 9M 2014 and excluding the impact of (i) Other income, in 9M 2015 and 9M 2014, and (ii) recent product launches, in 9M 2015, net profit would increase by 26% to €22.5Mn in 9M 2015.
- In July, ROVI paid a gross **dividend of €0.1690/share** on 2014 earnings, **+5%** vs last dividend.

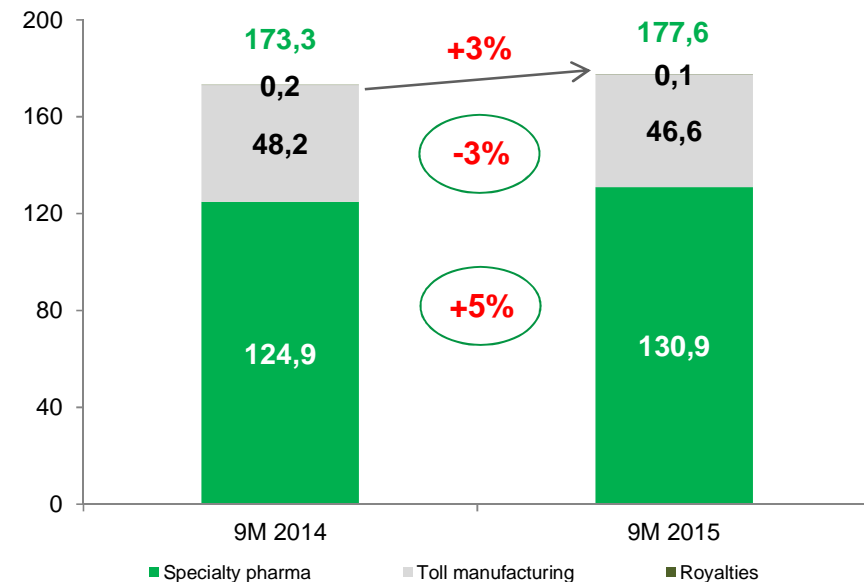
# Growth driven by the specialty pharmaceutical business strength...



Total operating revenue (€Mn)



Operating revenue growth by category (€Mn)



- Operating revenue increased by 3% in 9M 2015, up to €177.6Mn, driven by the strength of:
  - ✓ the specialty pharmaceutical business, where sales rose 5% in 9M 2015.
  - ✓ Toll manufacturing sales decreased by 3%.
- ROVI forecasts to continue growing despite the difficult situation that the Spanish pharmaceutical industry is going through:
  - ✓ slight 0.8% annual increase expected for 2015 and 2016, according to Farmaindustria<sup>1</sup>; and
  - ✓ zero to negative spending growth on medicine in Spain for the period 2014-2018 forecast by IMS Health<sup>2</sup>.

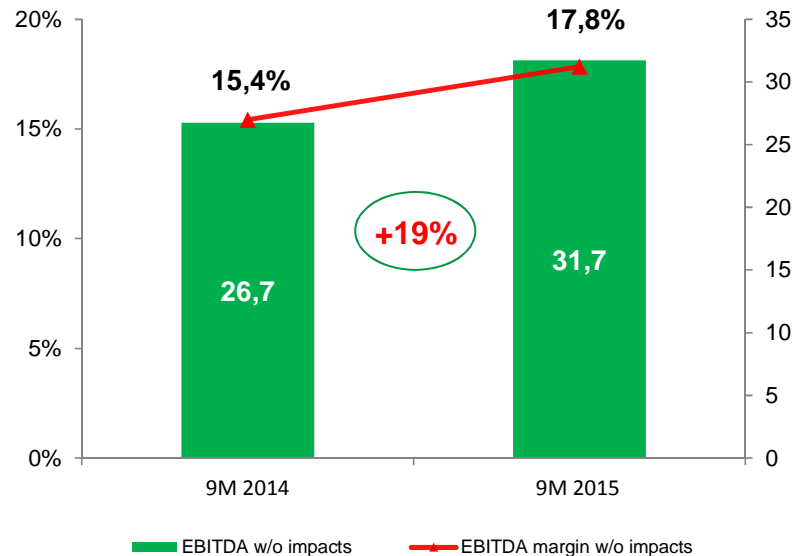
<sup>1</sup> <http://www.farmaindustria.es/web/indicador/analisis-de-la-evolucion-del-gasto-farmacologico-publico-en-espana-mes-mes-2/>

<sup>2</sup> <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad90f53c713c711nd8c22a/?vgnextoid=263e05267aca9410VgnVCM10000076192ca2RCRD&vgnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnextfmt=default>

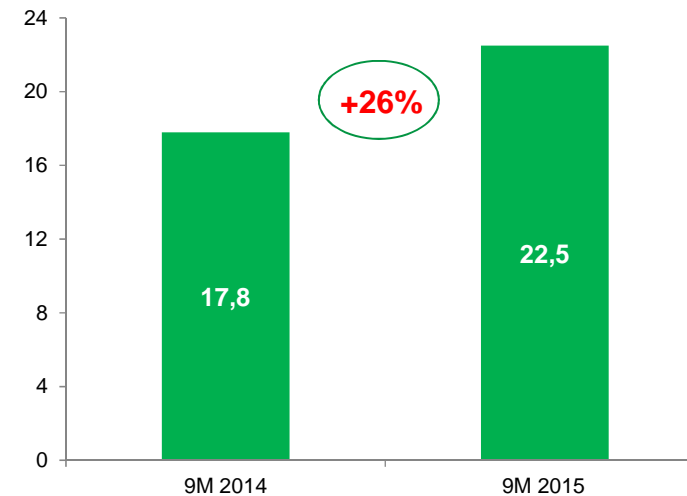


## ...with high profitability

### EBITDA (€Mn) and EBITDA margin (%) w/o impacts



### Net profit w/o impacts (€Mn)

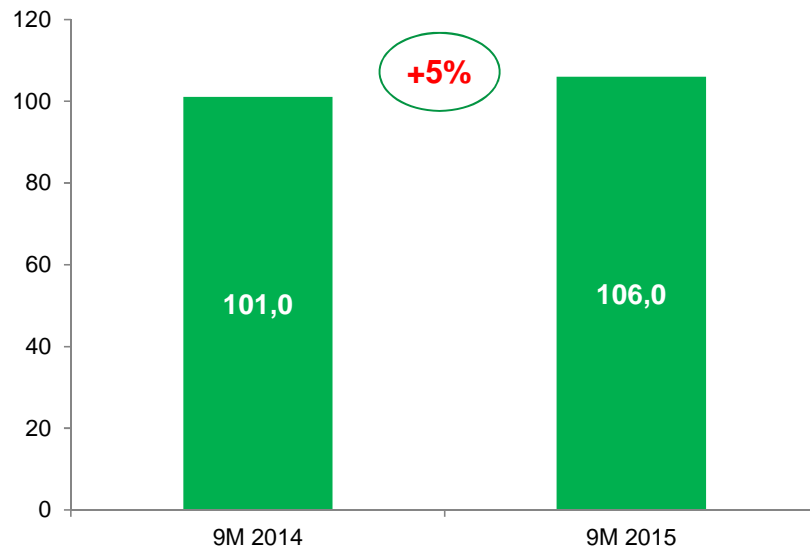


- In 9M 2015, EBITDA was impacted by (i) a 60% reduction in Other income (subsidies), (ii) a 44% increase in R&D expenses, mainly as a result of the development of the ISM-Risperidone Phase II study and (iii) recent product launches such as Hirobriz, Ulunar, Volutsa and Orvatez, which contributed SG&A expenses of €3.3Mn.
- Maintaining, in 9M 2015, the same amount of R&D expenses that was registered in 9M 2014 and excluding the impact of (i) Other income, in 9M 2015 and 9M 2014, and (ii) recent product launches, in 9M 2015,:
  - ✓ **EBITDA would increase by 19% to €31.7Mn, reflecting a 2.4 pp rise in the EBITDA margin to 17.8% in 9M 2015 up from 15.4% in 9M 2014; and**
  - ✓ **Net profit would increase by 26% to €22.5Mn.**

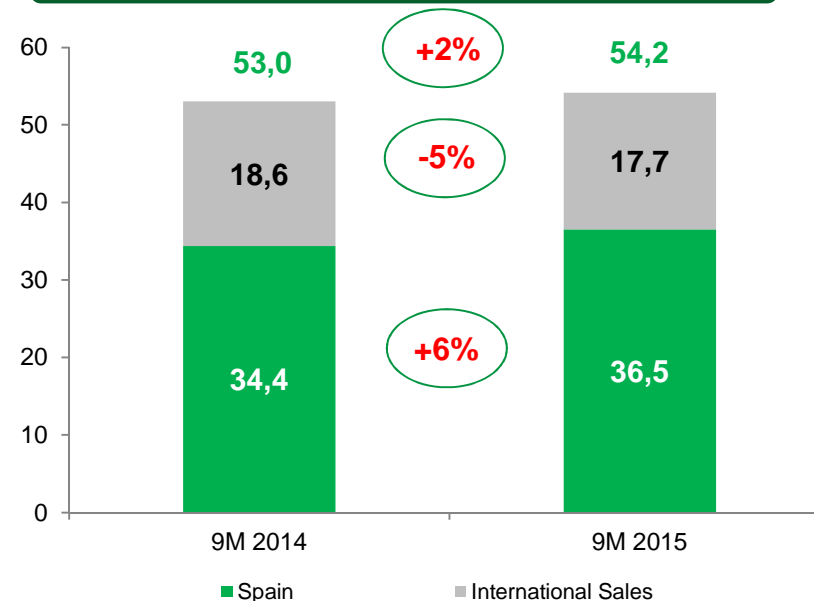


## Bemiparin in Spain, leading the growth

Prescription-based pharma products sales (€Mn)



Bemiparin sales (€Mn)

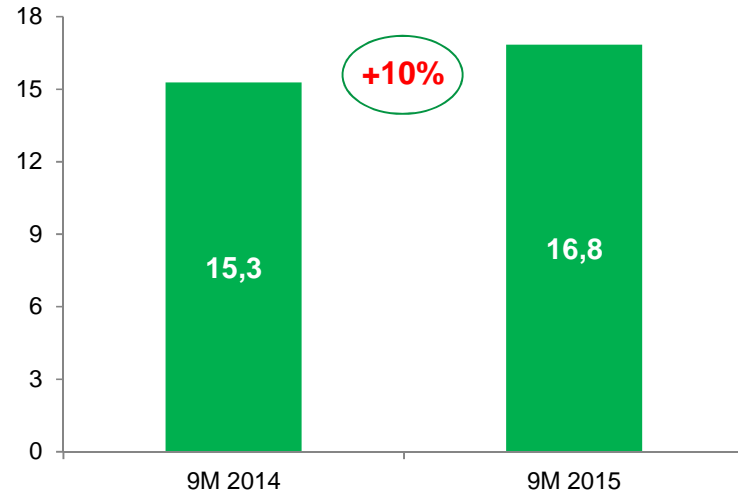


- Sales of **prescription-based pharmaceutical products** increased by **5%** to €106.0Mn in 9M 2015.
- **Bemiparin total sales** increased by **2%** to 54.2 million euros in 9M 2015.
  - ✓ **Bemiparin** performed well in **Spain** in 9M 2015, with sales up **6%** to €36.5Mn.
  - ✓ International sales decreased by 5% to €17.7Mn. ROVI expects Bemiparin marketing in China and Brasil, forecast for Q4 2015, as well as the launch of the product in new countries, such as Qatar in 9M 2015, to contribute to stable sales in 2015.

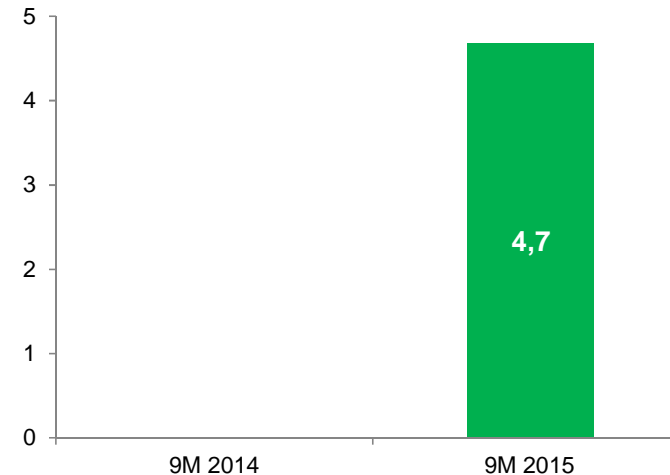


## Good performance of the product portfolio (1/2)

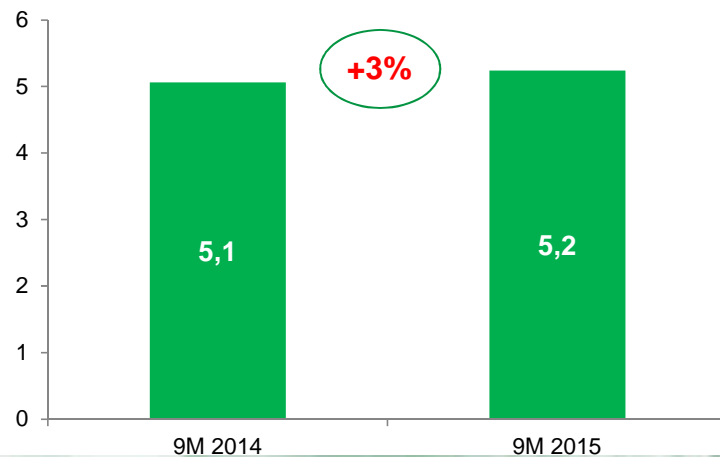
Absorcol, Vytorin and Orvatez sales (€Mn)



Hirobriz and Ulunar sales (€Mn)



Medicebran and Medikinet sales (€Mn)



- Sales of **Absorcol, Vytorin and Orvatez** (the last one launched in June 2015), **increased by 10%** to €16.8Mn in 9M 2015.
- Sales of **Hirobriz and Ulunar**, both products for patients with COPD, launched in Spain in Q4 2014 **reached €4.7Mn** in 9M 2015.
- Sales of **Medicebran and Medikinet**, products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, **increased by 3% to €5.2Mn** in 9M 2015.
- Sales of **Thymanax**, product launched in March 2010, decreased by 29% to €5.6Mn in 9M 2015.

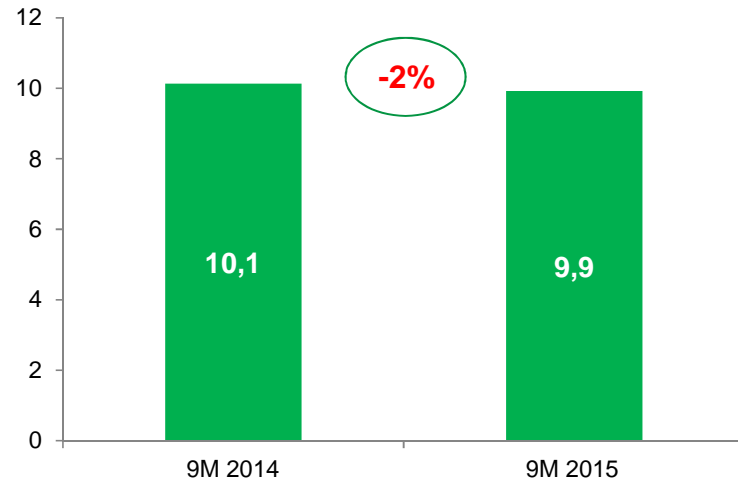
*Vytorin, Orvatez and Absorcol, the first of the five licenses of MSD, are indicated for the treatment of hypercholesterolemia. Hirobriz Breezhaler and Ulunar Breezhaler are both products from Novartis indicated for the treatment of COPD (Chronic Obstructive Pulmonary Disease). Medicebran and Medikinet are specialty products from Medice indicated for the treatment of ADHD in children and teenagers. Thymanax is an innovative antidepressant from Laboratoires Servier.*



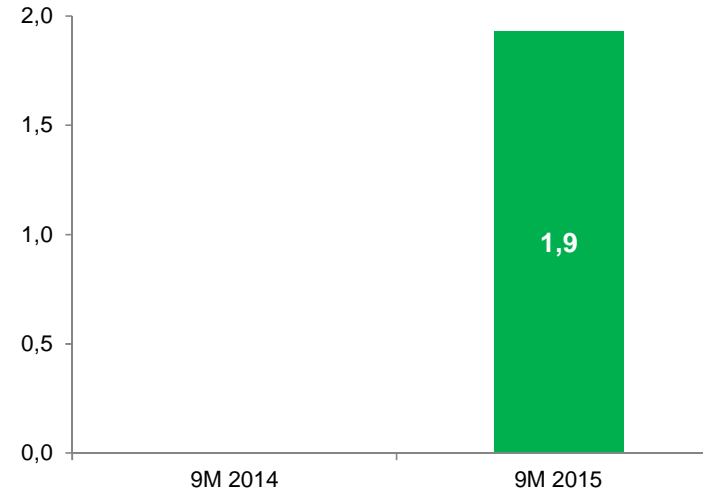


## Good performance of the product portfolio (2/2)

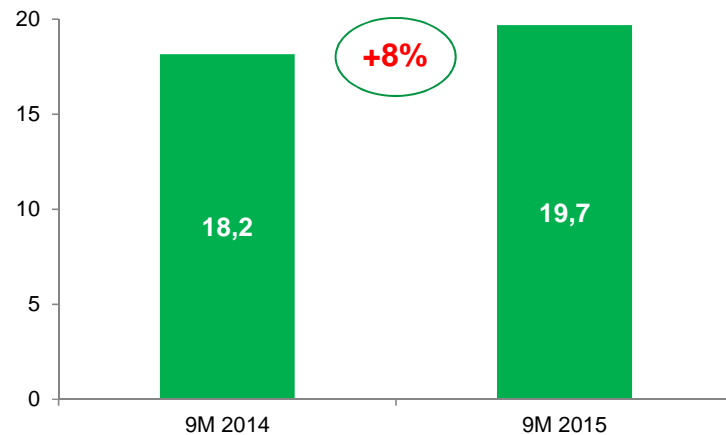
### Corlantor sales (€Mn)



### Volutsa sales (€Mn)



### Contrast imaging agents (€Mn)



- Sales of **Corlantor** decreased by 2% to €9.9Mn in 9M 2015.
- Sales of **Volutsa**, launched in Spain in February 2015, reached €1.9Mn in 9M 2015.
- **Exxiv** sales decreased by 13% to €4.5Mn, mainly due to a deceleration of the COX-2 market.
- **Contrast imaging agents** and other hospital products **increased by 8%** to €19.7Mn in 9M 2015.

*Corlantor is a specialty product for stable angina and chronic heart failure from Laboratoires Servier.*

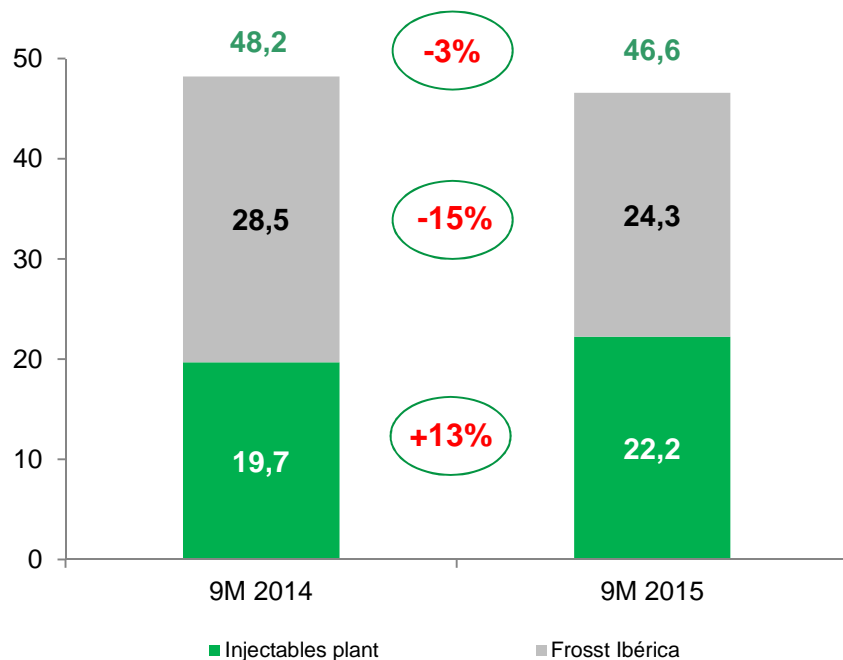
*Volutsa is a specialty product from Astellas indicated for the treatment of moderate to severe storage symptoms and voiding symptoms associated with benign prostatic hyperplasia.*

*Exxiv is a selective COX-2 inhibitor from Merck Sharp & Dohme (MSD).*



## Value added toll manufacturing services

### Toll manufacturing sales (€Mn)



- **Toll manufacturing** sales decreased by 3% to €46.6Mn in 9M 2015.
- Very positive evolution of the **injectables plant**, whose revenue **increased by 13%** to €22.2Mn in 9M 2015. In line with the increase in sales, spare capacity has been reduced.
- **Frosst Ibérica** plant revenue amounted to €24.3Mn in 9M 2015 compared to €28.5Mn in 9M 2014 because of a lower production for MSD.
- In 9M 2015, ROVI has strengthened its toll manufacturing area through:
  - ✓ The acquisition of assets of a manufacturing plant in San Sebastián de los Reyes; and
  - ✓ The signature of an agreement with Merus Labs to manufacture Sintrom.





## Guidance 2016

**2016 operating  
revenues growth rate**

high single digit –  
low double digit

### Our main strategic pillars to lead growth

#### Specialty pharma

- Bemiparin
- Recent launches such as Orvatez, Volutsa, Ulunar and Hirobriz
- Existing portfolio (Vytorin, Absorcol, Medikinet, Corlenter, contrast imaging agents...)
- New in-licensed products to be launched

#### Toll manufacturing

- Spare capacity in the injectable plants and in the oral compounds plant
- New customers to be acquired

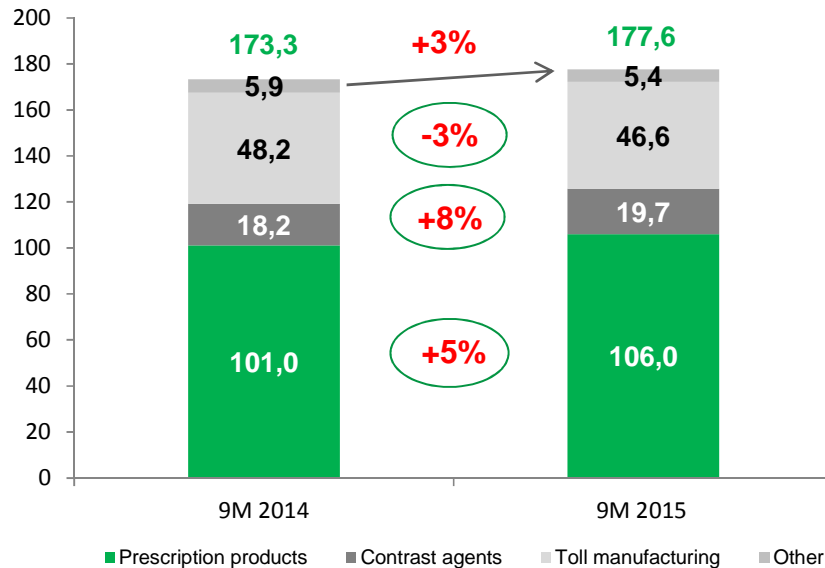


# Financial results

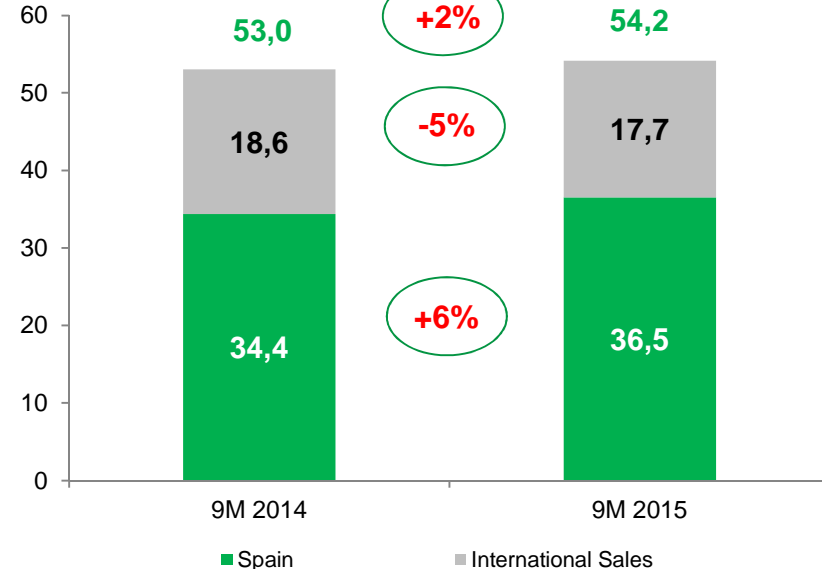
# Good revenue level with outstanding Bemiparin growth in Spain



Total operating revenue (€Mn)



Bemiparin sales (€Mn)



➤ **Operating revenue** at €177.6Mn, reaching a **3% growth** achieved on:

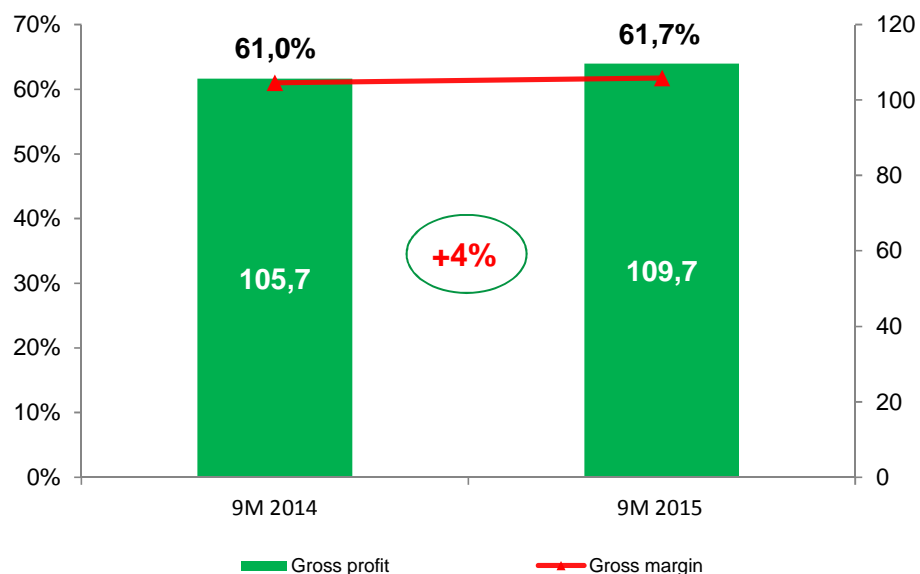
- ✓ 5% growth in prescription-based products;
- ✓ 8% growth in contrast agents and other hospital products;
- ✓ -3% growth in toll manufacturing; and
- ✓ OTC and other revenues decreased by 8% (including revenue from distribution licenses).

➤ **Bemiparin**, ROVI'S flagship product internally developed, reached sales of €54.2Mn (**2% rise** vs 9M 2014). Sales grew by 6% in the domestic market.

# Gross margin impacted by a reduction in Other income (subsidies)



## Gross profit (€Mn) & Gross margin (%)

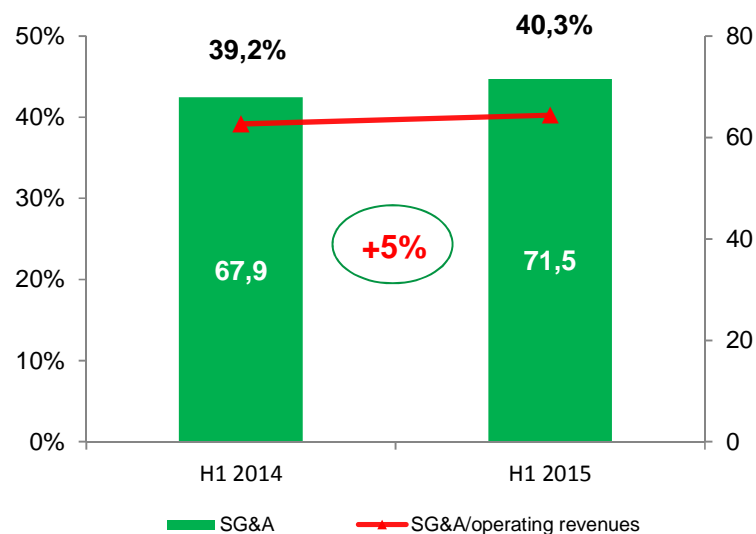


- **Gross profit increased by 4%** to €109.7Mn in 9M 2015.
- **Gross margin** increased by 0.8 pp in 9M 2015 to 61.7% vs 9M 2014.
- Excluding the impact of Other income (subsidies), which decreased by 60% in 9M 2015, gross margin would increase by 1.5 pp to 61.2% in 9M 2015 from 59.7% in 9M 2014.
- The decrease of the Bemiparin raw material cost impacted positively in 9M 2015 gross margin.

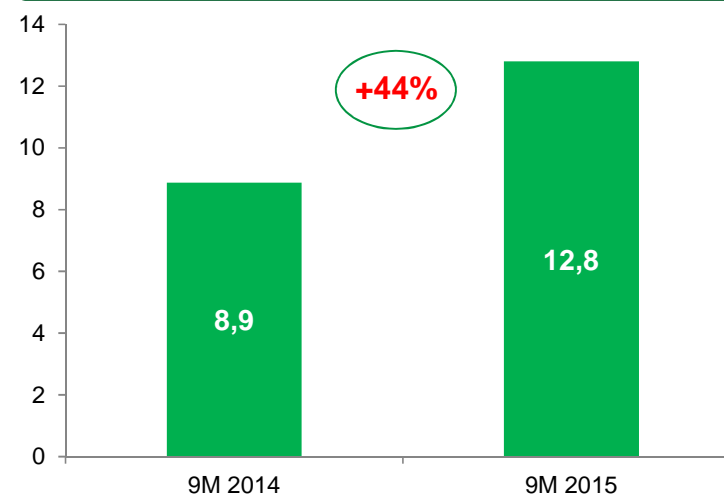
# Significant investment effort in new product launches and R&D



**SG&A expenses (€Mn)**



**R&D expenses (€Mn)**



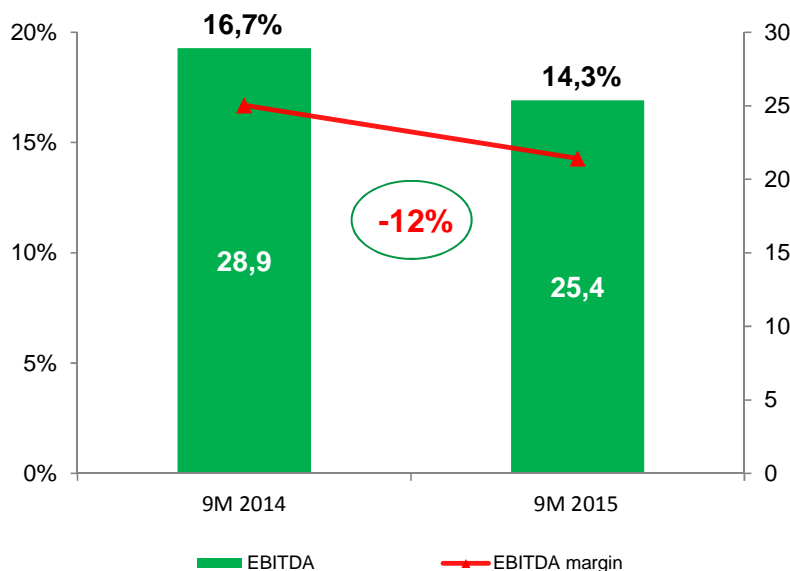
- **SG&A expenses** increased by 5% to €71.5Mn in 9M 2015 mainly due to recent product launches such as Hirobriz, Ulunar, Volutsa and Orvatez. However, excluding the impact of the launches mentioned above, which contributed expenses of €3.3 million euros in 9M 2015, SG&A expenses would increase by 1%. Also, the SG&A increase in 9M 2015 reflected ROVI investment effort in human capital to address pneumologists and primary care, main targets of Hirobriz and Ulunar products.
- **R&D expenses** increased by 44% to €12.8Mn mainly due to:
  - ✓ the development of the Risperidone-ISM<sup>®</sup> Phase II trial; and
  - ✓ the performing of development activities of the formulation for the Risperidone-ISM phase III trial and the Letrozole-ISM phase I trial.



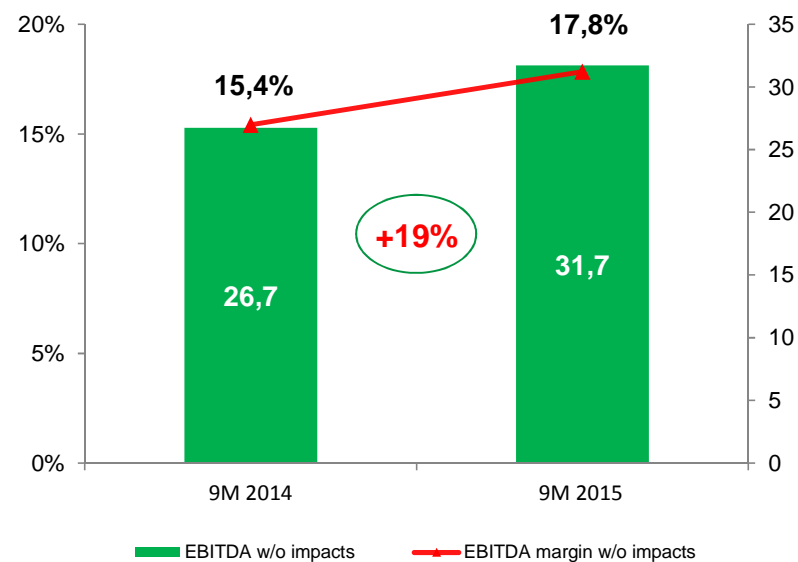


# EBITDA

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



### EBITDA (€Mn) and EBITDA margin (%) w/o impacts

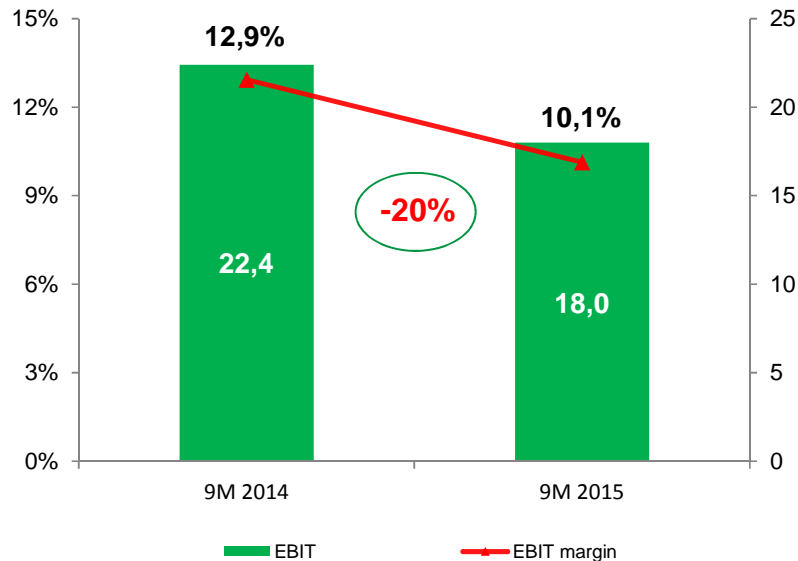


- **EBITDA decreased by 12%** to €25.4Mn in 9M 2015, reflecting a **2.4 pp fall in the EBITDA margin** to 14.3% in 9M 2015 down from 16.7% in 9M 2014.
- In 9M 2015, EBITDA was impacted by (i) a 60% reduction in Other income (subsidies), (ii) a 44% increase in R&D expenses, mainly as a result of the development of the ISM-Risperidone Phase II study and (iii) recent product launches which contributed selling, general and administrative expenses of €3.3Mn.
- However, maintaining, in 9M 2015, the same amount of R&D expenses that was registered in 9M 2014 and excluding the impact of (i) Other income, in 9M 2015 and 9M 2014, and (ii) recent product launches, in 9M 2015, **EBITDA would increase by 19%** to €31.7Mn, **reflecting a 2.4 pp rise in the EBITDA margin** to 17.8% in 9M 2015 up from 15.4% in 9M 2014.

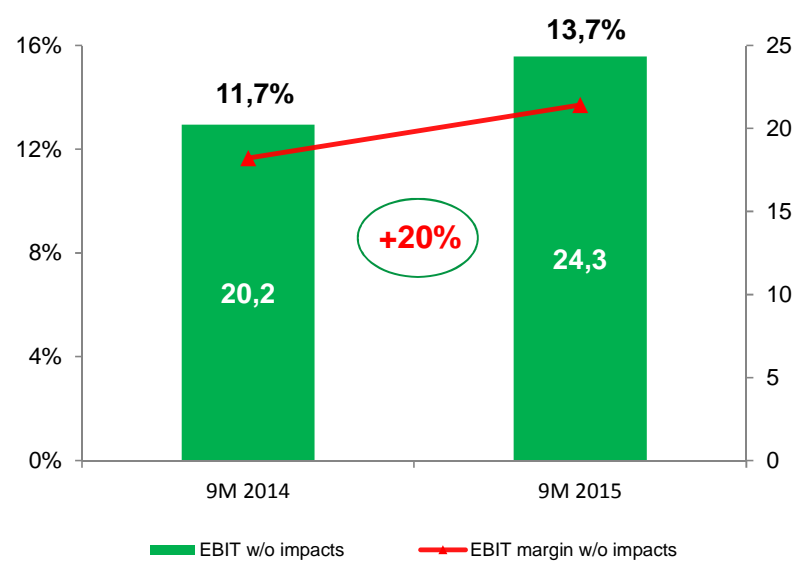


# EBIT

EBIT (€Mn) and EBIT margin (%)



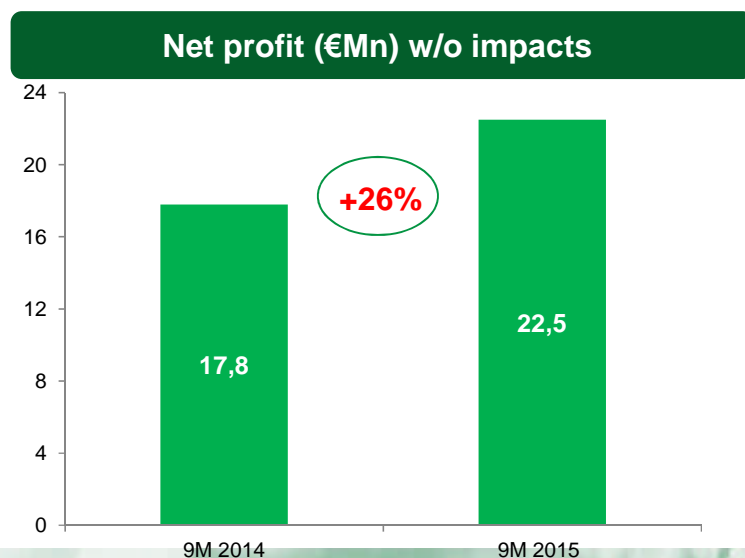
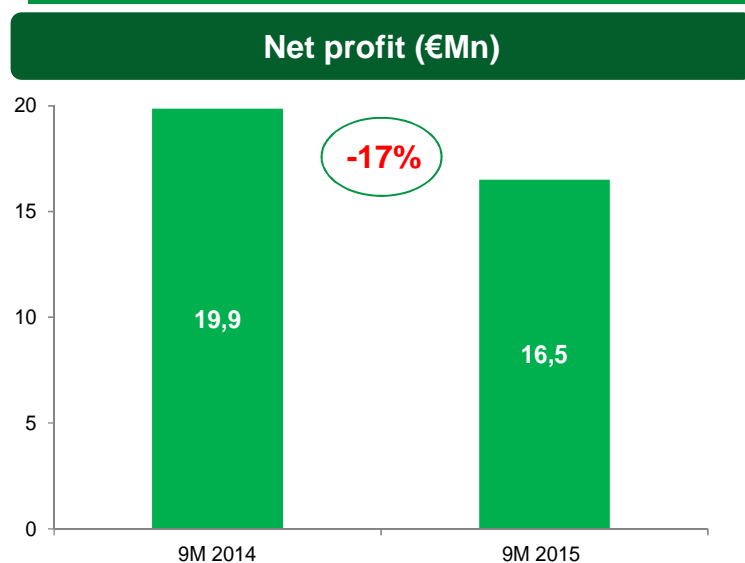
EBIT (€Mn) and EBIT margin (%) w/o impacts



- **Depreciation and amortization expenses** increased by 13% in 9M 2015, up to €7.4Mn, as a result of the new PP&E and intangible assets purchases made during the last twelve months.
- **EBIT decreased by 20%** to €18.0Mn in 9M 2015, compared to 9M 2014, reflecting a 2.8 pp decline in the EBIT margin to 10.1% down from 12.9% in 9M 2014.
- However, maintaining, in 9M 2015, the same amount of R&D expenses that was registered in 9M 2014 and excluding the impact of (i) Other income, in 9M 2015 and 9M 2014, and (ii) recent product launches, in 9M 2015, **EBIT would increase by 20%** to €24.3Mn, reflecting a 2.0 pp rise in the EBIT margin to 13.7% in 9M 2015 up from 11.7% in 9M 2014.



# Net profit

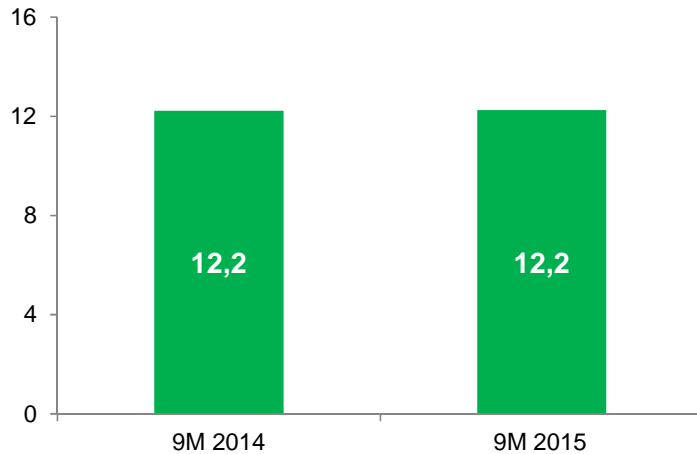


- **Net profit declined by 17%** to €16.5Mn in 9M 2015. However, maintaining, in 9M 2015, the same amount of R&D expenses that was registered in 9M 2014 and excluding the impact of (i) Other income, in 9M 2015 and 9M 2014, and (ii) recent product launches, in 9M 2015, **net profit would increase by 26%** to €22.5Mn.
- **Effective tax rate of 5.4%** in 9M 2015 vs 5.2% in 9M 2014. This favourable effective tax rate is due to:
  - ✓ deduction of existing R&D expenses; and
  - ✓ capitalisation of existing negative tax bases from Frosst Ibérica.
- As of 31 Dec 2014, Frosst Ibérica **negative tax bases amounted to €50.1Mn**, of which €7.7Mn will be used in the 2014 income tax and €4.7Mn in 9M 2015.
- On 27 Nov 2014, a deep tax reform was approved by law. These tax measures, that have been in force since Jan 2015, will positively affect ROVI income statement and income tax payable rate. ROVI expects to maintain an effective tax rate from mid to high single digit for the following years.
- Among the tax measures that will affect corporate income tax, it should be noted that:
  - ✓ the tax rate is reduced from 30% to 28% in 2015 and to 25% from 2016;
  - ✓ tax losses may offset positive taxable income faster and without time limit; and
  - ✓ R&D tax credit schedule is maintained.

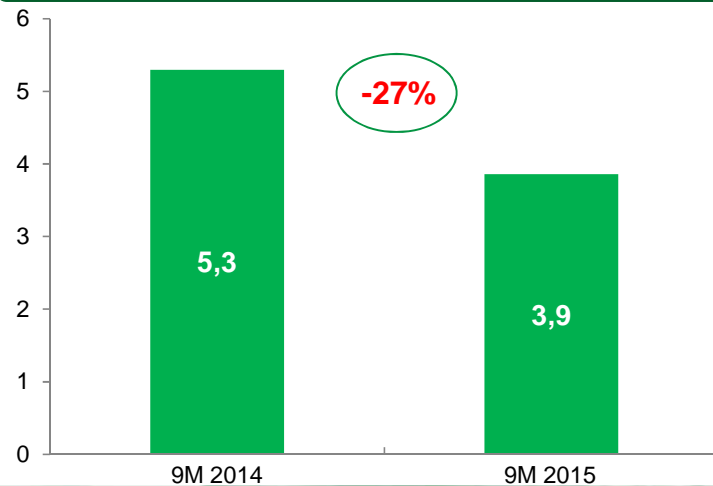


# Capital expenditure & Free Cash Flow

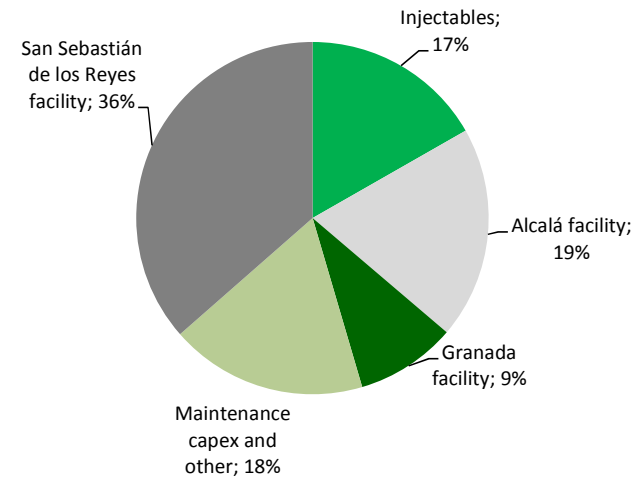
### Capex evolution (€Mn)



### FCF (€Mn)



### Capex breakdown (%)

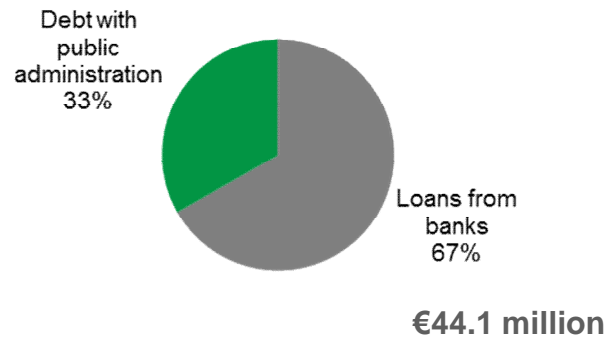


- €12.2Mn of **capex** invested in 9M 2015.
  - ✓ €2.1Mn of investment capex related to the injectables plant;
  - ✓ €1.1Mn of investment capex related to the Granada facility;
  - ✓ €2.4Mn of investment capex related to the Alcalá facility;
  - ✓ €2.2Mn of maintenance capex and other; and
  - ✓ The rest is mainly related to the acquisition of assets of a manufacturing plant in San Sebastián de los Reyes.
- **FCF** decreased to €3.9Mn mainly due to:
  - ✓ €10.4Mn reduction in “trade and other payables” in 9M 2015 vs €3.8Mn decrease in 9M 2014; and
  - ✓ €5.5Mn increase in “inventories” in 9M 2015 vs €4.7Mn increase in 9M 2014.

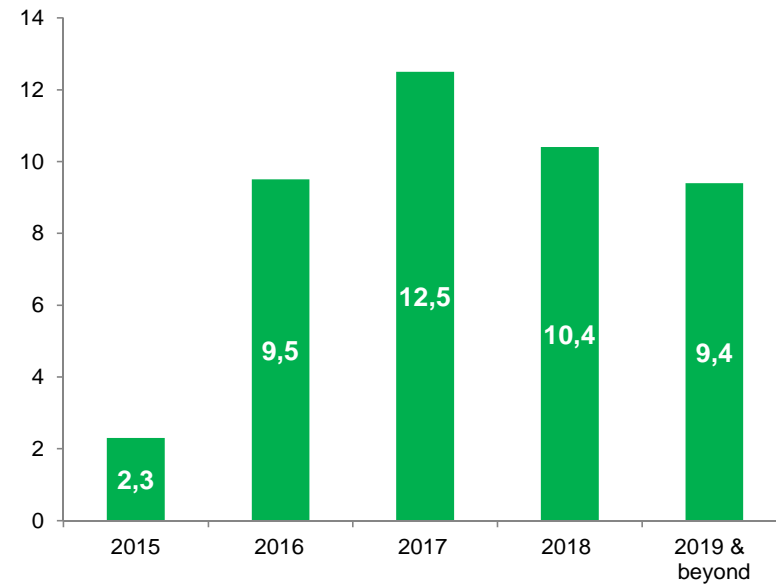


# Financial debt

## Debt breakdown by source (%)



## Debt maturities by year (€Mn)



- **Debt with public administration** represented **33%** of total debt, with 0% interest rate.
- **Gross cash position of €27.0Mn** as of 30 September 2015 vs €28.0Mn as of 31 December 2014.
- **Net debt of €17.1Mn** as of 30 September 2015 vs €8.3Mn as of 31 December 2014.
- On July 2, ROVI paid a dividend of €0.1690 per share on 2014 earnings. This dividend meant an increase of 5% compared to the dividend on 2013 earnings.



## News-flow 2015/2016

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### Specialty pharma

- Additional new in-licensing products to be launched

### Toll manufacturing

- New contracts to be announced

### R&D

- Final positive results from ISM-Risperidone<sup>®</sup> Phase II to be released in Q4 2015
- Start of ISM-Risperidone<sup>®</sup> Phase III in H1 2016
- Potential authorisation for the marketing of a biosimilar of enoxaparin



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