



FIRST HALF 2018 FINANCIAL RESULTS

JULY 2018

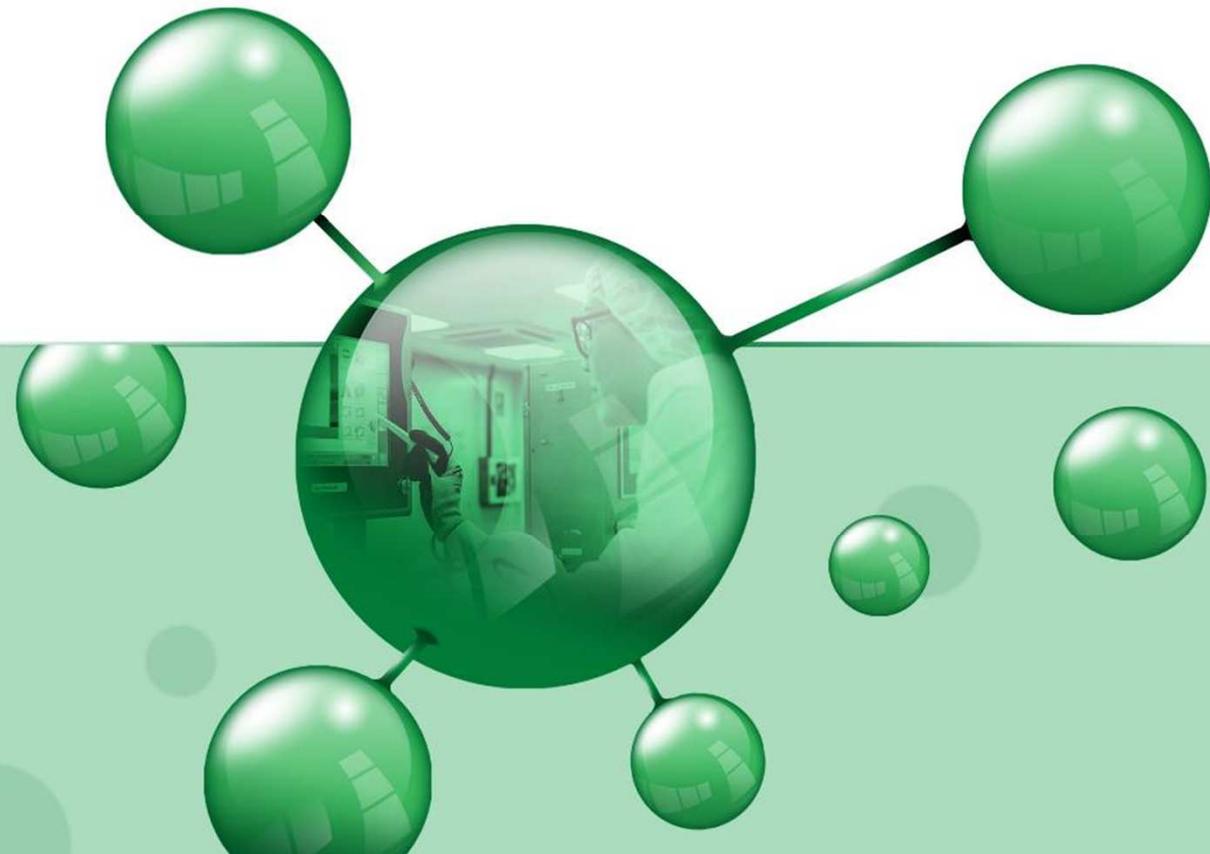


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# Operating results

Juan López-Belmonte  
Chief Executive Officer





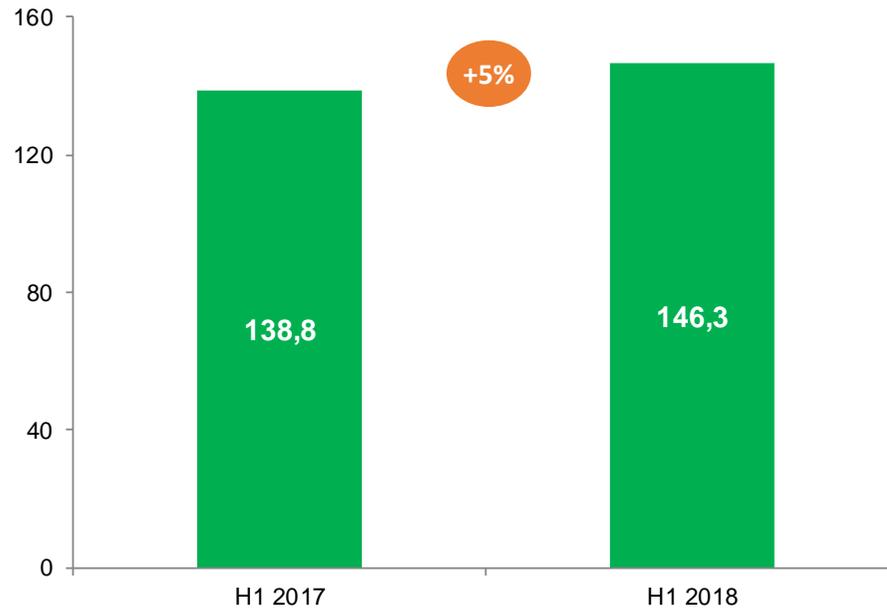
# H1 2018 financial results - Highlights

- **Operating revenue** increased by 5% to 146.3Mn in H1 2018, driven by the strength the specialty pharmaceutical business, where sales rose 14%, strongly outperforming the market. Total revenue increased by 5% to €147.1Mn in H1 2018.
- In H1 2018, ROVI **commenced the marketing of Enoxaparin biosimilar in UK and Italy**, two top Enoxaparin market in Europe together with Germany where the company commenced marketing in September 2017.
- In H1 2018, ROVI announced the signature of **two licensing agreements** for the distribution and marketing of its Enoxaparin biosimilar, the **first with Hikma Pharmaceuticals** for 17 MENA (Middle East and North Africa) countries and **the second with Sandoz** for 14 countries/regions.
- By 30<sup>th</sup> June 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 and Denmark**.
- **Sales of the Enoxaparin biosimilar amounted to €8.9Mn** in H1 2018.
- For 2018, **ROVI expects a mid-single digit growth rate for operating revenue, with a range of €20m to €30m sales of biosimilar of Enoxaparin**.
- **Very good performance of Bemiparin**: 13% growth to €48.3Mn; this growth came from national (16%) and international (7%) sales.
- **Sales of Absorcol & Vytarin & Orvatez** increased by 3% to €19.6Mn; **Hirobriz and Ulunar** increased by 9% to €7.7Mn; **Volutsa** increased sales by 25% to €5.4Mn; and **Neparvis**, launched in December 2016, reached sales of €5.9Mn in H1 2018.
- In H1 2018, EBITDA was affected by non-recurring expenses of €2.6Mn. €1.5Mn of this amount were related to the study and analysis of potential corporate operations, while €1.1Mn were linked to a substantial change to Frosst Ibérica employees working conditions.
- **EBITDA “pre-R&D”** (w/o R&D and non recurring expenses) decreased by 1%, from €33.0Mn in H1 2017 to €32.7Mn in H1 2018, reflecting a 1.4 pp fall in the EBITDA margin to 22.4% in H1 2018. Likewise, recognising the same amount of R&D expenses in H1 2018 as in H1 2017 and excluding the impact of the non recurring expenses in H1 2018, EBITDA would have decreased by 1% to €23.4Mn, reflecting a 1.1 pp fall in the EBITDA margin to 16.0% in H1 2018.
- **Net profit “pre-R&D”** (w/o R&D and non recurring expenses) increased by 17%, from €24.3Mn in H1 2017 to €28.4Mn in H1 2018.

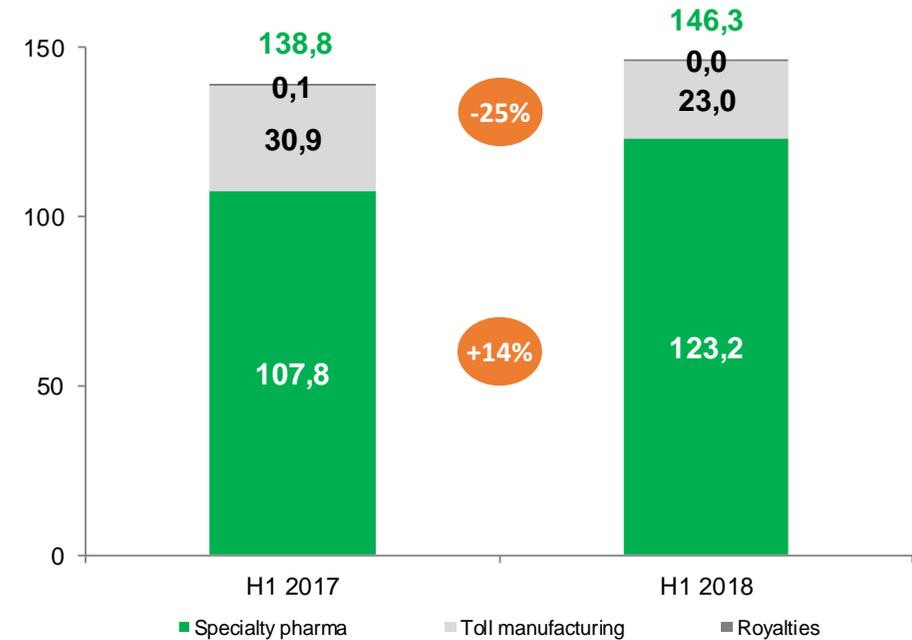


## Growth driven by specialty pharma business...

Total operating revenue (€Mn)



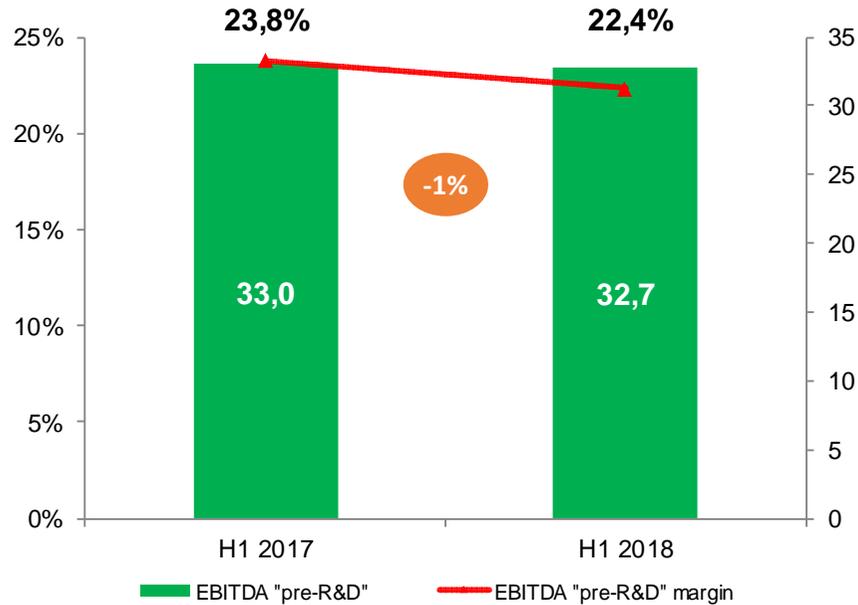
Operating revenue growth by category (€Mn)



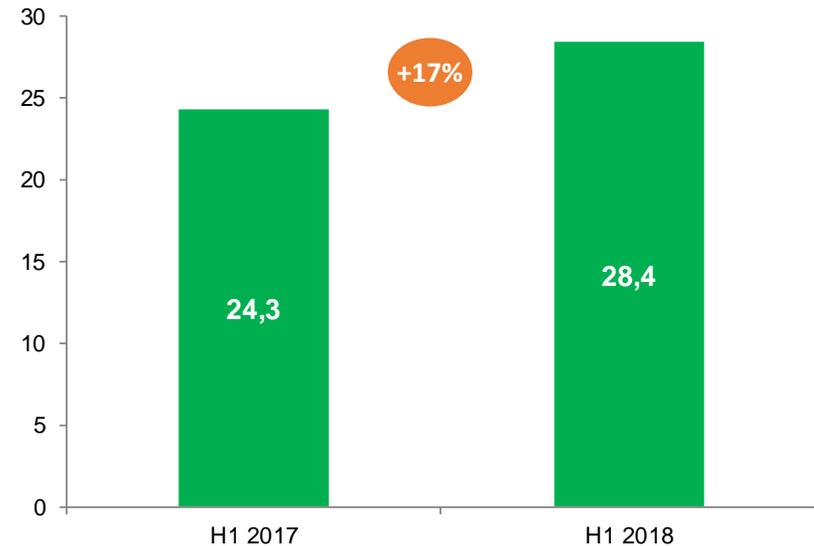
- **Operating revenue increased by 5%** to €146.3Mn in H1 2018 driven by the strength of:
  - the specialty pharmaceutical business, where sales rose 14%
- ROVI forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in the first five months of 2018, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 3.5%.

## ...with high profitability

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



**Net profit “pre-R&D” (w/o R&D and non recurring expenses) (€Mn)**



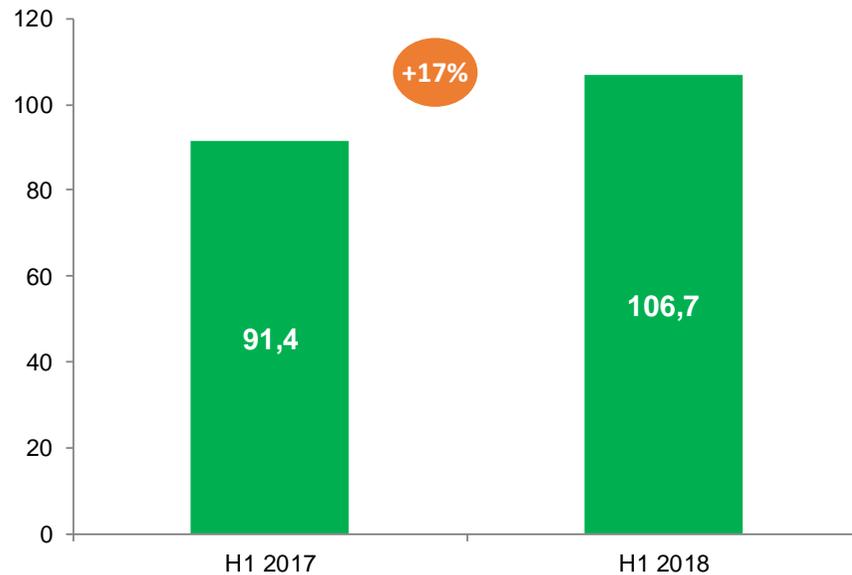
- In H1 2018, EBITDA was affected by non-recurring expenses of €2.6Mn. €1.5Mn of this amount were related to the study and analysis of potential corporate operations, while €1.1Mn were linked to a substantial change to Frosst Ibérica employees working conditions.
- **EBITDA “pre-R&D” (w/o R&D and non recurring expenses) decreased by 1%**, from €33.0Mn in H1 2017 to €32.7Mn in H1 2018, reflecting a 1.4 percentage point fall in the EBITDA margin to 22.4% in H1 2018.
- **Net profit “pre-R&D” (w/o R&D and non recurring expenses) increased by 17%**, from €24.3Mn in H1 2017 to €28.4Mn in H1 2018.

Note: EBITDA and Net profit “pre-R&D” calculated excluding R&D expenses in H1 2018 and H1 2017 and the impact of non recurring expenses in H1 2018

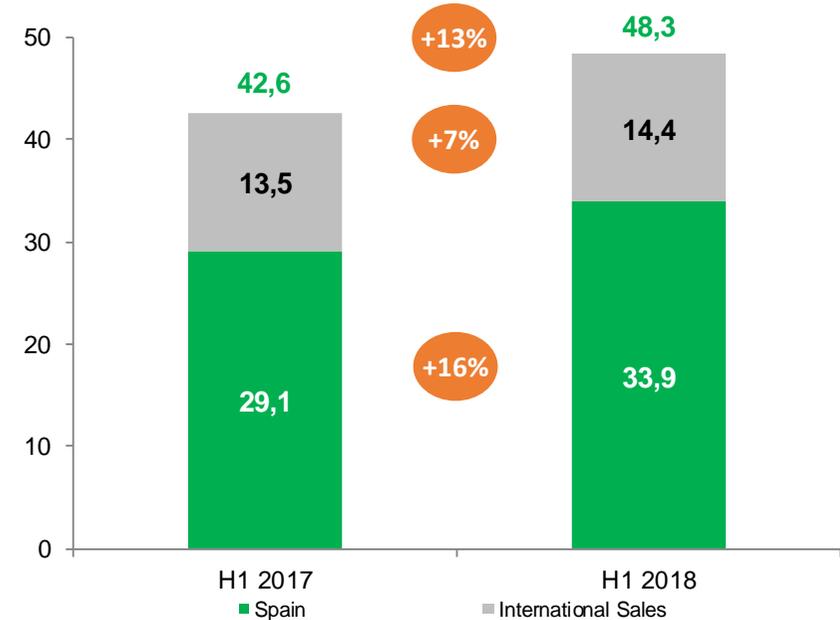


# Bemiparin, leading the specialty pharmaceutical business

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



## Bemiparin sales (€Mn)



- Sales of prescription-based pharmaceutical products increased by 17% to €106.7Mn in H1 2018.
  - Bemiparin total sales increased by 13% to €48.3Mn in H1 2018:
    - Sales in Spain increased 16% to €33.9Mn.
    - International sales increased by 7% to €14.4Mn.



# 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 and in **UK and Italy** in H1 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

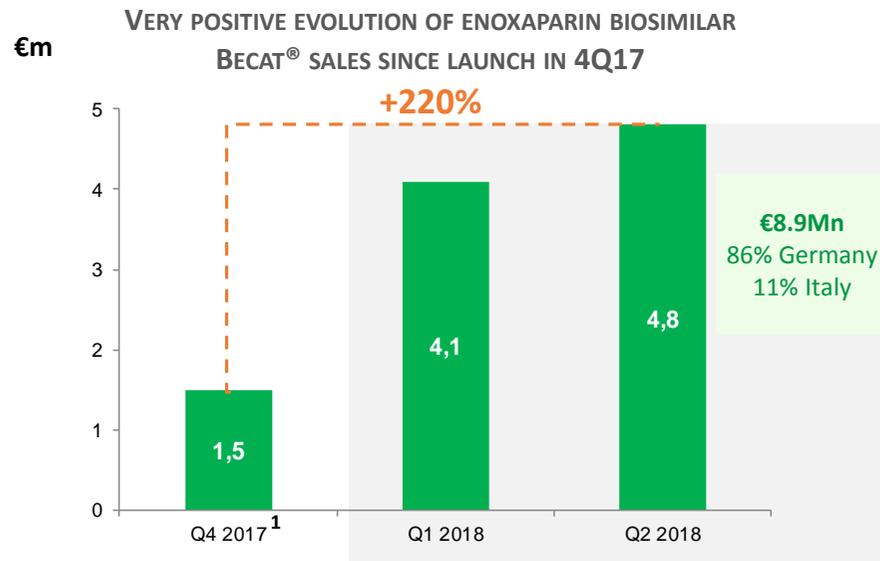
Directly Marketed in **Germany, UK and Italy**

Approved; To Be Directly Marketed **4 Countries**

Approved; To Be Out-Licensed **14 Countries**

Pending Approval; To Be Out-Licensed **50 Countries**

## Enoxaparin Biosimilar Becat® Sales Ramp-up



## Stage I of Commercial Strategy

Focus on Europe...

...the largest enoxaparin market with **€1.0bn** sales<sup>2</sup>

ROVI expects to directly market enoxaparin biosimilar Becat® in **7** European countries...

...which account for **c.75%** of the European market<sup>3</sup>

In the long-term, **biosimilars** tend to reach a...

**50-70%** Market Share<sup>4</sup>

...of the reference product market

In Europe, there are only ...

**2 other** Authorized Biosimilars

...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

**€0.6bn**  
2017  
Market Sales<sup>2</sup>

**6.5%**  
2017  
Market Growth<sup>2</sup>

Already Signed Out-Licensed Agreements: **45 Countries**

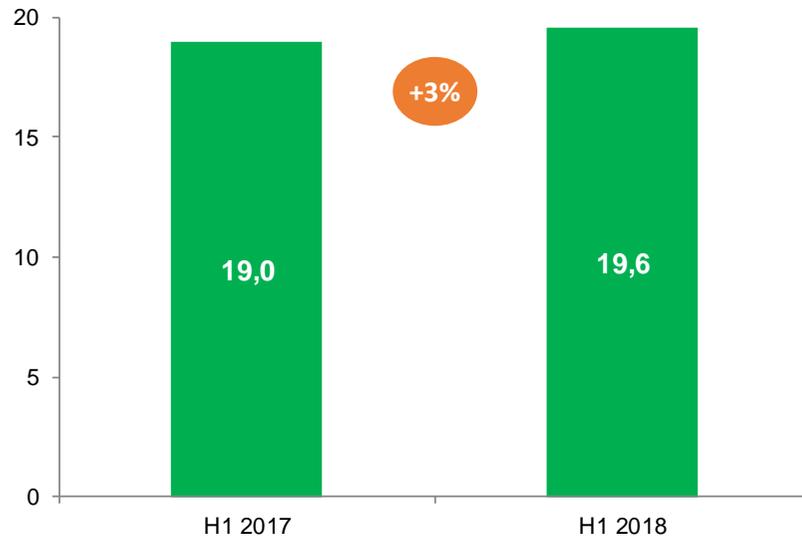
ROVI signed a licensing agreement with Sandoz to distribute enoxaparin biosimilar Becat® in 14 countries/regions and with Hikma in 17 Middle East and North African countries.

1. Becat® 4Q 2017 sales include sales throughout September. As the product was launched that month, sales were negligible.  
2. Estimates based on Sanofi-Aventis reported 2017A sales.

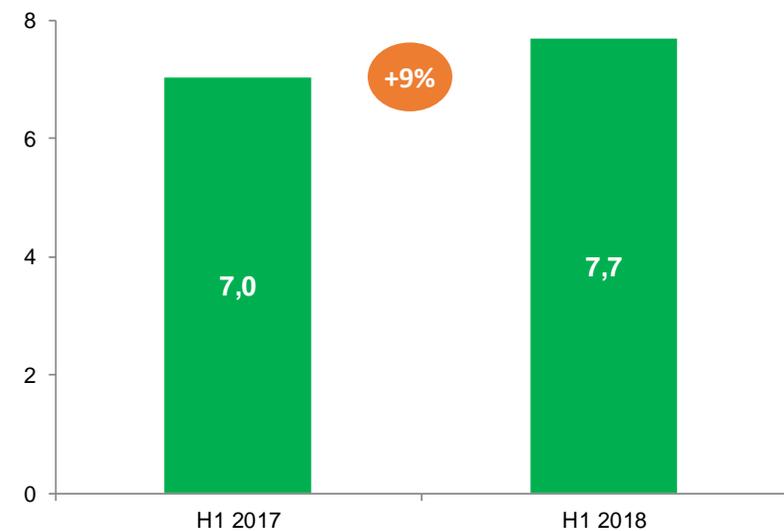
3. QuintilesIMS, 2015.  
4. Technavio 2016 biosimilars report.

## Strong 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 **Vytorin**<sup>®</sup>, **Orvatez**<sup>®</sup> and **Absorcol**<sup>®</sup> **increased by 3%** to €19.6Mn in H1 2018. In 2Q 2018, the active principle ezetimibe went out of patent and the price of Absorcol<sup>®</sup> was reduced. Likewise, generics formulated with ezetimibe and simvastatin have recently been marketed, so the price of Vytorin<sup>®</sup> has been reduced to be competitive. However, Vytorin<sup>®</sup> is patent protected until April 2019, then ROVI is evaluating the most convenient way to protect its licensing rights.
- Sales of **Hirobriz** and **Ulunar**, both products for patients with COPD, launched in Spain in Q4 2014 **increased by 9%** to €7.7Mn in H1 2018.
- Sales of **Medicebran** and **Medikinet**, products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, decreased 3% to €3.9Mn in H1 2018.

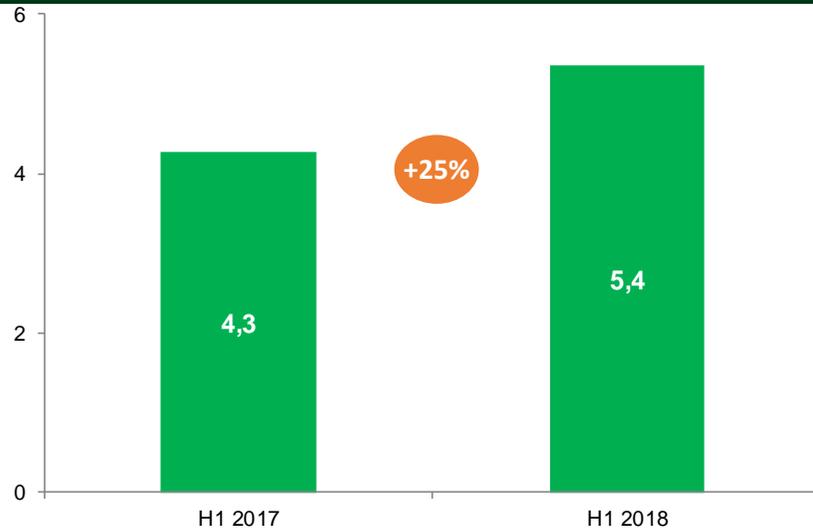
*Vytorin, Orvatez and Absorcol, the first of the five licenses of MSD, are indicated for the treatment of hypercholesterolemia.*

*Hirobriz Breezhaler and Ulunar Breezhaler are both products from Novartis indicated for the treatment of COPD (Chronic Obstructive Pulmonary Disease).*

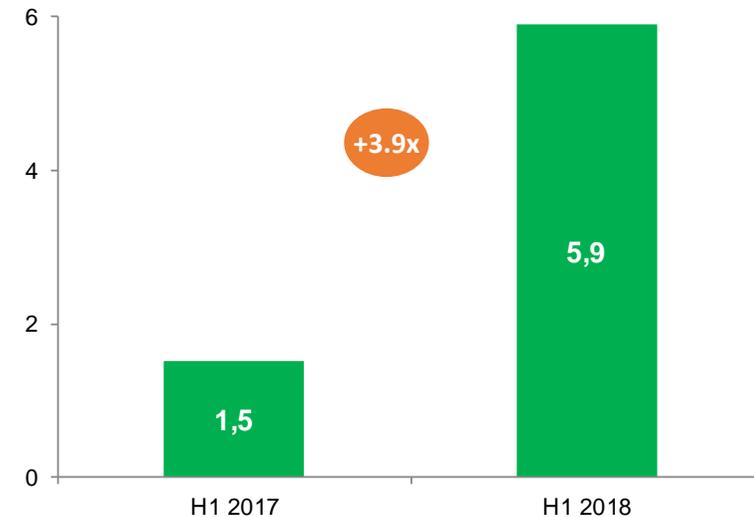
*Medicebran and Medikinet are specialty products from Medice indicated for the treatment of ADHD in children and teenagers.*

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

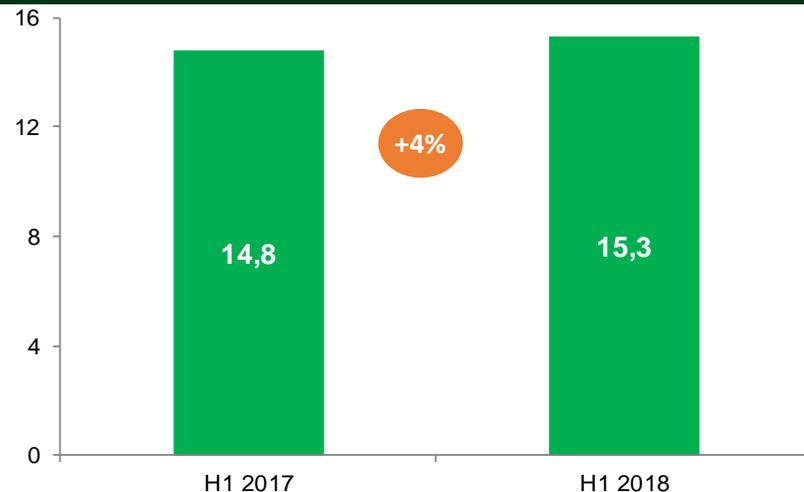
### Volutsa sales (€Mn)



### Neparvis sales (€Mn)



### Contrast imaging agents sales (€Mn)

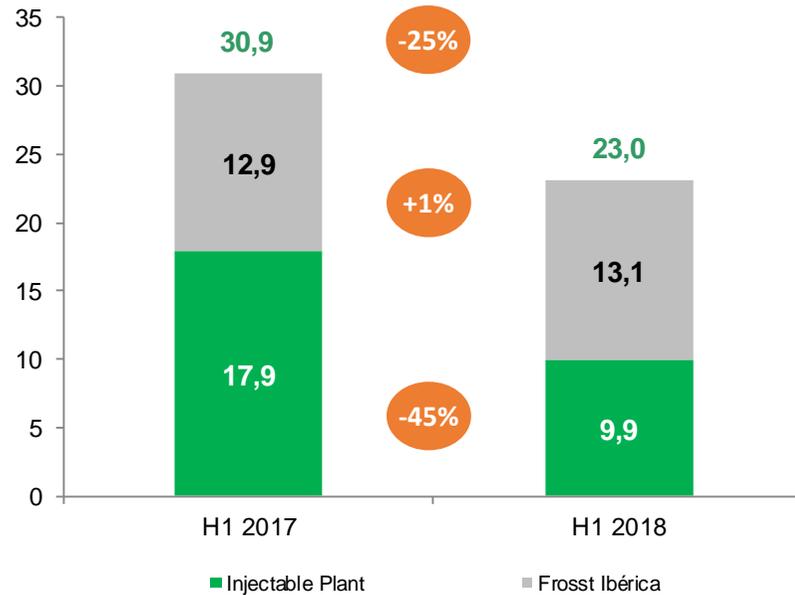


- Sales of **Volutsa**, launched in Spain in February 2015, **increased by 25%** to €5.4Mn in H1 2018.
- Sales of **Neparvis**, a specialty product from Novartis launched in December 1Q 2017, reached €5.9Mn in H1 2018, from €1.5Mn in H1 2017.
- **Exxiv** sales decreased by 47% to €1.2Mn, mainly due to a deceleration of the COX-2 market.
- **Contrast imaging agents and other hospital products increased by 4%** to €15.3Mn in H1 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 (€Mn)



- **Toll manufacturing sales** decreased by 25% to €23.0Mn in H1 2018, compared to H1 2017, mainly because of the reduction of the injectable business compared to H1 2017, when exceptional high volumes were manufactured for some customers.
  - Frosst Ibérica plant sales increased by 1% to €13.1Mn in H1 2018 compared to H1 2017.
- By the end of 2018, a mid-teen decline (from 10-20%) in toll manufacturing is expected.





**2018 operating revenue growth rate**

**Mid-single digit**

## THE KEY GROWTH LEVERS IN 2018

### Specialty Pharma Business

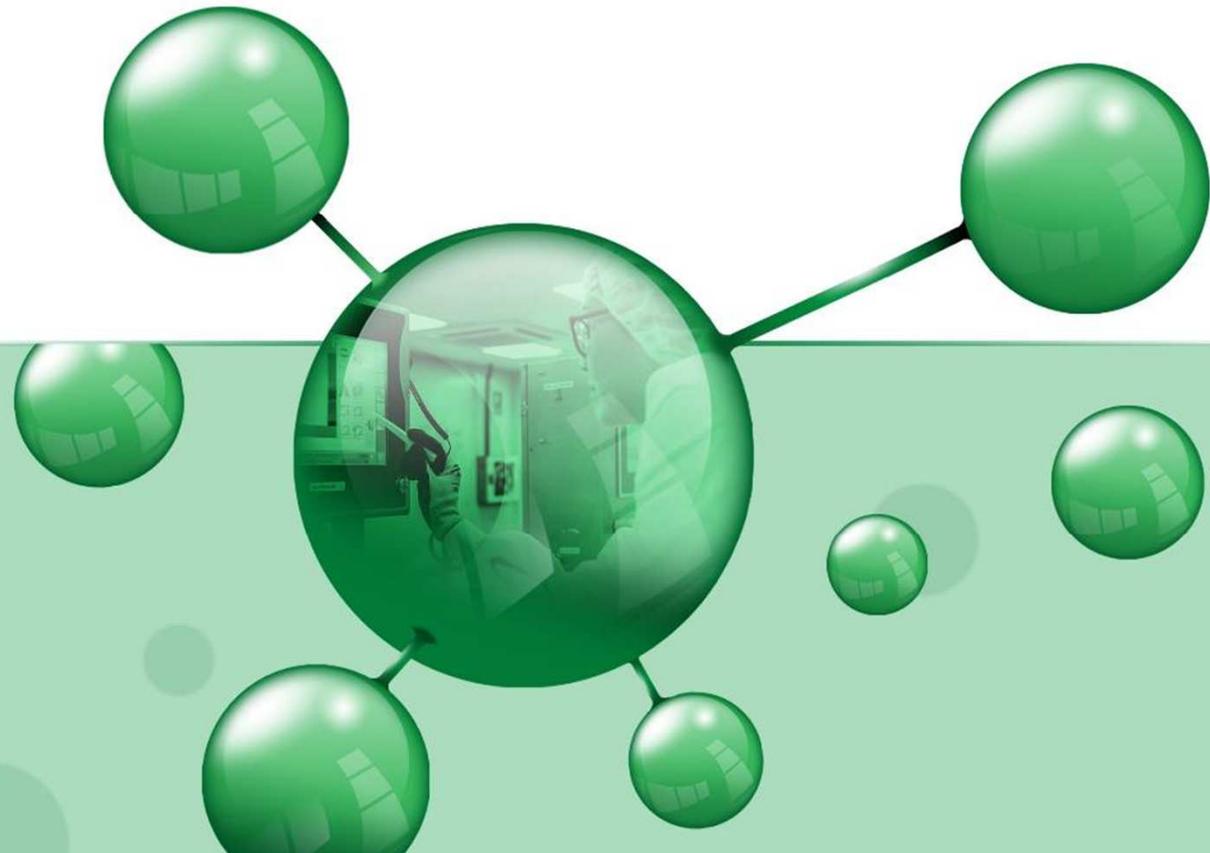
- ✓ Bemiparin
- ✓ Latest launches such as Neparvis, Orvatez, Volutsa and Ulunar
- ✓ Existing portfolio of specialty pharmaceuticals
- ✓ New in-licensed products to be launched
- ✓ Biosimilar of Enoxaparin (estimated range of €20Mn to €30Mn sales in 2018)

### Toll Manufacturing Services

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

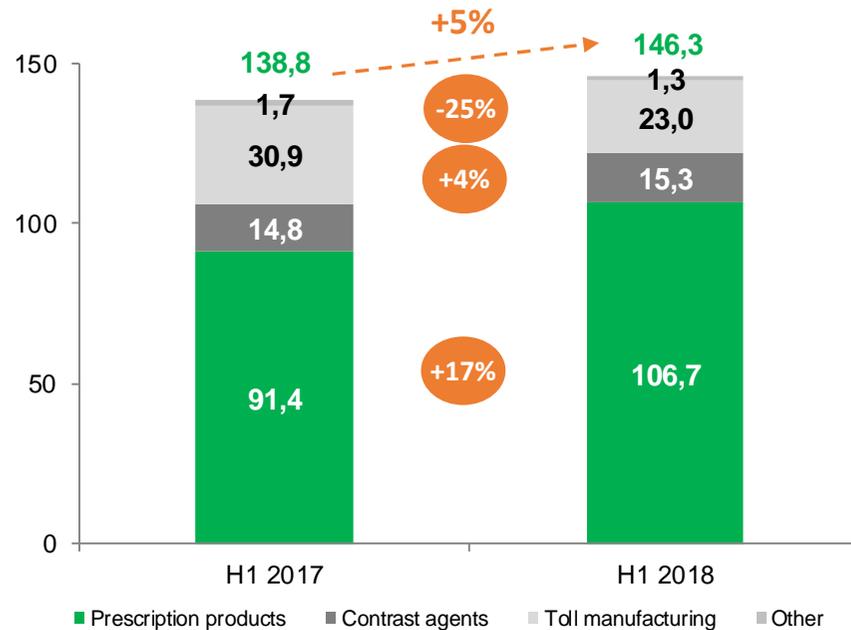
# Financial results

Javier López-Belmonte  
Chief Financial Officer

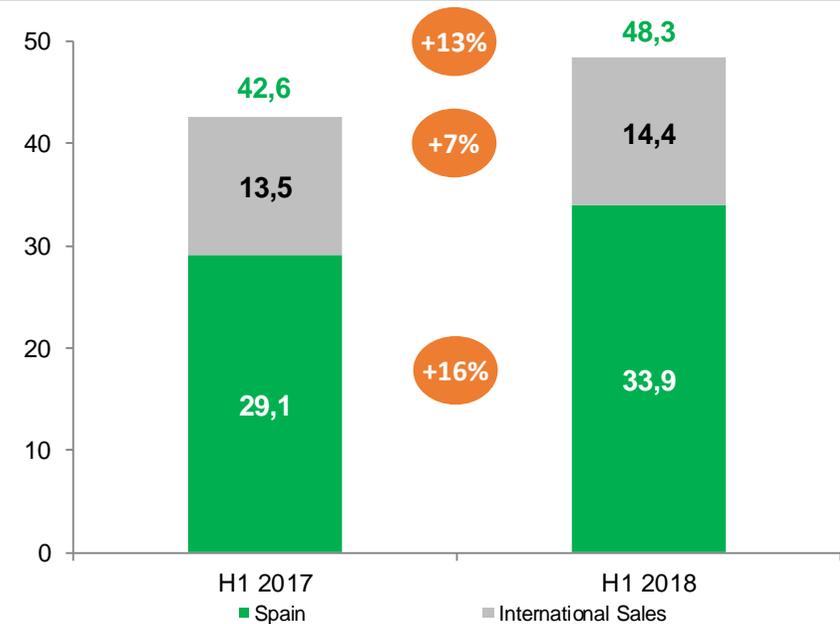


# Good revenue level with outstanding Bemiparin growth...

## Total operating revenue (€Mn)



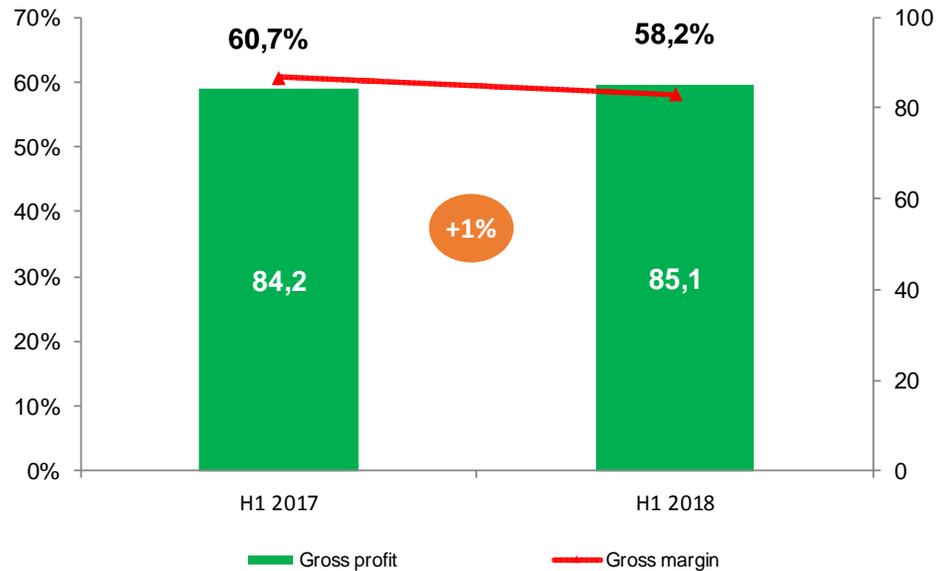
## Bemiparin sales (€Mn)



- **Operating revenue** increased by 5% to €146.3Mn, achieved on:
  - 17% growth in prescription-based products;
  - 4% growth in contrast agents and other hospital products;
  - 25% reduction in toll manufacturing; and
  - OTC and other revenues decreased by 24% (including revenue from distribution licenses).
- **Bemiparin**, ROVI's flagship product internally developed, reached sales of €48.3Mn (**13% growth** vs H1 2017). **Sales grew by 16% in the domestic market and by 7% in the international market.**

# Gross margin impacted by the decrease of injectable toll manufacturing sales

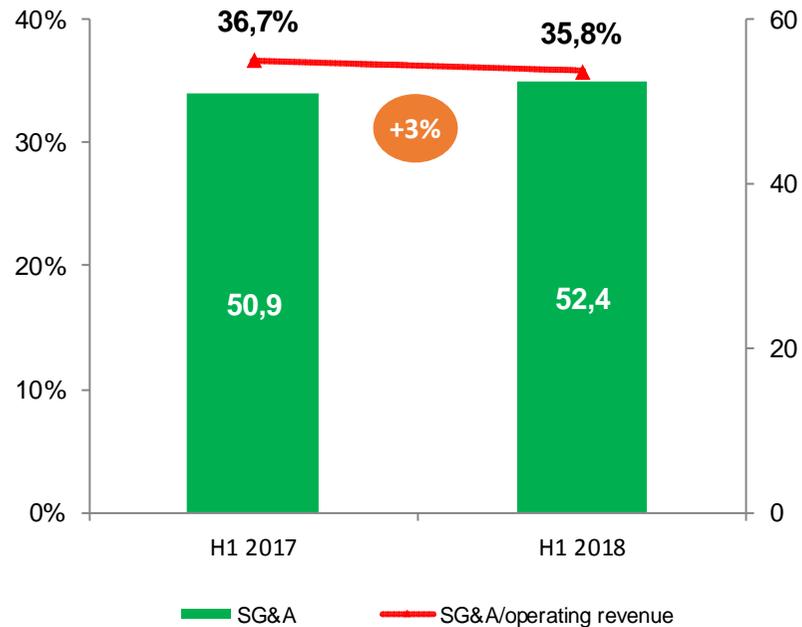
## Gross profit (€Mn) and Gross margin (%)



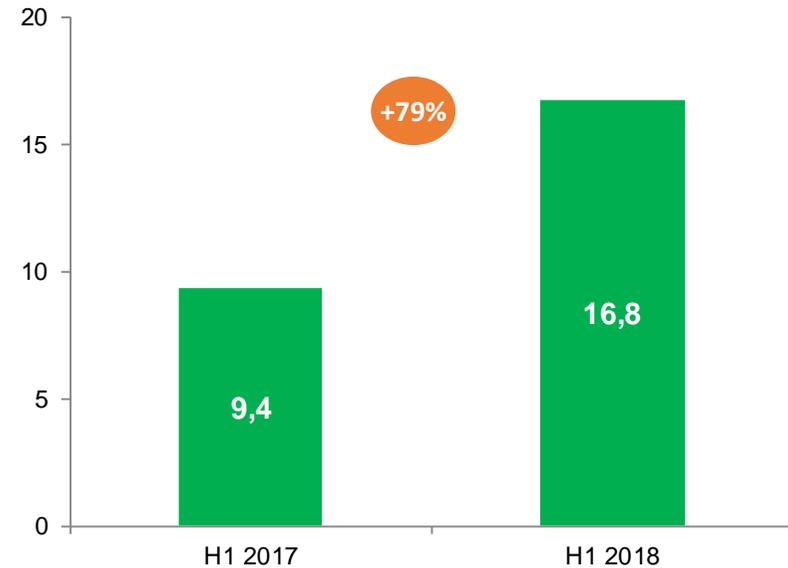
- **Gross profit increased by 1%** to €85.1Mn in H1 2018, reflecting a decrease of 2.5 pp in the gross margin to 58.2% in H1 2018 from 60.7% in H1 2017.
- The reduction of gross margin is mainly due to the decrease of the injectable business which added higher margins in H1 2017.

# Cost control along with commitment to R&D

## SG&A expenses (€Mn)



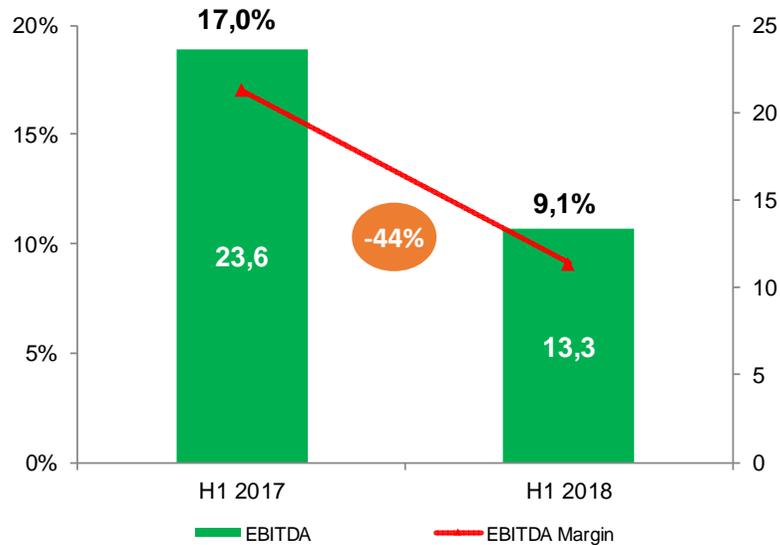
## R&D expenses (€Mn)



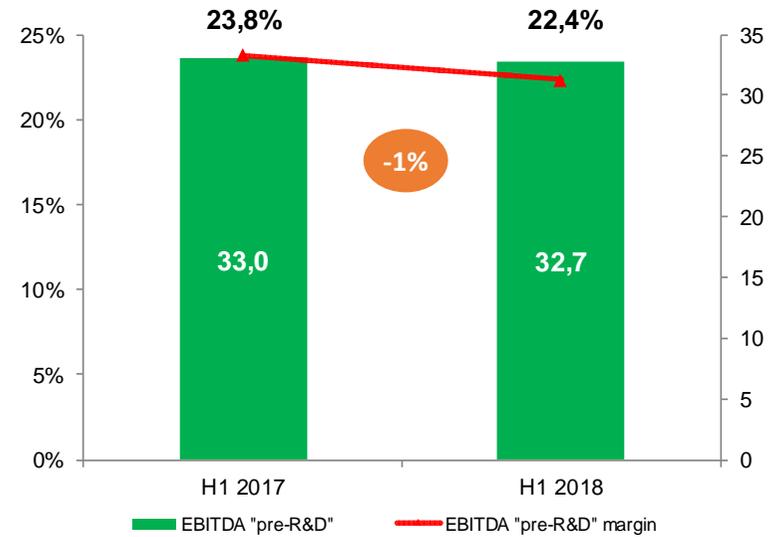
- **SG&A expenses rose 3%** to €52.4Mn in H1 2018 mainly due to:
  - international subsidiaries expenses, which amounted to €2.6Mn compared to €0.2Mn in H1 2017.
  - Excluding expenses related to international subsidiaries, SG&A would have decreased by 2% in H1 2018.
- **R&D expenses increased 79%** to €16.8Mn in H1 2018 mainly due to the development of the Risperidone-ISM<sup>®</sup> (Doria<sup>®</sup>) Phase III trial and the Letrozole-ISM<sup>®</sup> Phase I trial.

# EBITDA

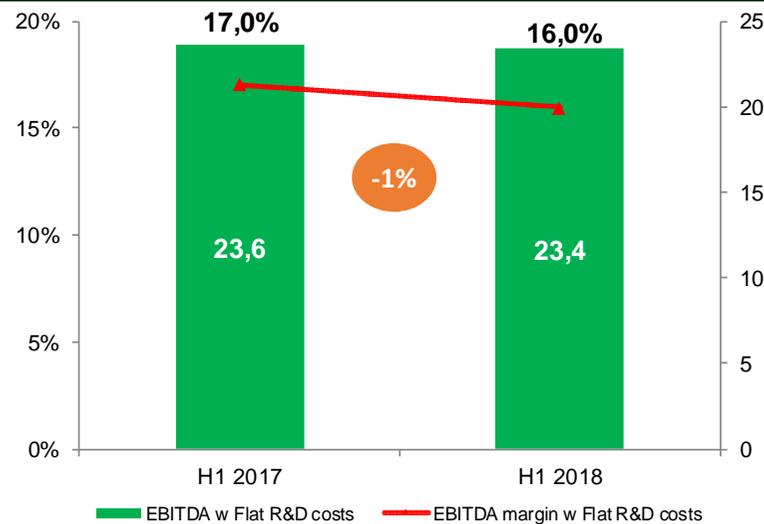
## EBITDA (€Mn) and EBITDA margin (%)



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



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

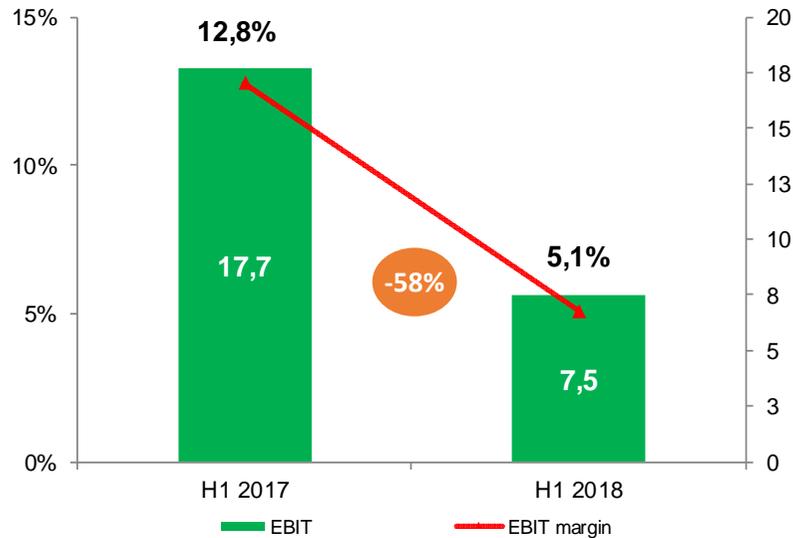


- In H1 2018, EBITDA was affected by non-recurring expenses of €2.6Mn. €1.5Mn of this amount were related to the study and analysis of potential corporate operations, while €1.1Mn were linked to a substantial change to Frosst Ibérica employees working conditions.
- **EBITDA** decreased to €13.3Mn in H1 2018, reflecting a 7.9 pp fall in the EBITDA margin, which was down to 9.1% in H1 2018 from 17.0% in H1 2017.
- **EBITDA “pre-R&D”** (w/o R&D and non recurring expenses) decreased by 1%, from €33.0Mn in H1 2017 to €32.7Mn in H1 2018, reflecting a 1.4 pp fall in the EBITDA margin to 22.4% in H1 2018. Likewise,
  - recognising the same amount of R&D expenses in H1 2018 as in H1 2017 and excluding the impact of the non recurring expenses in H1 2018, EBITDA would have decreased by 1% to €23.4Mn, reflecting a 1.1 pp fall in the EBITDA margin to 16.0% in H1 2018.

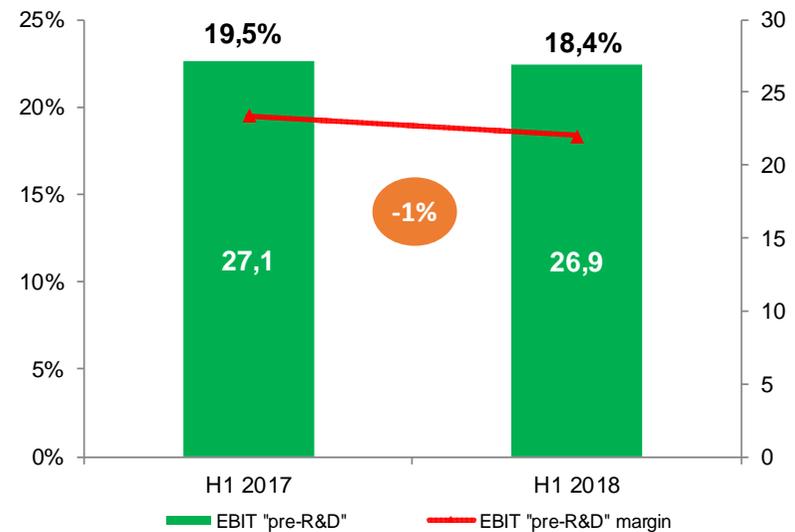
Note: EBITDA “pre-R&D” calculated excluding R&D expenses in H1 2018 and H1 2017 and the impact of non recurring expenses in H1 2018

# EBIT

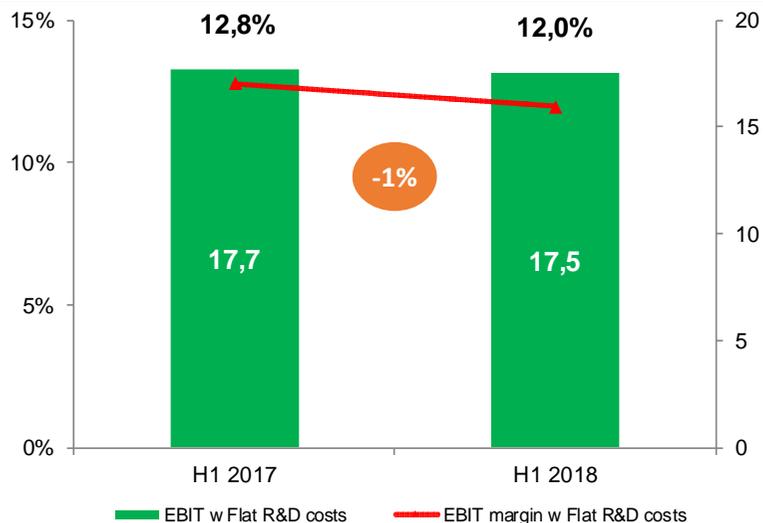
## EBIT (€Mn) and EBIT margin (%)



## EBIT (€Mn) and EBIT "pre-R&D" (w/o R&D and non recurring expenses) margin (%)



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

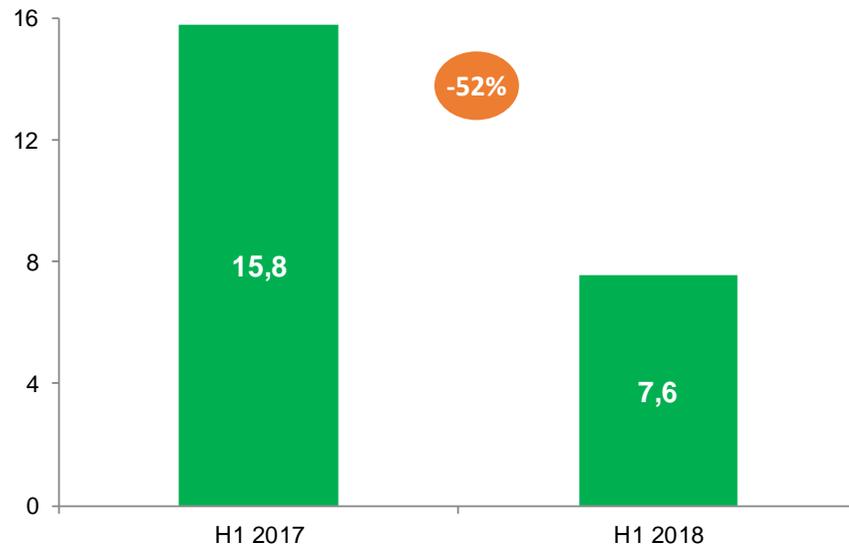


- **Depreciation and amortisation** expenses decreased by 1% to €5.9Mn in H1 2018.
- **EBIT** decreased to €7.5Mn in H1 2018, reflecting a 7.7 pp fall in the EBIT margin, which was down to 5.1% in H1 2018 from 12.8% in H1 2017.
- **EBIT "pre-R&D"** (w/o R&D and non recurring expenses) decreased by 1%, from €27.1Mn in H1 2017 to €26.9Mn in H1 2018, reflecting a 1.2 pp fall in the EBIT margin to 18.4% in H1 2018. Likewise,
  - recognising the same amount of R&D expenses in H1 2018 as in H1 2017 and excluding the impact of the non recurring expenses in H1 2018, EBIT would have decreased by 1% to €17.5Mn, reflecting a 0.8 pp fall in the EBIT margin to 12.0% in H1 2018.

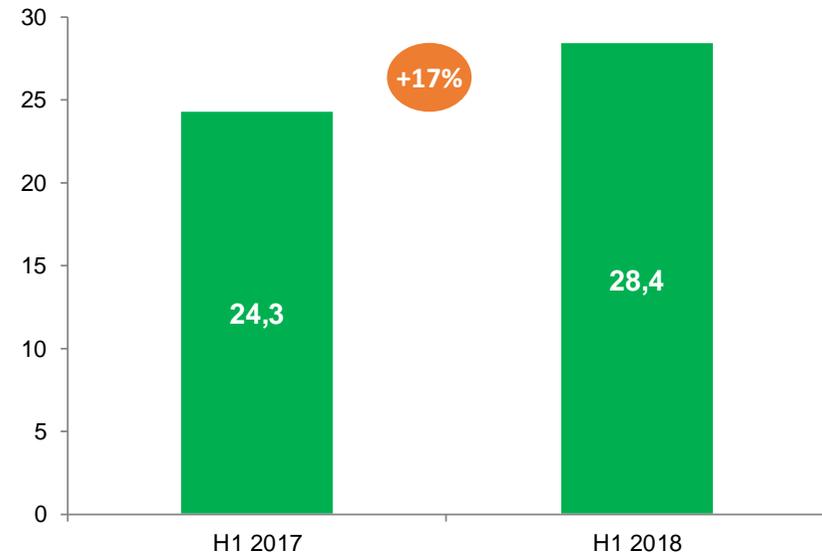
Note: EBIT "pre-R&D" calculated excluding R&D expenses in H1 2018 and H1 2017 and the impact of non recurring expenses in H1 2018

# Net profit

Net profit (€Mn)



Net profit “pre-R&D” (w/o R&D and non recurring expenses) (€Mn)

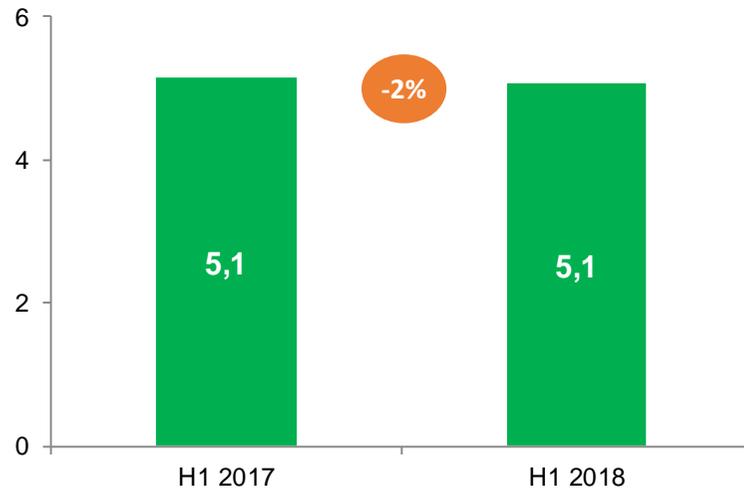


- **Net profit** decreased to €7.6Mn in H1 2018, a 52% fall compared to H1 2017.
- **Net profit “pre R&D”** (w/o R&D and non recurring expenses) increased by 17%, from €24.3Mn in H1 2017 to €28.4Mn in H1 2018. Likewise,
  - recognising the same amount of R&D expenses in H1 2018 as in H1 2017 and excluding the impact of the non recurring expenses in H1 2018, net profit would have increased by 16% to €18.3Mn.
- **Effective tax rate of -7.4%** in H1 2018 vs 8.6% in H1 2017. This improvement in the effective tax rate is due to the increase in the capitalization of:
  - R&D deductions; and
  - negative tax bases from Frosst Ibérica.
- As of 30 June 2018, Frosst Ibérica **negative tax bases amounted to €35.1Mn**, of which €1.5Mn will be used in the 2017 income tax and 0.7 million euros in H1 2018.
- While the Risperidone-ISM<sup>®</sup> Phase III trial is ongoing, adding higher R&D expenses, ROVI expects a very beneficial effective tax rate to be applicable, which could cause the income tax item to be positive income. 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.

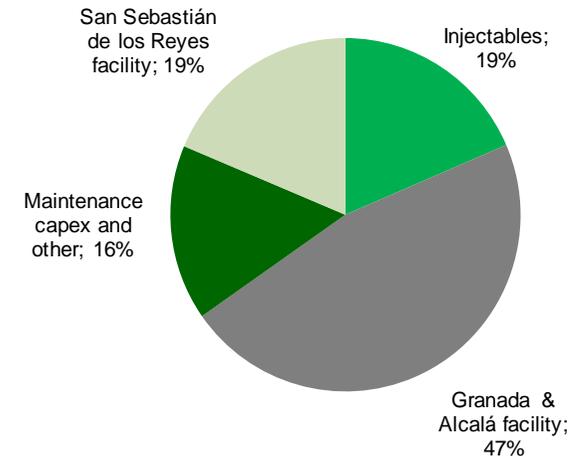
Note: Net profit “pre-R&D” calculated excluding R&D expenses in H1 2018 and H1 2017 and the impact of non recurring expenses in H1 2018. Same effective tax rate as the reported net profit.

# Capital expenditure and Free Cash Flow

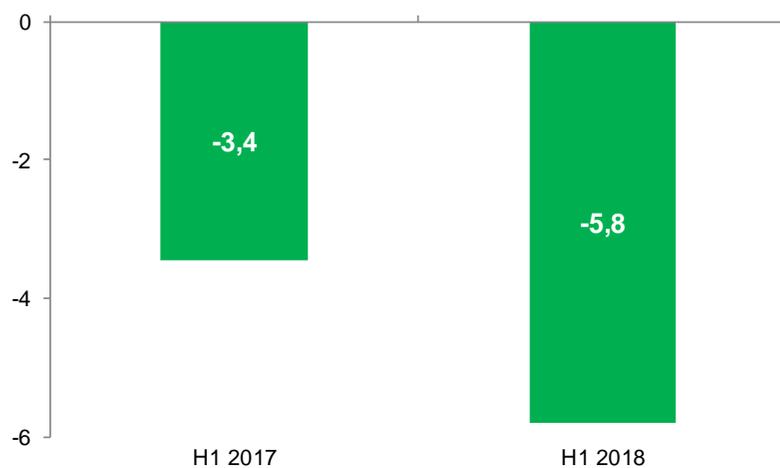
## Capex evolution (€Mn)



## Capex breakdown (%)



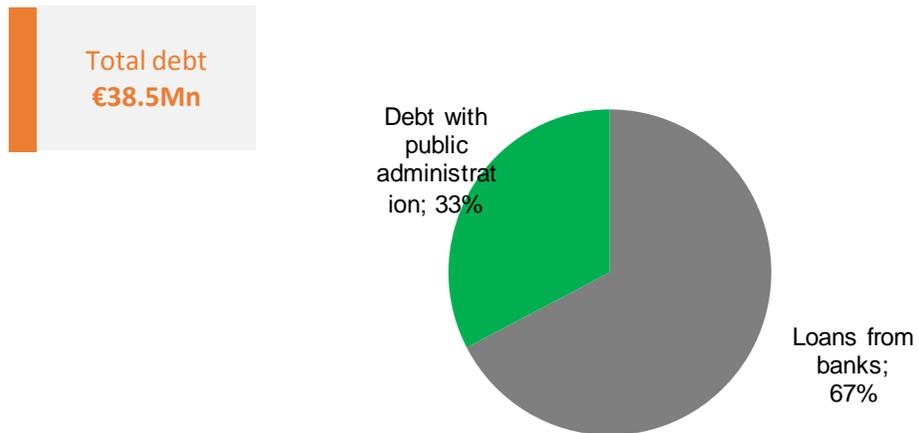
## Free Cash Flow (€Mn)



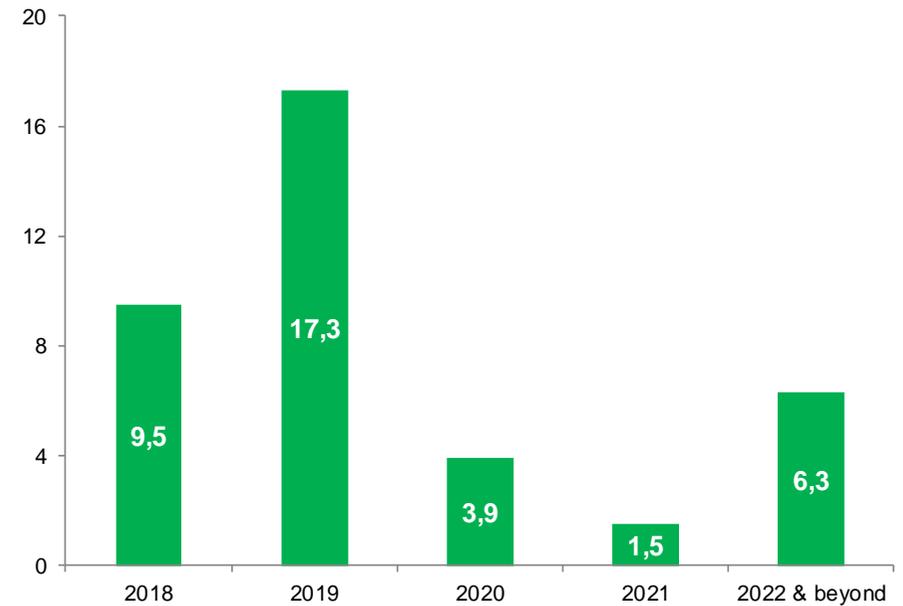
- €5.1Mn of **capex** invested in H1 2018.
  - €0.9Mn of investment capex related to the injectable plant;
  - €1.2Mn of investment capex related to the Granada facility;
  - €1.2Mn of investment capex related to the Alcalá de Henares facility;
  - €0.9Mn of investment capex related to the San Sebastián de los Reyes facility; and
  - €0.8Mn of maintenance capex and other capex.
- **FCF** decreased to €-5.8Mn mainly due to:
  - €15.9Mn increase in “inventories” in H1 2018 vs €6.0Mn increase in H1 2017;
  - €7.4Mn increase in “trade and other receivables” in H1 2018 vs €0.8Mn decrease in H1 2017;
  - €18.4Mn increase in “trade and other payables” in H1 2018 vs €6.8Mn decrease in H1 2017;
  - €10.2Mn decrease in “profit before income tax” in H1 2018 vs H1 2017.

# 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 €31.4Mn** as of 30 June 2018 vs €42.1Mn as of 31 December 2017.
- **Net debt of €7.0Mn** as of 30 June 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



## Specialty Pharma

Sales of biosimilar of Enoxaparin (sales range of 20 to 30 million euros in 2018)

Additional new in-licensing products to be launched

Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar in 5 EU countries (21 already granted)

## Toll manufacturing

New contracts to be announced

## ISM<sup>®</sup> technology platform

Continue the recruiting of Doria<sup>®</sup> Phase III

Start of ISM-Letrozole<sup>®</sup> Phase I in November 2017

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