



FIRST QUARTER 2019 FINANCIAL RESULTS

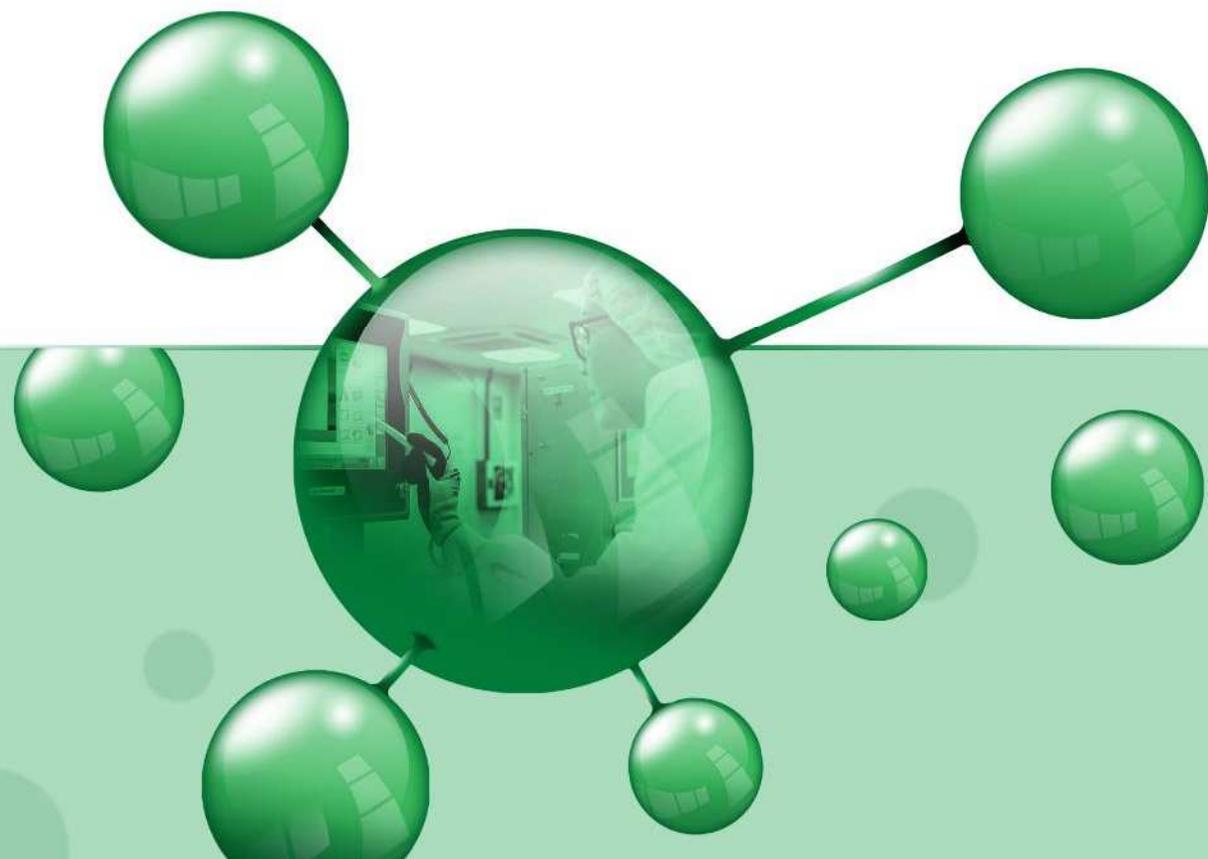
MAY 2019



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# Operating results





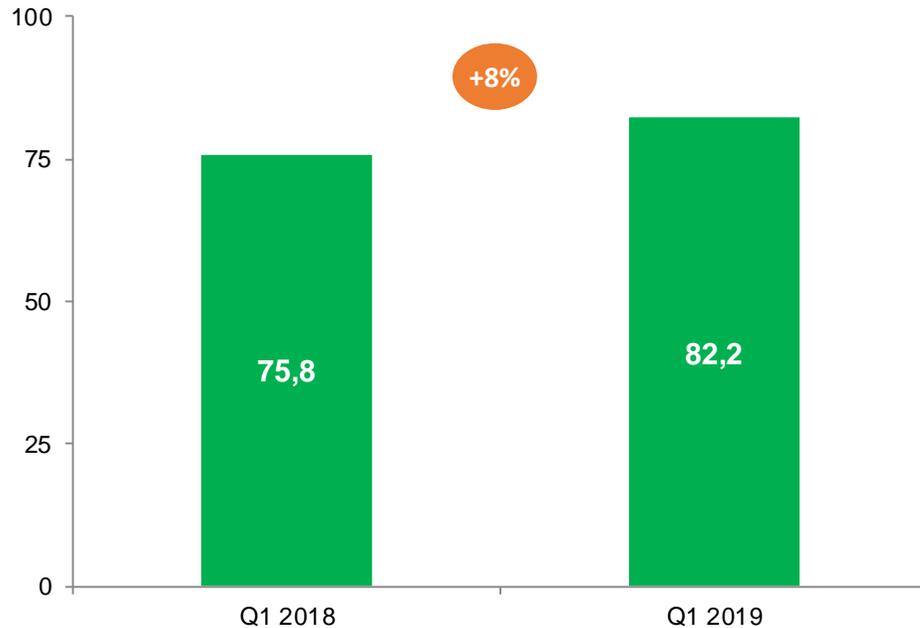
# First quarter 2019 financial results - Highlights

- **Operating revenue** increased by 8% to €82.2Mn in Q1 2019, driven by the strength the specialty pharmaceutical business, where sales rose 12%, strongly outperforming the market. Total revenue increased by 8% to €82.4Mn in Q1 2019.
- **ROVI is upgrading its operating revenue guidance for the full year 2019, from high-single-digit growth rate to low-double-digit growth rate.**
- In March 2018, ROVI announced **Positive Topline Results from Phase 3 study of Doria®**. These advanced final results show that primary and key secondary efficacy endpoints were achieved with both doses tested for the treatment of patients with acute exacerbation of schizophrenia. The application for registration with the FDA in USA is planned for the second half of 2019.
- ROVI launched its **enoxaparin biosimilar** in **Germany** in 2017; in **UK, Italy, Spain, France , Austria, Latvia and Estonia** in 2018; and in **Portugal** and **Costa Rica** in Q1 2019.
- As of 31/03/2019, all the EU countries (25 countries) where ROVI had applied for the national registration of the Enoxaparin biosimilar had approved such registration, except Luxembourg.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** increased by 34% to €37.6Mn in Q1 2019. **LMWH sales represented 46%** of operating revenue in Q1 2019 compared to 37% in Q1 2018. **Sales of the Enoxaparin biosimilar** amounted to **€16.5Mn** in Q1 2019 and **positive performance of Bemiparin in Spain (+4%** to €17.6Mn).
- Sales of **Neparvis**, launched in December 2016, increased 60% to €4.3Mn in Q1 2019.
- On the 1<sup>st</sup> January, 2019, IFRS 16 “Leases” became effective. The new standard affects ROVI’s financial statements. The principal new feature of IFRS 16 states that lessees must recognise a financial liability for the present value of the payments to be made over the remaining life of the lease contract and an asset for the right of use of the underlying asset. Additionally, the lessee will recognise as an expense for amortisation of the asset and a financial expense for the discounting of the lease liability, not recording the lease expense. The impacts of the application of IFRS 16 in ROVI as of March 31, 2019 were:
  - Recognition of assets under the “Property, plant and equipment” caption (non-current assets) for an amount of €21.0Mn.
  - Increase in debt under the captions “Financial liabilities for non-current and current leases” of €18.9Mn and €2.1Mn, respectively.
  - Lower operating expenses and, consequently, an increase of EBITDA of €0.8Mn, since operating lease payments were recognized under the SG&A caption.
  - Higher expense for the depreciation of the right-of-use asset of €0.7Mn.
  - An increase of €0.1Mn in the finance costs of the lease liabilities.
- **EBITDA** increased by 17%, from €10.2Mn in Q1 2018 to €11.9Mn in Q1 2019, reflecting a 1.0 pp rise in the EBITDA margin to 14.4% in Q1 2019.
- **Net profit** increased by 1%, from €6.8Mn in Q1 2018 to €6.9Mn in Q1 2019.
- ROVI will put a proposal to the General Shareholders’ Meeting to allocate the 2018 profit to, firstly, the reserves item on the Company’s statement of financial position and, secondly, the distribution of a **dividend of 0.0798 euros/share** entitled to receive it, which would entail the distribution of ~25% of the consolidated net profit for 2018.

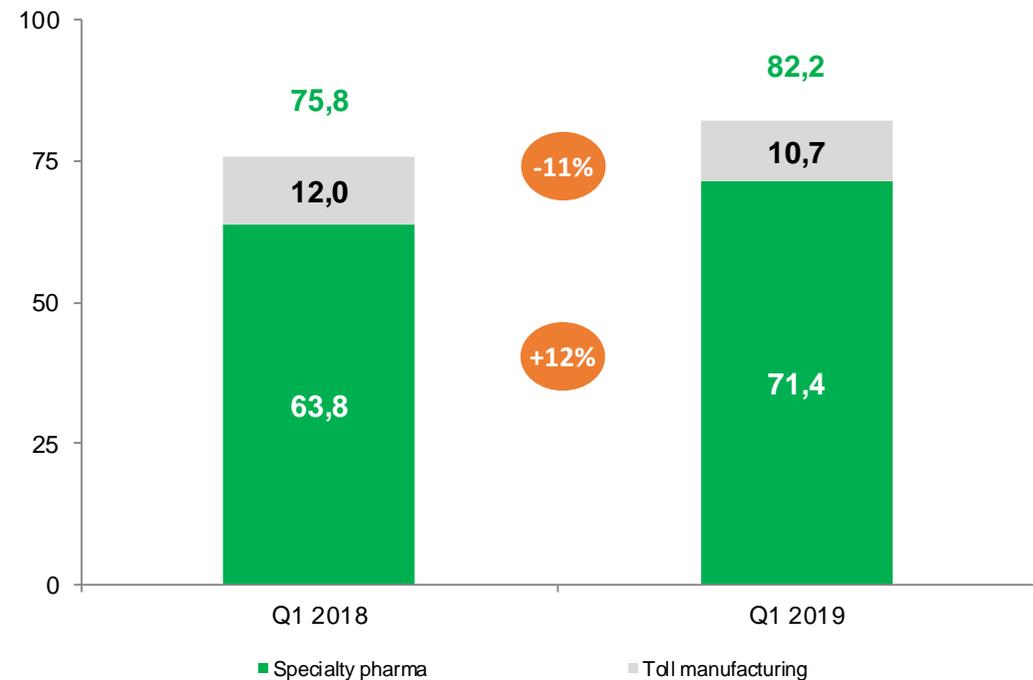


## Growth driven by specialty pharma business...

Total operating revenue (€Mn)



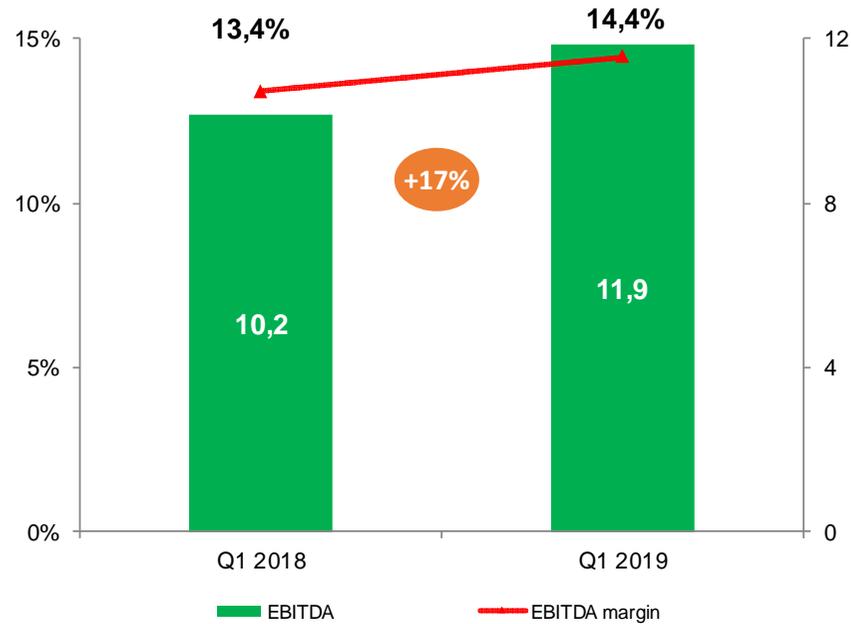
Operating revenue growth by category (€Mn)



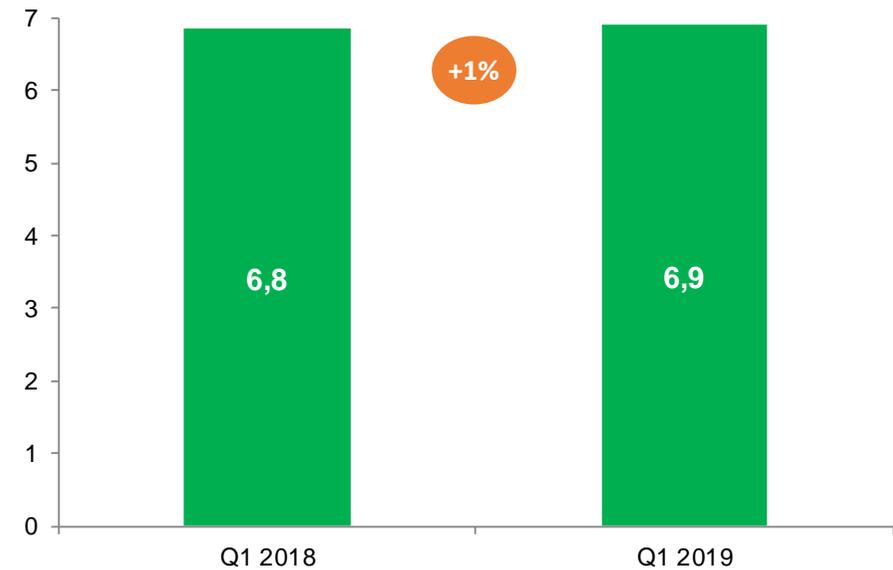
- **Operating revenue increased by 8%** to €82.2Mn in Q1 2019 driven by the strength of:
  - the specialty pharmaceutical business, where sales rose 12%
- ROVI forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in the first two months of 2019, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 3%.

## ...with high profitability

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



### Net profit (€Mn)

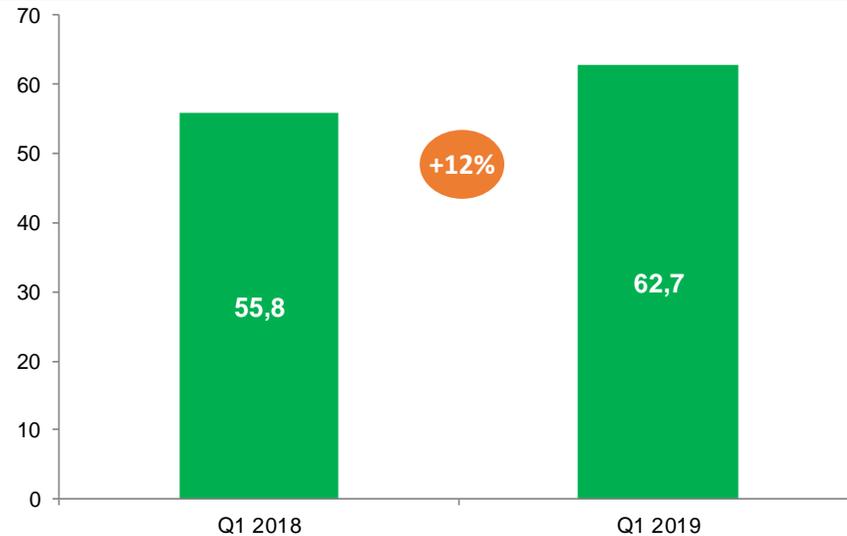


- As a result of the IFRS 16 application, EBITDA was positively impacted by €0.8Mn in Q1 2019.
- **EBITDA increased by 17%**, from €10.2Mn in Q1 2018 to €11.9Mn in Q1 2019, reflecting a 1.0 percentage point rise in the EBITDA margin to 14.4% in Q1 2019.
- **Net profit increased by 1%**, from €6.8Mn in Q1 2018 to €6.9Mn in Q1 2019.

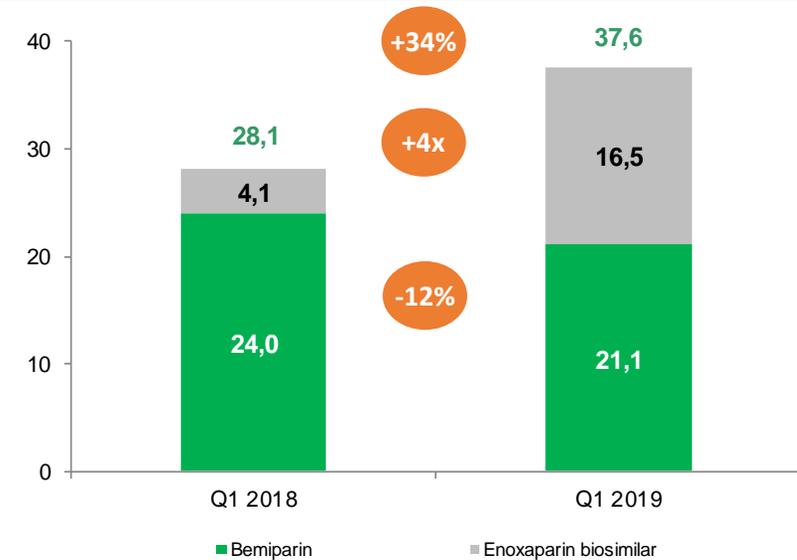


# LMWH, leading the specialty pharmaceutical business

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

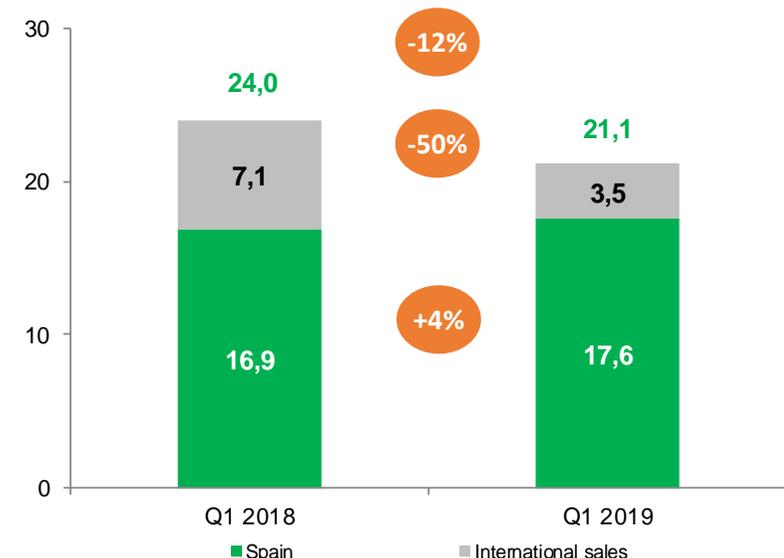


## LMWH franchise sales (€Mn)



- Sales of **prescription-based pharmaceutical products increased by 12%** to €62.7Mn in Q1 2019.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** (Enoxaparin biosimilar and Bemparin) **increased by 34%** to €37.6Mn in Q1 2019.
- **LMWH sales represented 46% of operating revenue in Q1 2019 compared to 37% in Q1 2018.**
  - Sales of the **Enoxaparin biosimilar** amounted to **€16.5Mn** in Q1 2019.
  - **Bemparin total sales decreased by 12%** to €21.1Mn in Q1 2019:
    - Sales in **Spain increased 4%** to €17.6Mn.
    - **International sales decreased by 50%** to €3.5Mn. This significant decrease was specifically linked to Q1 2019 and ROVI expects international Bemparin sales to remain stable in 2019.

## Bemparin Sales Ramp-up (€Mn)





# Strong growth potential of Enoxaparin Biosimilar Becat®

## Strong Commercial Launch with a Clear Strategy

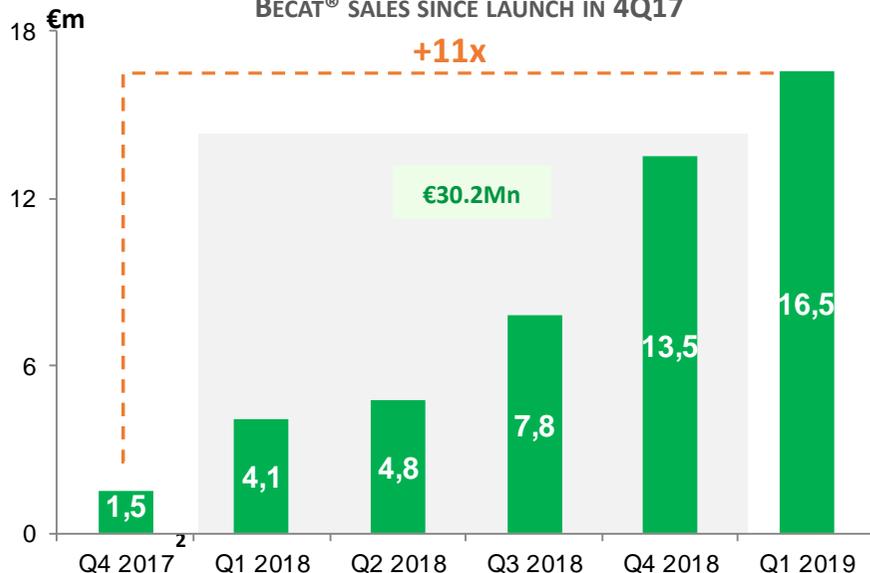
- ROVI launched enoxaparin biosimilar Becat® in **Germany** (first EU market) in September 2017; in **UK, Italy, Spain, France<sup>1</sup>, Austria, Latvia and Estonia** in 2018; and in **Portugal** and **Costa Rica** in Q1 2019.
- Enoxaparin biosimilar Becat® expected to **launch in key European markets** in 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 <b>Germany, UK, Italy, Spain &amp; Portugal</b>	Approved; To Be Directly Marketed <b>2 Countries</b>	Approved; To Be Out-Licensed <b>18 Countries</b>	Pending Approval; To Be Out-Licensed <b>65 Countries</b>
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### Enoxaparin Biosimilar Becat® Sales Ramp-up

VERY POSITIVE EVOLUTION OF ENOXAPARIN BIOSIMILAR BECAT® SALES SINCE LAUNCH IN 4Q17



1. ROVI has started to sell Becat® in France through Biogaran and expects to sell it directly in 2019.  
 2. Becat® 4Q 2017 sales include sales throughout September. As the product was launched that month, sales were negligible.  
 3. Estimates based on Sanofi-Aventis reported 2018 sales.

## Stage I of Commercial Strategy

<p>Focus on Europe...</p> <p>...the largest enoxaparin market with <b>€0.9bn</b> sales<sup>3</sup></p>	<p>ROVI expects to directly market enoxaparin biosimilar Becat® in <b>7</b> European countries...</p> <p>...which account for <b>c.75%</b> of the European market<sup>4</sup></p>	<p>In the long-term, <b>biosimilars</b> tend to reach a...</p> <p><b>50-70%</b> Market Share<sup>5</sup></p> <p>...of the reference product market</p>	<p>In Europe, there are only ...</p> <p><b>2 other</b> Authorized Biosimilars</p> <p>...already in the market</p>
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## Stage II of Commercial Strategy

Continue international expansion in other markets with strong growth potential through out-licensing agreements

Already Signed Out-Licensed Agreements: **69 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.

**€0.5bn** 2018 Market Sales<sup>3</sup>

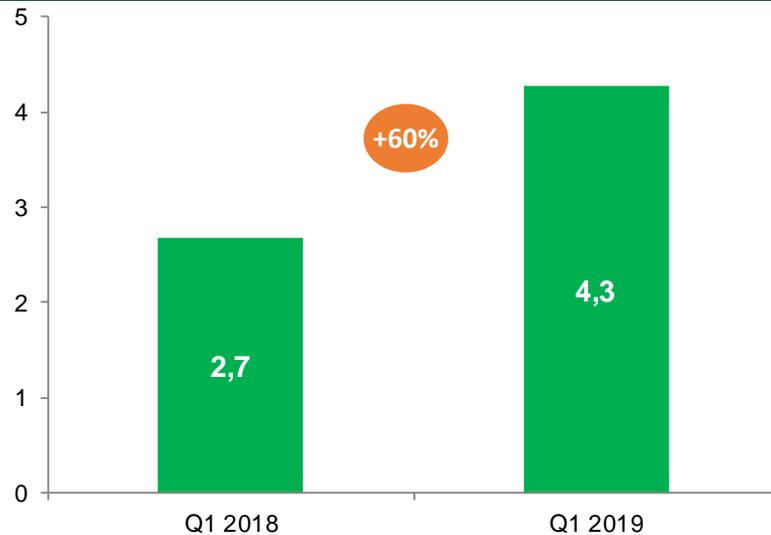
**11.4%** 2018 Market Growth<sup>3</sup>

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

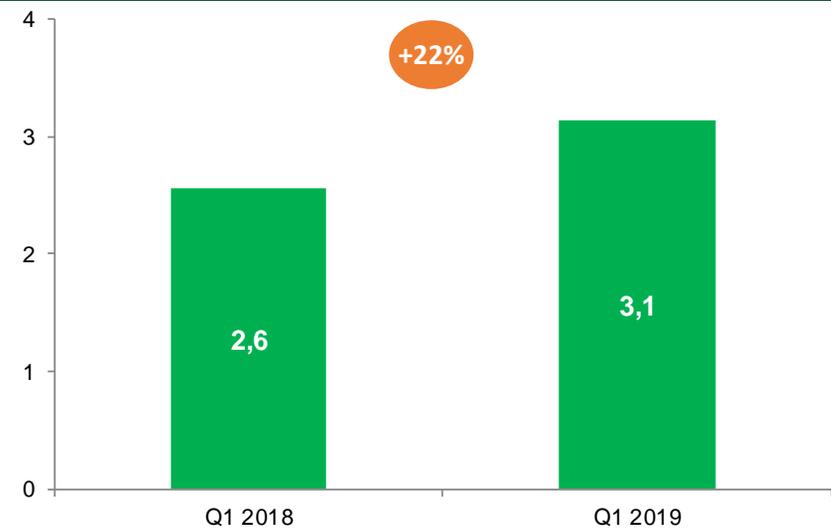


## Strong performance of the product portfolio (1/2)

### Neparvis sales (€Mn)



### Volutsa sales (€Mn)



### Medicebran and Medikinet sales (€Mn)



- Sales of **Neparvis**, a specialty product from Novartis launched in December 2016, **reached €4.3Mn** in Q1 2019, from €2.7Mn in Q1 2018.
- Sales of **Volutsa**, launched in Spain in February 2015, **increased by 22%** to €3.1Mn in Q1 2019.
- Sales of **Medicebran and Medikinet**, products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, increased 6% to €2.1Mn in Q1 2019.

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

*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.*

*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)

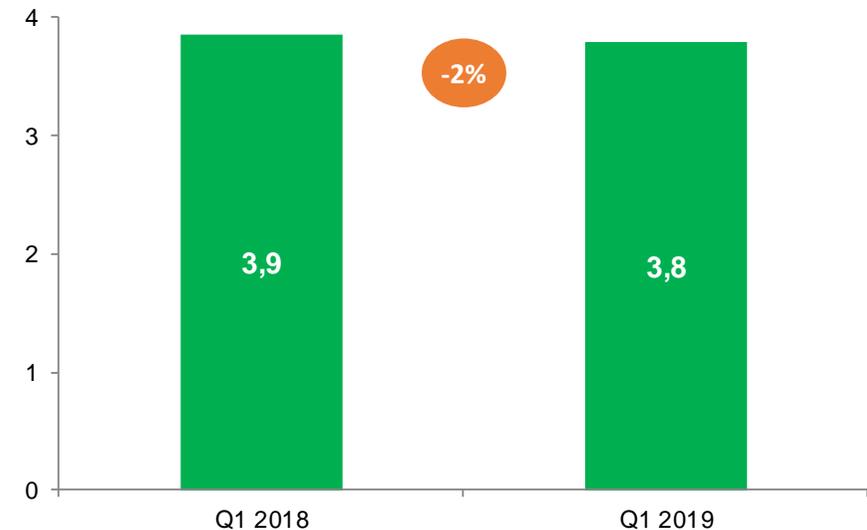
### Absorcol, Vytorin and Orvatez sales (€Mn)



### Contrast imaging agents sales (€Mn)



### Hirobriz and Ulunar sales (€Mn)



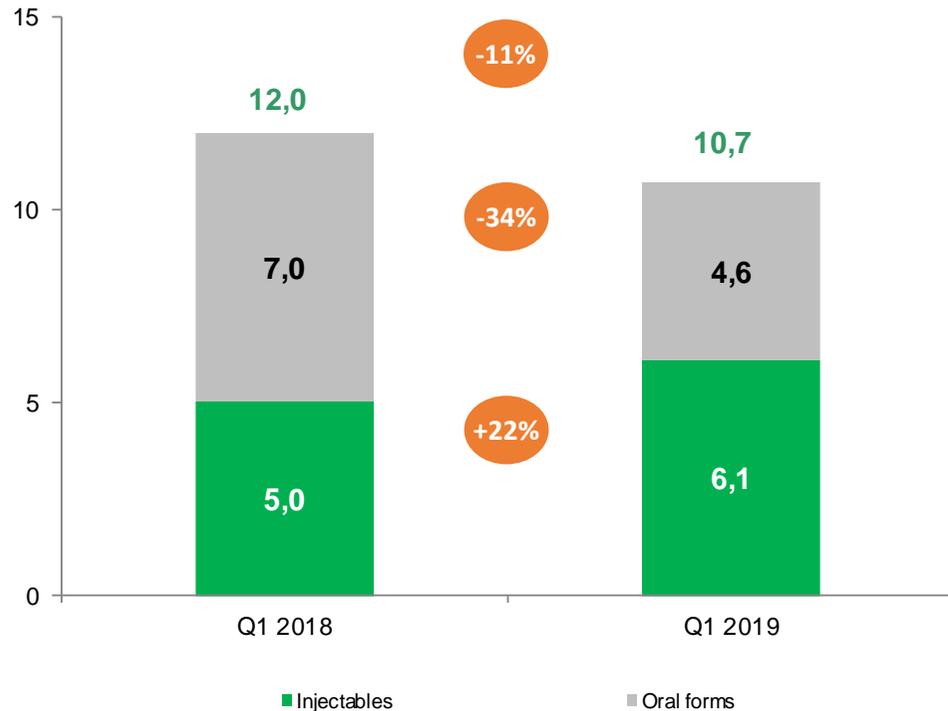
- Sales of **Vytorin**<sup>®</sup>, **Orvatez**<sup>®</sup> and **Absorcol**<sup>®</sup> decreased by 44% to €7.3Mn in Q1 2019. In 2Q 2018, the active principle ezetimibe went out of patent and the price of Absorcol<sup>®</sup> was reduced. Likewise, generics formulated with ezetimibe and simvastatin were marketed in the same period, so the price of Vytorin<sup>®</sup> was reduced to be competitive. In addition, sales of Orvatez<sup>®</sup> amounted to €8.2Mn in Q1 2018, an extraordinary rise of 89% compared to Q1 2017.
- Sales of **Hirobriz** and **Ulunar**, both products for patients with COPD, launched in Spain in Q4 2014 decreased by 2% to €3.8Mn in Q1 2019.
- **Contrast imaging agents and other hospital products** increased by 8% to €8.2Mn in Q1 2019.

*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).*

# Value added toll manufacturing services

## Toll manufacturing sales (€Mn)



- **Toll manufacturing** sales decreased by 11% to €10.7Mn in Q1 2019 mainly because of the reduction of the oral forms business compared to Q1 2018.
- Injectable business sales increased by 22% to €6.1Mn in Q1 2019 compared to the same period of the previous year.
- By the end of 2019, a mid-single-digit growth rate in toll manufacturing is expected.





# DORIA®: Positive Topline Results from Phase 3 study

## Phase III clinical trial

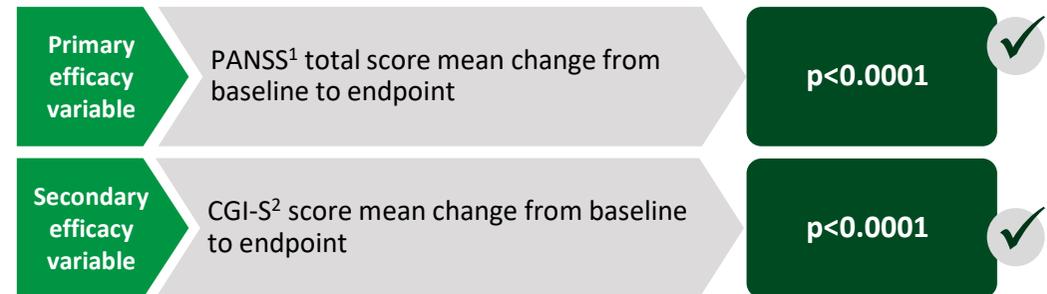
- It is double-blind (+ open-label extension), parallel, multicentre (31 sites/ 2 countries)
- The objectives of Phase III are:
  - Evaluate the efficacy and safety of DORIA® compared to placebo in the treatment of subjects with acute exacerbation of schizophrenia
  - Health Resources Utilization (HRU), Health-Related Quality of Life (HRQL), and Social Functioning in subjects treated with DORIA® versus placebo for an acute exacerbation of schizophrenia
  - Explore pharmacokinetic characteristics of DORIA® and associations with efficacy

[ClinicalTrials.gov # NCT03160521]

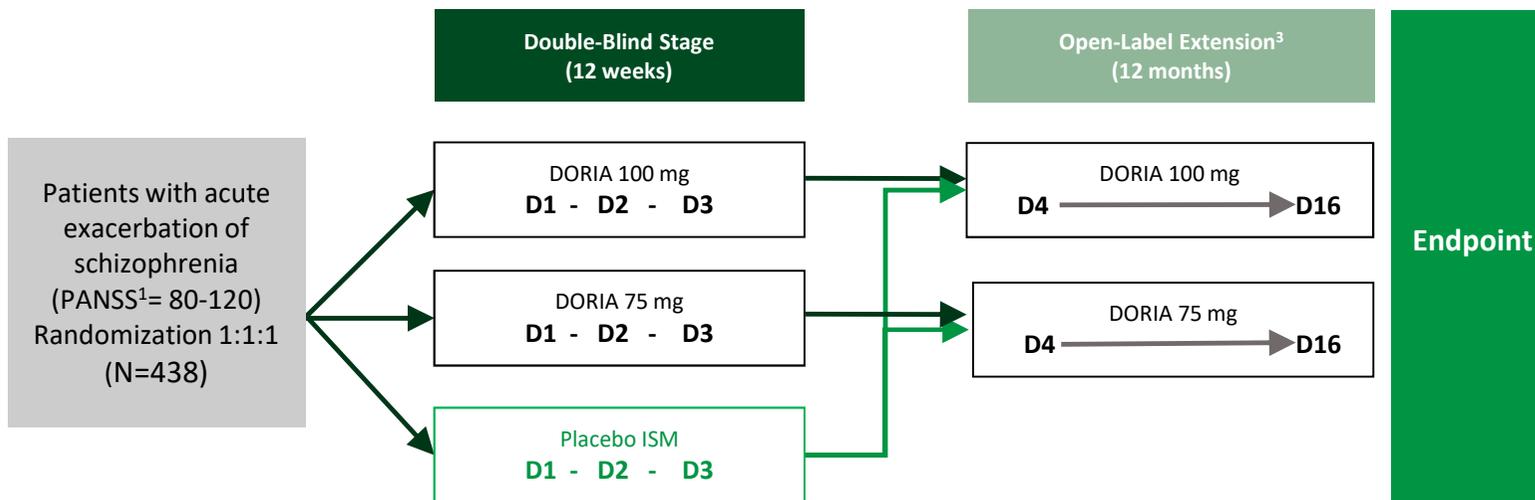
## Main efficacy variables achieved

Endpoint: Study day 85 or the last post-baseline double-blind assessment

Doria 75mg vs Placebo & Doria 100mg vs Placebo



## Pivotal study PRISMA-3 design [clinicaltrials.gov#NCT03160521]



## Upcoming key catalysts

- Final clinical report will be available by June 2019
- New Drug Application (NDA) to the FDA planned for H2 2019
- Open-Label Extension stage to be completed by January 2020

<sup>1</sup> PANSS: Positive and Negative Syndrome Scale is a medical scale used for measuring symptom severity of patients with schizophrenia. It is widely used in the study of antipsychotic therapy.

<sup>2</sup> CGI: Clinical Global Impression are measures of illness severity (CGIS), global improvement or change (CGIC) and therapeutic response.

<sup>3</sup> Additionally, 41 clinically stable (PANSS < 70; CGI-S ≤ 3); not hospitalized/exacerbated over the last 3 months) "de novo" patients (not previously enrolled in the double-blind stage) have been recruited in the Open-Label Extension stage [ClinicalTrials.gov # NCT03870880]

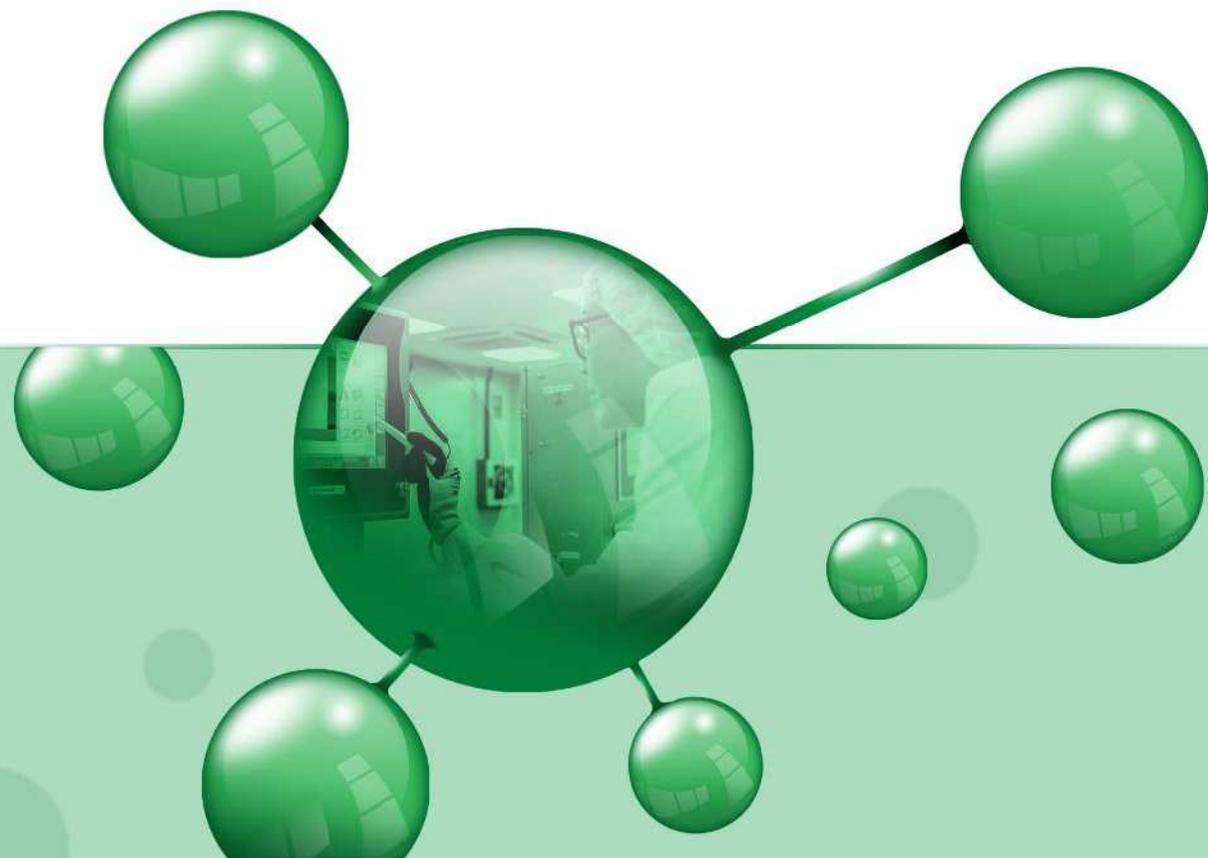


**2019 operating revenue growth rate**  
**Updated from High-single-digit to Low-double-digit**

## THE KEY GROWTH LEVERS IN 2019

Specialty Pharma Business	Toll Manufacturing Services
<ul style="list-style-type: none"><li>✓ Bemiparin</li><li>✓ Biosimilar of Enoxaparin</li><li>✓ Latest launches such as Tetridar, Neparvis, Orvatez, Volutsa and Ulunar</li><li>✓ Existing portfolio of specialty pharmaceuticals</li><li>✓ New acquisitions (Falithrom and Polaramine)</li></ul>	<ul style="list-style-type: none"><li>✓ Spare capacity in the injectable plants and in the oral compounds plant</li><li>✓ New customers to be acquired</li></ul>

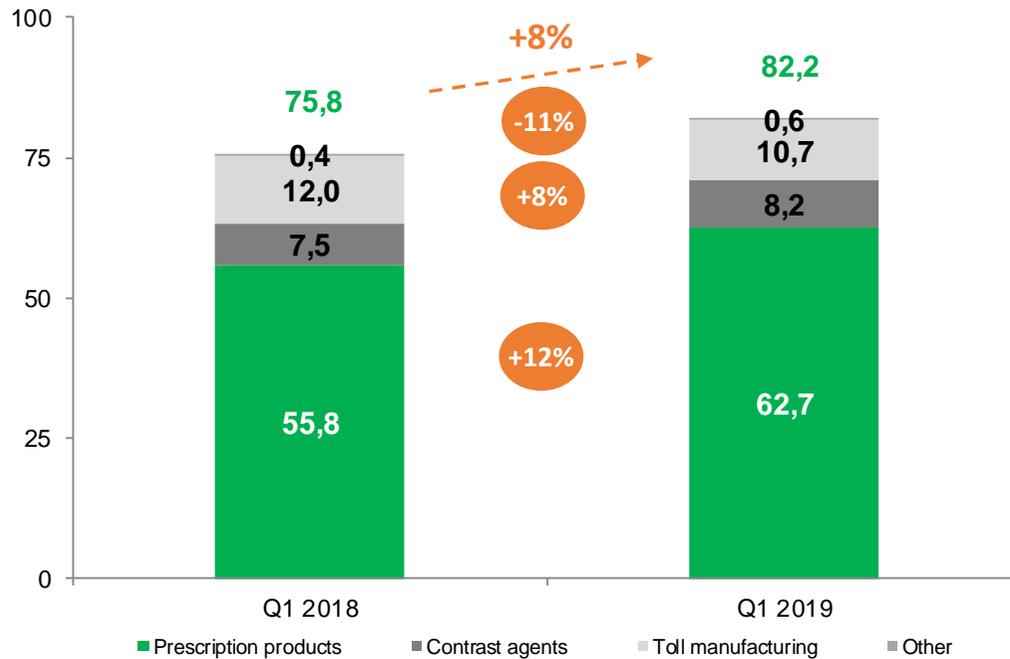
# Financial results



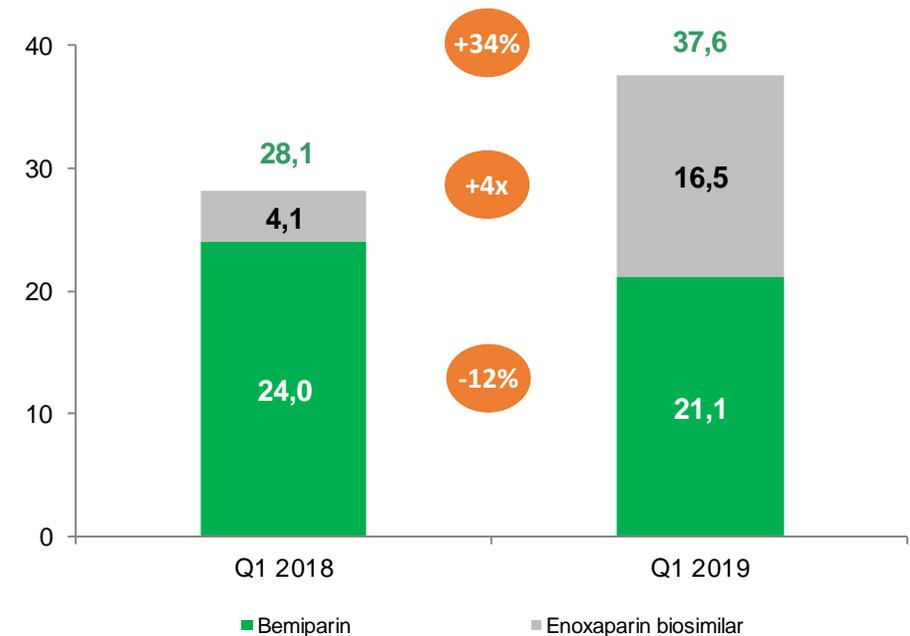


# Good revenue level with outstanding LMWH franchise growth

## Total operating revenue (€Mn)



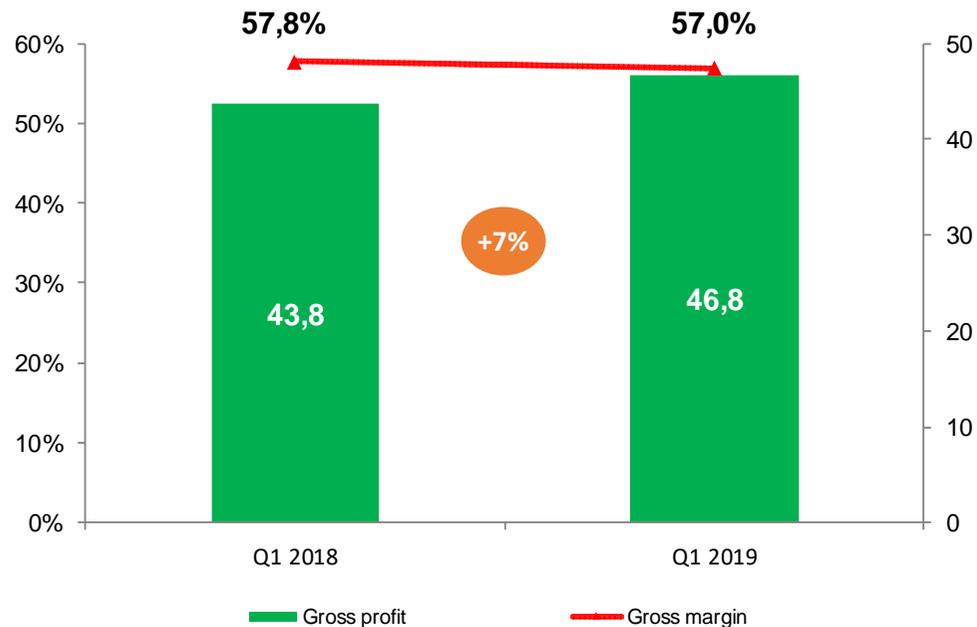
## LMWH franchise sales (€Mn)



- **Operating revenue** increased by 8% to €82.2Mn, achieved on:
  - 12% growth in prescription-based products;
  - 8% growth in contrast agents and other hospital products;
  - 11% reduction in toll manufacturing; and
  - OTC and other revenues increased by 28%.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** increased by 34% to €37.6Mn in Q1 2019, representing 46% of operating revenue in Q1 2019 vs 37% in Q1 2018.
  - **Enoxaparin biosimilar sales reached €16.5Mn** and Bemiparin sales decreased by 12%.

# Gross margin impacted by the increase of enoxaparin biosimilar sales and the increase of LMWH raw material prices

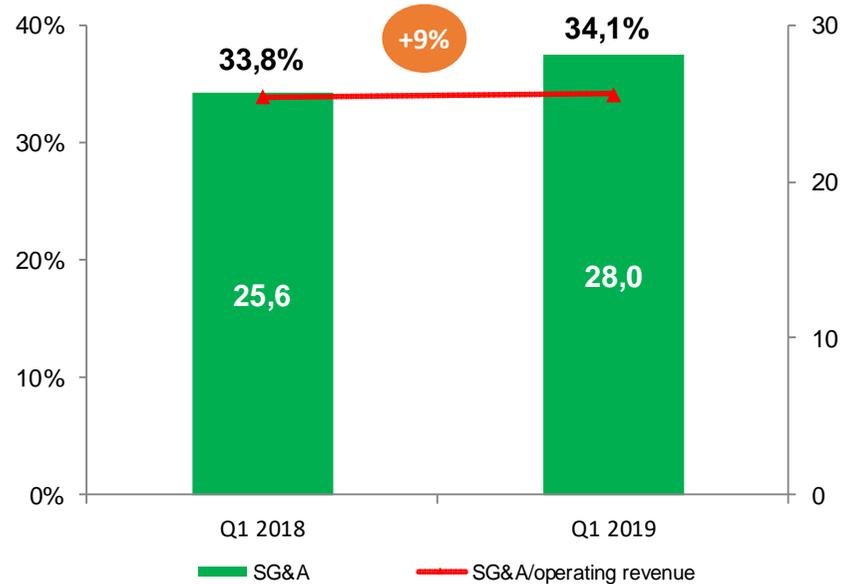
## Gross profit (€Mn) and Gross margin (%)



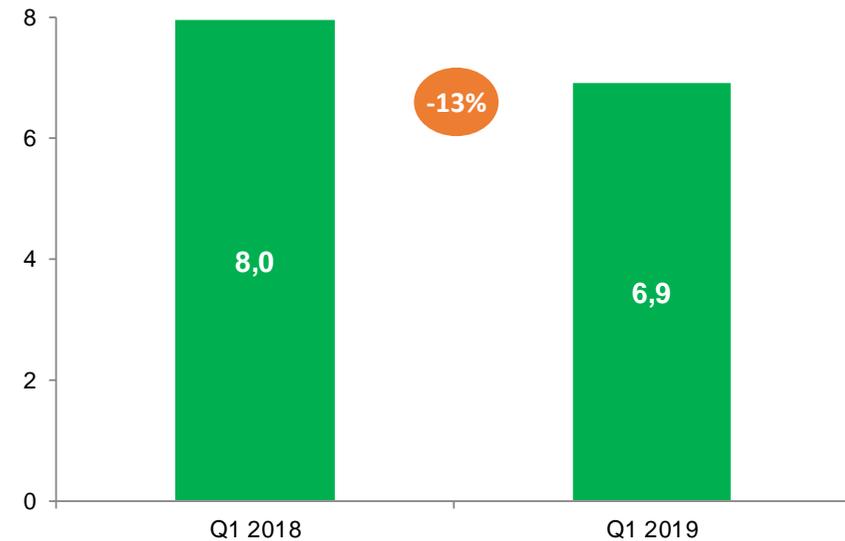
- **Gross profit** increased by 7% to €46.8Mn in Q1 2019, the gross margin showing a decrease of 0.8 percentage points from 57.8% in Q1 2018 to 57.0%, mainly due to:
  - the increase of Enoxaparin biosimilar sales, which added lower margins in the first quarter of 2019 after the launch of the product in eight new markets; and
  - the increase in the LMWH raw material prices, which, in the first quarter of 2019, were running around 30% over first quarter 2018 prices. ROVI expects this rising trend to continue during 2019.

# Cost control along with commitment to R&D

## SG&A expenses (€Mn)



## R&D expenses (€Mn)



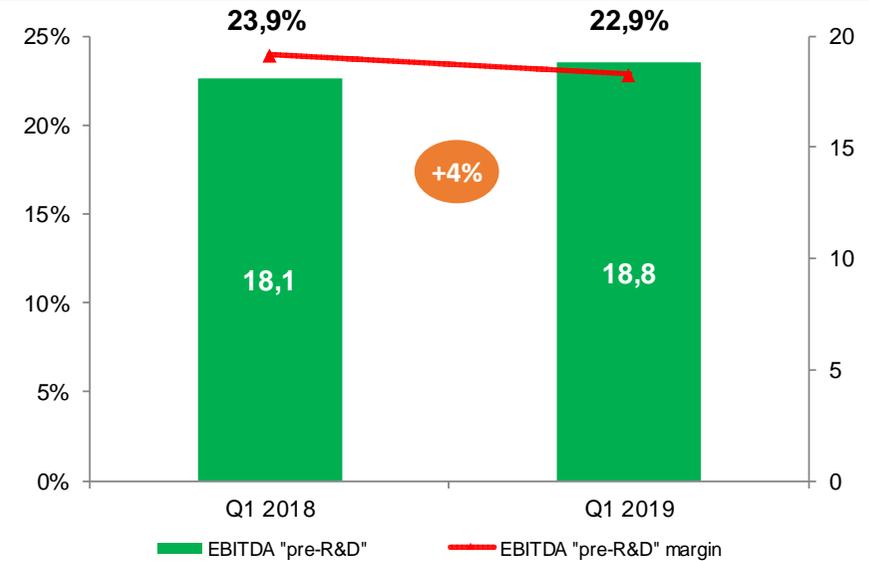
- **SG&A expenses rose 9%** to €28.0Mn in Q1 2019 mainly due to:
  - international subsidiaries expenses, which amounted to €1.9Mn compared to €1.1Mn in Q1 2018; and
  - a larger volume of enoxaparin biosimilar production.
  - In 2019, expenses related to international subsidiaries are expected to be around 10 million euros.
- **R&D expenses decreased 13%** to €6.9Mn in Q1 2019. These expenses are related to the development of the Risperidone-ISM<sup>®</sup> Phase III trial and the Letrozole-ISM<sup>®</sup> Phase I trial.

# EBITDA

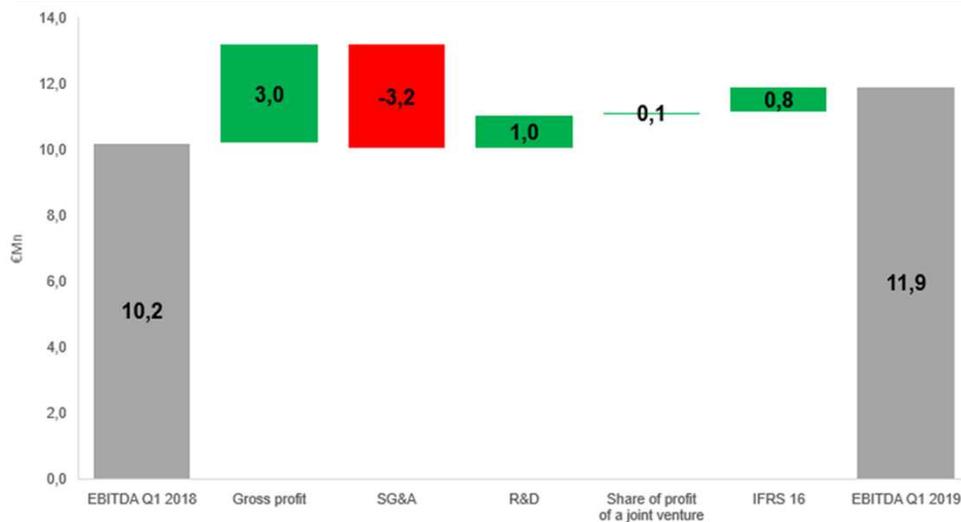
## EBITDA (€Mn) and EBITDA margin (%)



## EBITDA (€Mn) and EBITDA "pre-R&D" margin (%)



## Q1 2019 EBITDA impacts (€Mn)

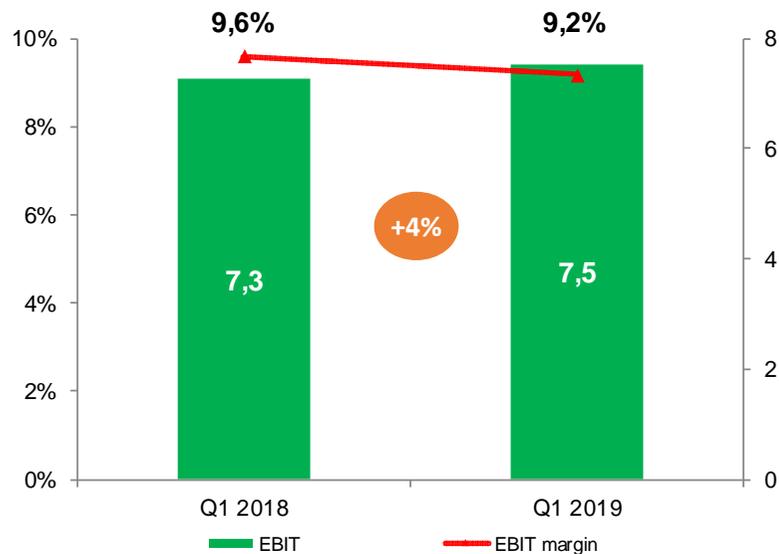


- **EBITDA** increased to €11.9Mn in Q1 2019, reflecting a 1.0 pp rise in the EBITDA margin, which was up to 14.4% in Q1 2019 from 13.4% in Q1 2018.
- **EBITDA "pre-R&D"** increased by 4% to €18.8Mn in Q1 2019, reflecting a 1.1 pp fall in the EBITDA margin to 22.9% in Q1 2019. Likewise,
  - recognising the same amount of R&D expenses in Q1 2019 as in Q1 2018, EBITDA would have increased by 7% to €10.8Mn, reflecting a 0.2 pp fall in the EBITDA margin to 13.2% in Q1 2019.

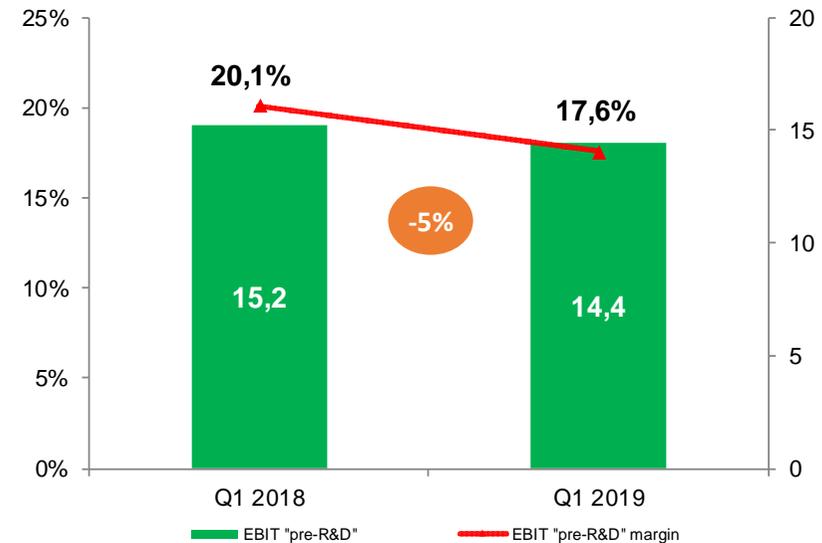
Note: EBITDA "pre-R&D" calculated excluding R&D expenses in Q1 2019 and Q1 2018

# EBIT

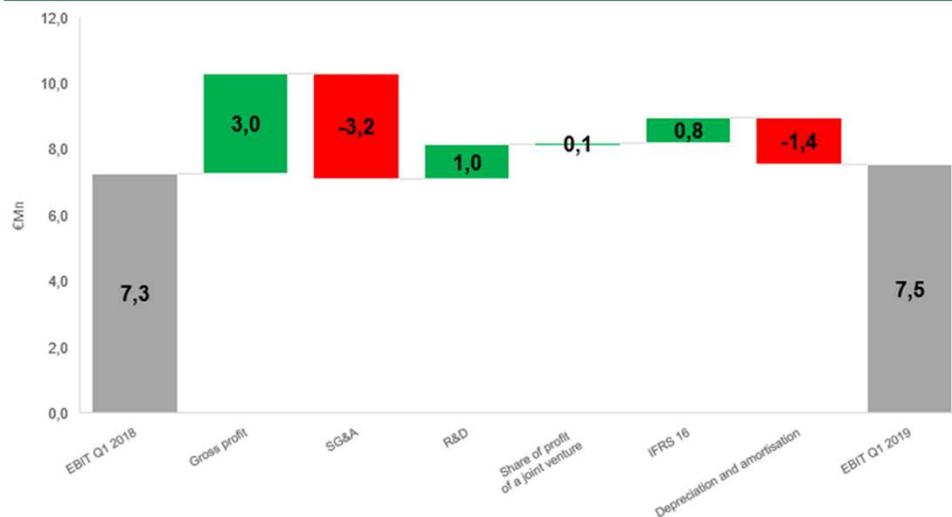
## EBIT (€Mn) and EBIT margin (%)



## EBIT (€Mn) and EBIT "pre-R&D" margin (%)



## Q1 2019 EBIT impacts (€Mn)

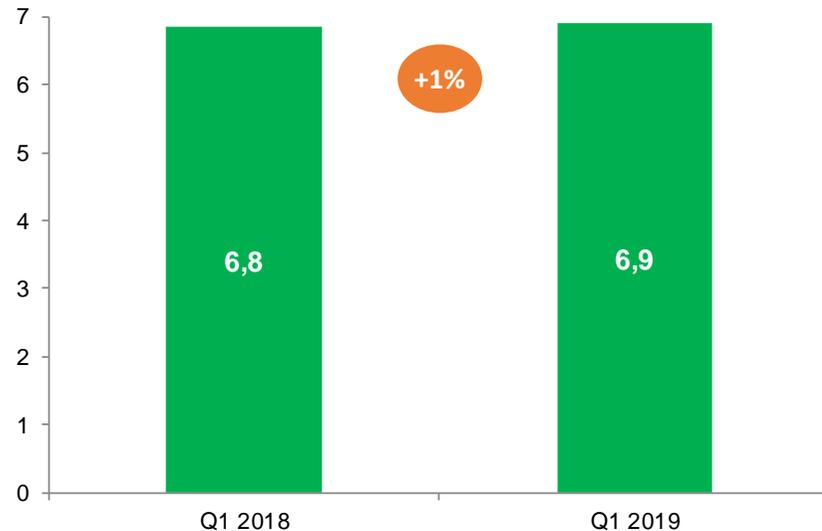


- As a result of the IFRS 16 application and the new PP&E and intangible assets purchases made during the last twelve months, **depreciation and amortisation** expenses increased by 50% to €4.3Mn in Q1 2019.
- **EBIT** increased to €7.5Mn in Q1 2019, reflecting a 0.4 pp fall in the EBIT margin, which was down to 9.2% in Q1 2019.
- **EBIT "pre-R&D"** decreased by 5%, from €15.2Mn in Q1 2018 to €14.4Mn in Q1 2019, reflecting a 2.5 pp fall in the EBIT margin to 17.6% in Q1 2019. Likewise,
  - recognising the same amount of R&D expenses in Q1 2019 as in Q1 2018, EBIT would have decreased by 11% to €6.5Mn, reflecting a 1.7 pp fall in the EBIT margin.

Note: EBIT "pre-R&D" calculated excluding R&D expenses in Q1 2019 and Q1 2018

# Net profit

## Net profit (€Mn)



## Net profit “pre-R&D” (€Mn)

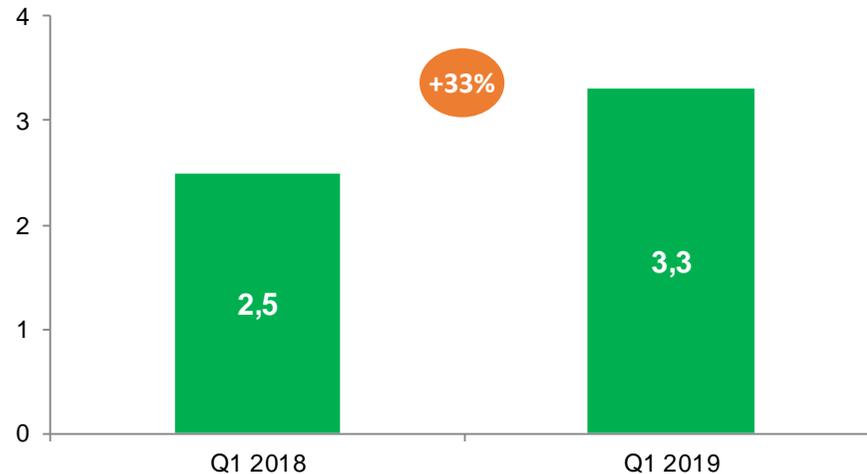


- **Net profit** increased to €6.9Mn in Q1 2019, a 1% rise compared to Q1 2018.
- **Net profit “pre R&D”** decreased by 9%, from €14.6Mn in Q1 2018 to €13.3Mn in Q1 2019. Likewise,
  - recognising the same amount of R&D expenses in Q1 2019 as in Q1 2018, net profit would have decreased by 13% to €5.9Mn.
- **Effective tax rate of 6.9%** in Q1 2019, compared to 2.6% in Q1 2018. This favourable effective tax rate is due to:
  - R&D deductions; and
  - negative tax bases.
- As of 31 March 2019, **negative tax bases amounted to €36.3Mn**, of which €1.4Mn will be used in the 2018 income tax and €0.2Mn in Q1 2019.
- 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 (i.e. between 0 and 10%) in the following years.

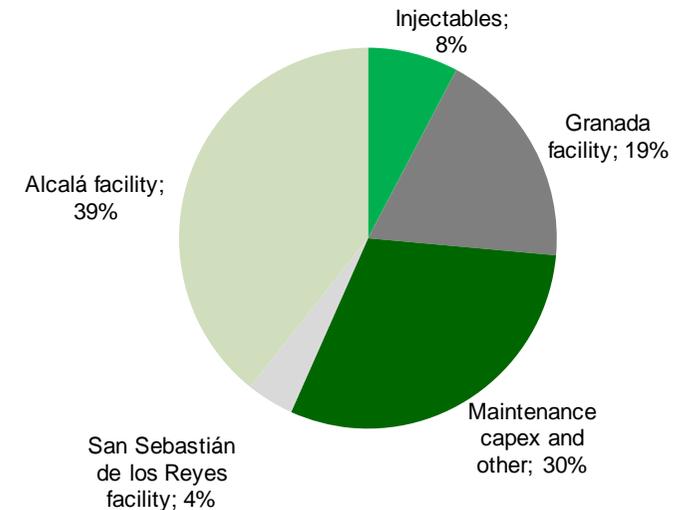
Note: Net profit “pre-R&D” calculated excluding R&D expenses in Q1 2019 and Q1 2018. Same effective tax rate as the reported net profit.

# Capital expenditure and Free Cash Flow

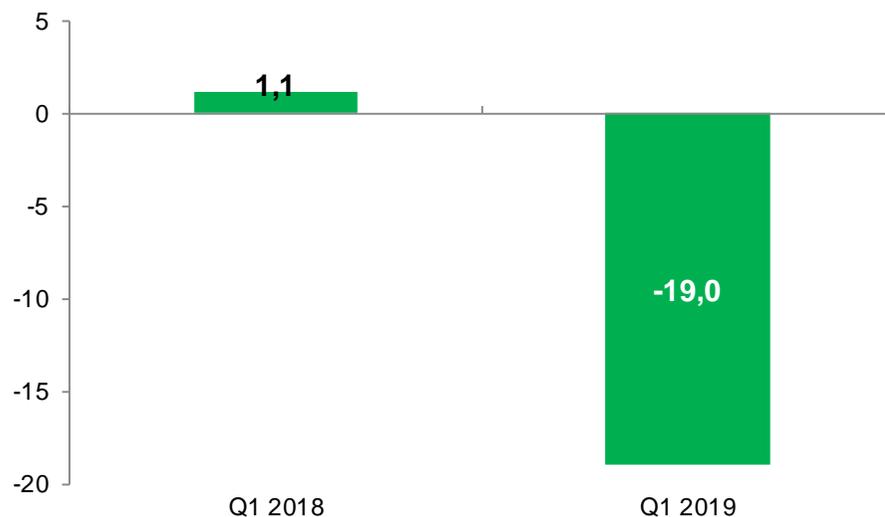
## Capex evolution (€Mn)



## Capex breakdown (%)



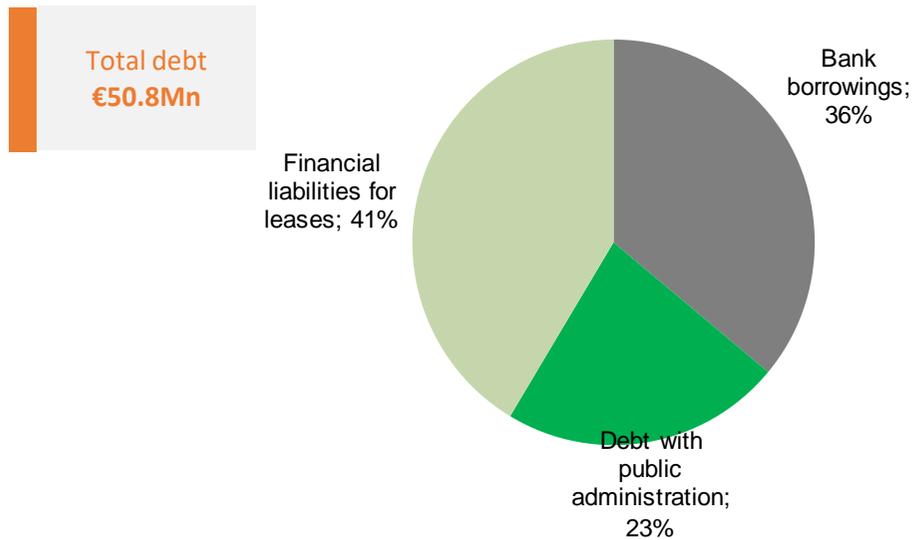
## Free Cash Flow (€Mn)



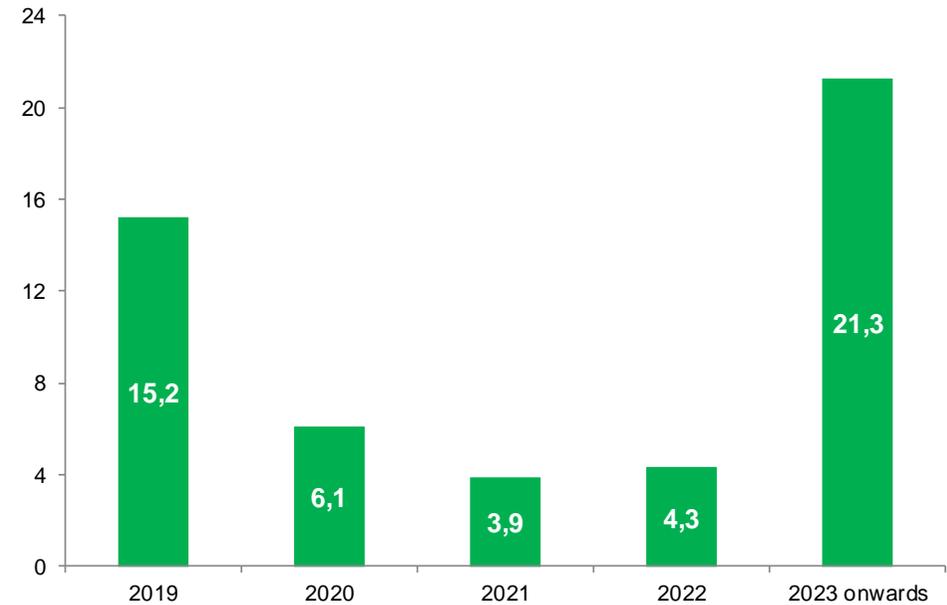
- €3.3Mn of **capex** invested in Q1 2019.
  - €0.3Mn of investment capex related to the injectable plant;
  - €0.6Mn of investment capex related to the Granada facility;
  - €1.3Mn of investment capex related to the Alcalá de Henares facility;
  - €0.1Mn of investment capex related to the San Sebastián de los Reyes facility;
  - €1.0Mn of maintenance capex and other capex
- €13.5Mn invested in Q1 2019 for the acquisition of Polaramine®.
- **FCF** decreased to €-19.0Mn mainly due to:
  - €14.3Mn increase in capex mainly because of the acquisition of Polaramine®;
  - €13.4Mn increase in “inventories” in Q1 2019 vs €6.3Mn increase in Q1 2018; and
  - €2.0Mn increase in “trade and other payables” in Q1 2019 vs €4.9Mn increase in Q1 2018.
  - The “trade and other receivables” line increased by €2.3Mn in Q1 2019 compared to an increase of €5.2Mn in Q1 2018.

# Financial debt

## Debt breakdown by source (%)



## Debt maturities by year (€Mn)



- **Debt with public administration** represented 23% of total debt, with 0% interest rate.
- As a result of the IRFS 16 application in Q1 2019,
  - **Gross cash position of €72.8Mn** as of 31 March 2019 vs €97.0Mn as of 31 December 2018.
  - **Net cash of €22.0Mn** as of 31 March 2019 vs €62.8Mn as of 31 December 2018.
- ROVI will put a proposal to the General Shareholders' Meeting to allocate the 2018 profit to, firstly, the reserves item on the Company's statement of financial position and, secondly, the distribution of a **dividend of 0.0798 euros per share** entitled to receive it, which would entail the distribution of approximately 25% of the consolidated net profit for 2018.

# News-flow 2019



## Specialty Pharma

Sales of biosimilar of Enoxaparin

Additional new products to be launched

Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar in 1 EU country (25 already granted)

## Toll manufacturing

New contracts to be announced

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

Risperidone ISM<sup>®</sup> final Phase III data will be available in Q2 2019

Letrozole ISM<sup>®</sup> Phase I data readout in Q2 2019

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