# FULL YEAR 2019 FINANCIAL RESULTS

FEBRUARY 2020

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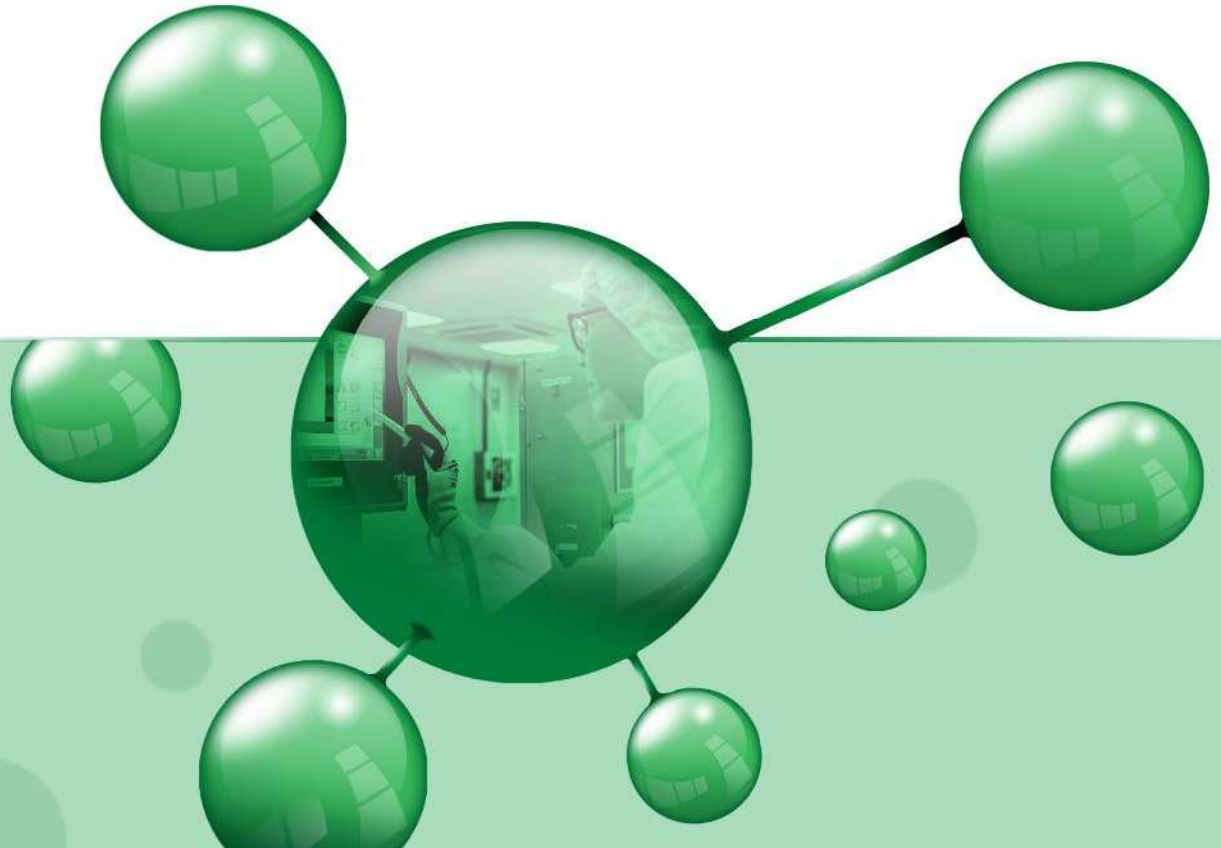
# Operating results

Juan López-Belmonte
Chief Executive Officer

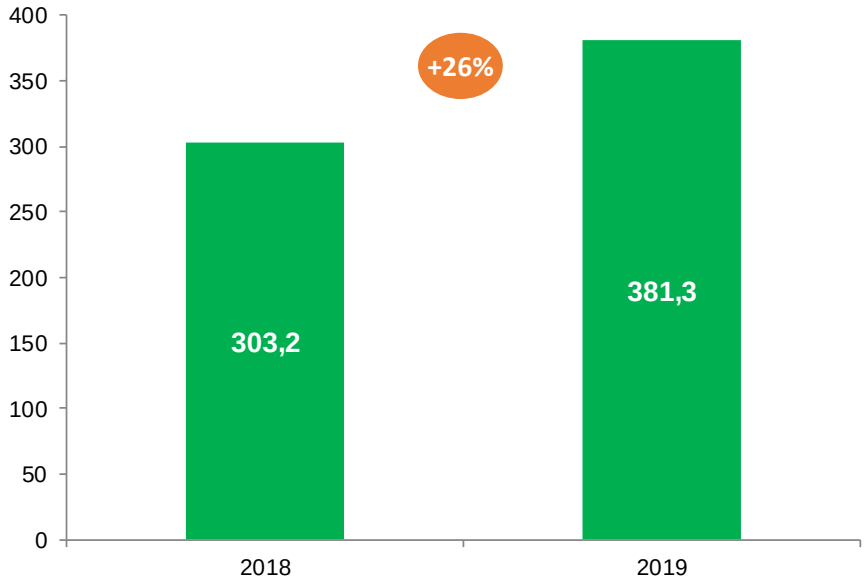


# 2019 financial results - Highlights

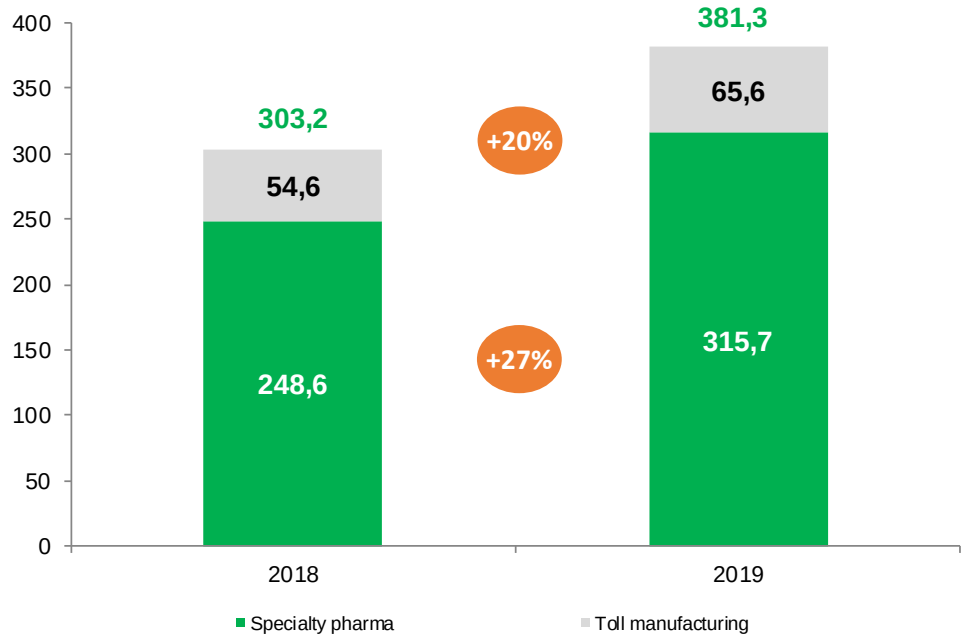
- **Operating revenue** increased by 26% to €381.3Mn in 2019, driven by the strength of the specialty pharmaceutical business, where sales rose 27%, strongly outperforming the market, and by the toll manufacturing business, which grew by 20%. Total revenue increased by 25% to €382.5Mn in 2019, more than tripling total revenue for 2007 when ROVI held its IPO.
- **For 2020, ROVI expects a mid-single-digit growth rate for the operating revenue.**
- Sales of the **Low Molecular Weight Heparin** (LMWH) **franchise** increased by 46% to €177.6Mn in 2019. **LMWH sales represented 47%** of operating revenue in 2019 compared to 40% in 2018. **Sales of the Enoxaparin biosimilar** amounted to **€80.9Mn** in 2019 and **positive performance of Bemiparin (+6%** to €96.8Mn).
- Sales of **Neparvis**, launched in December 2016, increased 62% to €22.0Mn in 2019.
- ROVI filed its application for **marketing authorisation for Doria®** with the European health authorities, the European Medicines Agency (EMA), through the Centralised Procedure on 27 December, 2019. After passing the validation phase satisfactorily, the dossier **was admitted for evaluation** on 30 January, 2020.
- On the 1st 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 December 31, 2019 were:
    - Recognition of assets under the "Property, plant and equipment" caption (non-current assets) for an amount of €20.6Mn.
    - Increase in debt under the captions "Financial liabilities for non-current and current leases" of €17.4Mn and €3.5Mn, respectively.
    - Lower operating expenses and, consequently, an increase of EBITDA of €3.6Mn, since operating lease payments were recognized under the SG&A caption.
    - Higher expense for the depreciation of the right-of-use asset of €3.6Mn.
    - An increase of €0.3Mn in the finance costs of the lease liabilities.
- **EBITDA** increased by 106%, from €29.5Mn in 2018 to €60.9Mn in 2019, reflecting a 6.2 pp rise in the EBITDA margin to 16.0% in 2019.
- **Net profit** increased by 119%, from €17.9Mn in 2018 to €39.3Mn in 2019. **In 2019, ROVI achieved the highest EBITDA and net profit figures in its history.**
- ROVI will propose to the Shareholders General Meeting a **dividend of 0.1751 euros per share** with dividend rights on 2019 earnings. This proposed dividend would mean an increase of 119% compared to the dividend on 2018 earnings (€0.0798/share) and represents a 25% pay out.

# Growth driven by specialty pharma and toll manufacturing businesses…

## Total operating revenue (€Mn)



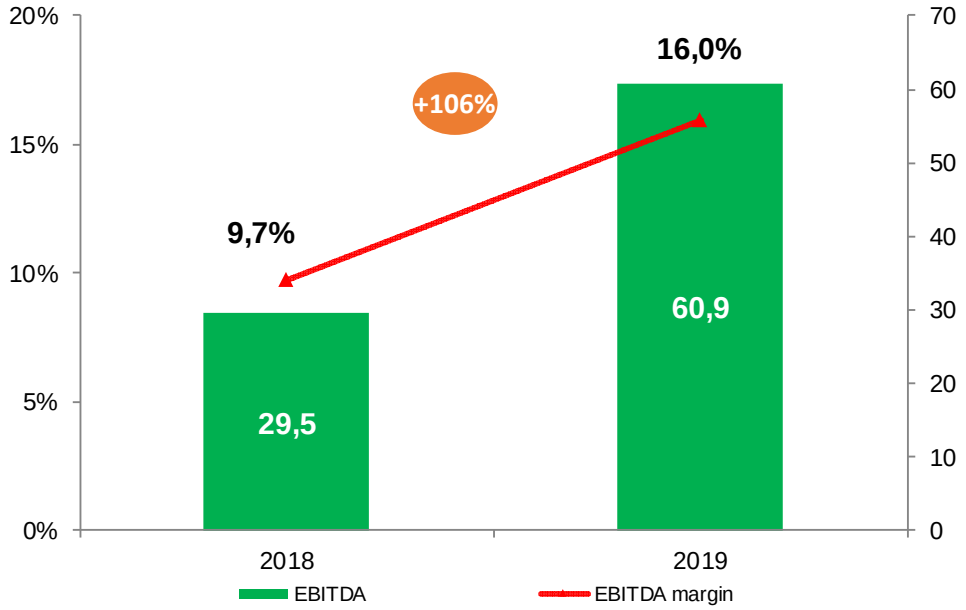

## Operating revenue growth by category (€Mn)



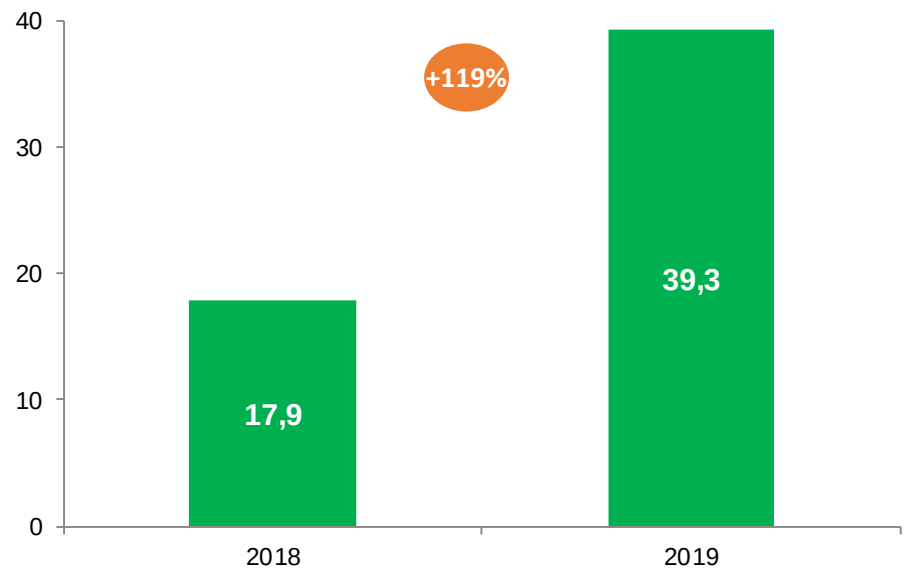

- **Operating revenue increased by 26%** to €381.3Mn in 2019 driven by the strength of:
  - the specialty pharmaceutical business, where sales rose 27%; and
  - the toll manufacturing business, which grew by 20%.
- ROVI forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in 2019, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 3.0%.

# …with high profitability

## EBITDA (€Mn) and EBITDA margin (%)



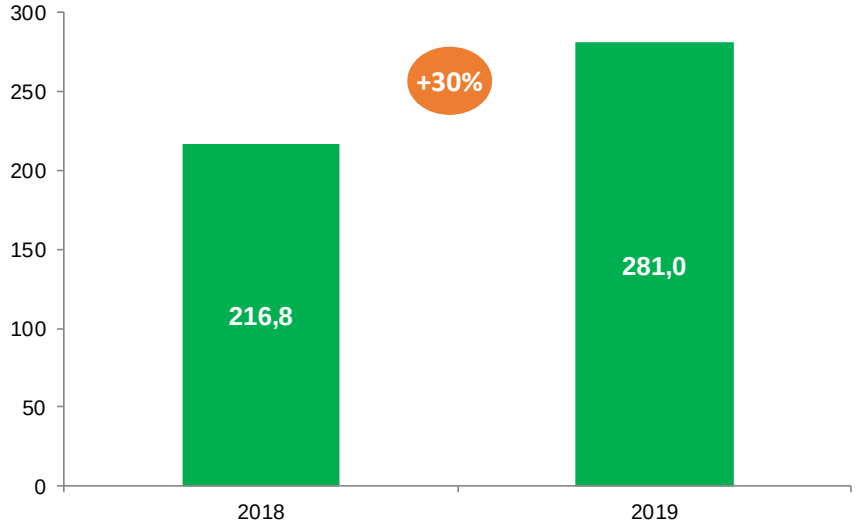

## Net profit (€Mn)



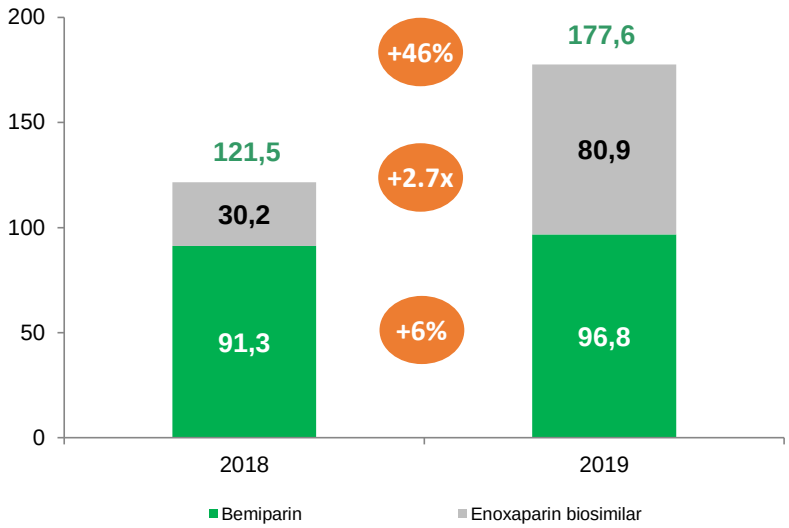

- In 2018, EBITDA was affected by non-recurring expenses of €1.1Mn.
- As a result of the IFRS 16 application, EBITDA was positively impacted by €3.6Mn in 2019.
- **EBITDA increased by 106%**, from €29.5Mn in 2018 to €60.9Mn in 2019, reflecting a 6.2 percentage point rise in the EBITDA margin to 16.0% in 2019.
- **Net profit** increased by 119%, from €17.9Mn in 2018 to €39.3Mn in 2019.

# LMWH, leading the specialty pharmaceutical business

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

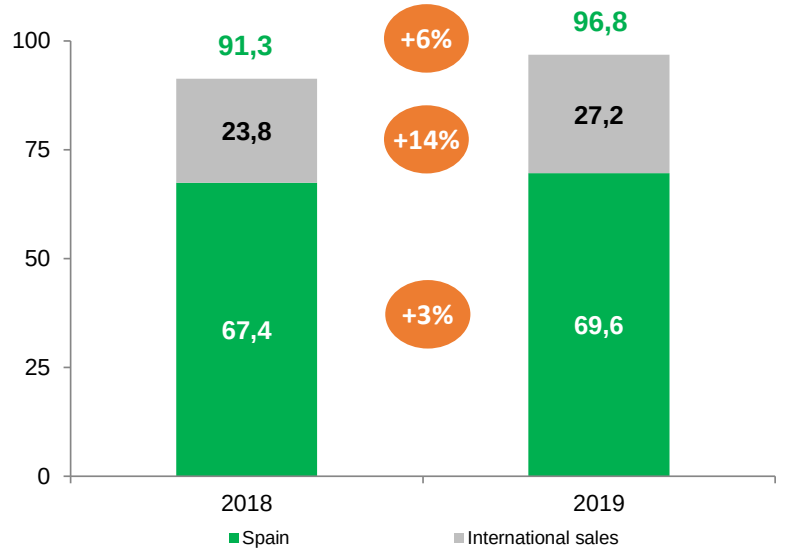



## LMWH franchise sales (€Mn)




- Sales of **prescription-based pharmaceutical products increased by 30%** to €281.0Mn in 2019.
- Sales of the **Low Molecular Weight Heparin** (LMWH) **franchise** (Enoxaparin biosimilar and Bemiparin) **increased by 46%** to €177.6Mn in 2019.
- **LMWH sales represented 47% of operating revenue in 2019 compared to 40% in 2018.**
  - **Sales of the Enoxaparin biosimilar** amounted to **€80.9Mn** in 2019.
  - **Bemiparin total sales increased by 6%** to €96.8Mn in 2019:
    - **Sales in Spain increased 3%** to €69.6Mn.
    - **International sales increased by 14%** to €27.2Mn.

## Bemiparin Sales Ramp-up (€Mn)

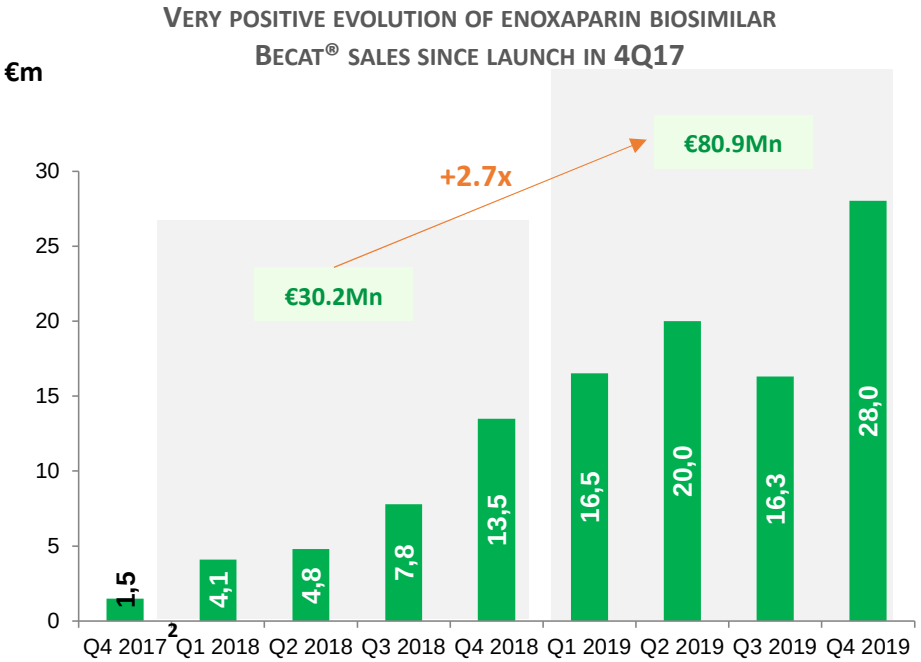


# Strong growth potential of Enoxaparin Biosimilar Becat®

## 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**[1]**, Austria, Latvia and Estonia** in 2018; and in **Portugal, Poland, Costa Rica, Finland and Sweden** in 2019.
- Newly-established European sales offices provide **pan-European infrastructure** that is **highly leverageable for further growth** of ROVI's heparin franchise and broader portfolio.

### Enoxaparin Biosimilar Becat® Sales Ramp-up




## Well-Established Network to Minimize Time-to-Market

Direct Marketed in **Germany, UK, Italy, Spain, Portugal** and **Poland**

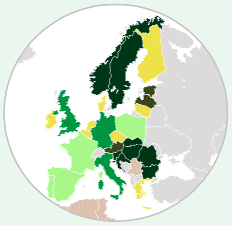
Approved in **26 countries** in Europe and 5 in the Rest of the World

Launched in **13 countries**

Pending approval in **71 countries**

### Stage I of Commercial Strategy

**Focus on Europe…**



**…the largest enoxaparin market with €0.9bn sales**[3]

**ROVI will directly market enoxaparin biosimilar Becat® in 7 European countries…**

**…which account for c.75% of the European market**[4]

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

**50-70%** Market Share[5]

**…of the reference product market**

### Stage II of Commercial Strategy

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

**€0.5bn** 2019 Market Sales[3]

**13.9%** 2019 Market Growth[3]

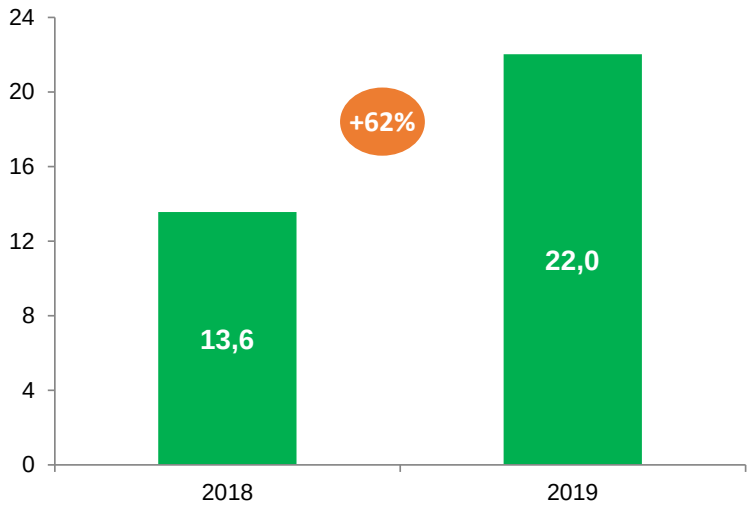
Already Signed Out-Licensed Agreements: **85 Countries**

*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.*

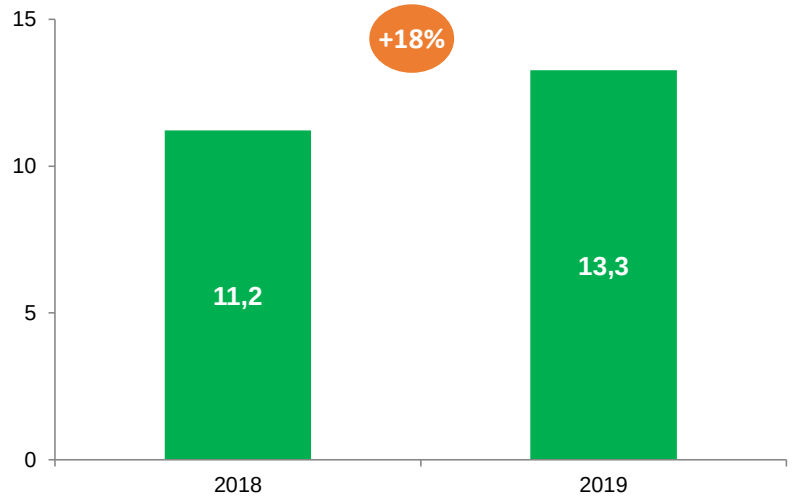
1. ROVI has started to sell Becat® in France though Biogaran
2. Becat® 4Q 2017 sales include sales throughout September. As the product was launched that month, sales were negligible.
3. Estimates based on Sanofi-Aventis reported 2019 sales.
4. QuintilesIMS, 2015.
5. Technavio 2016 biosimilars report.

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

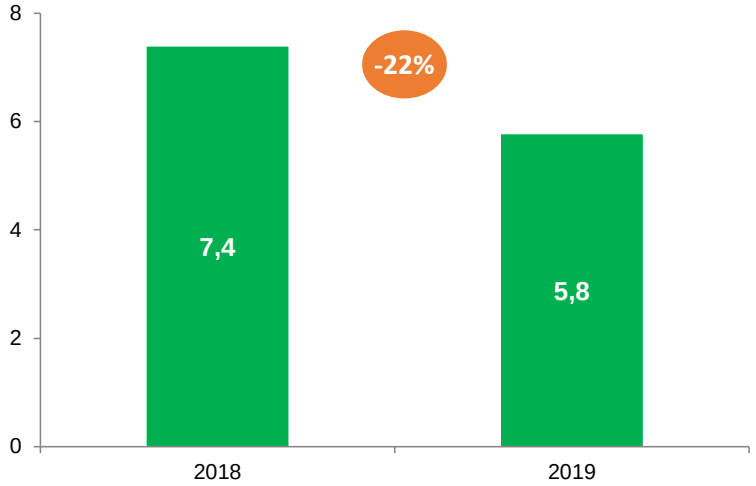
## Neparvis sales (€Mn)




## Volutsa sales (€Mn)




## Medicebran and Medikinet sales (€Mn)

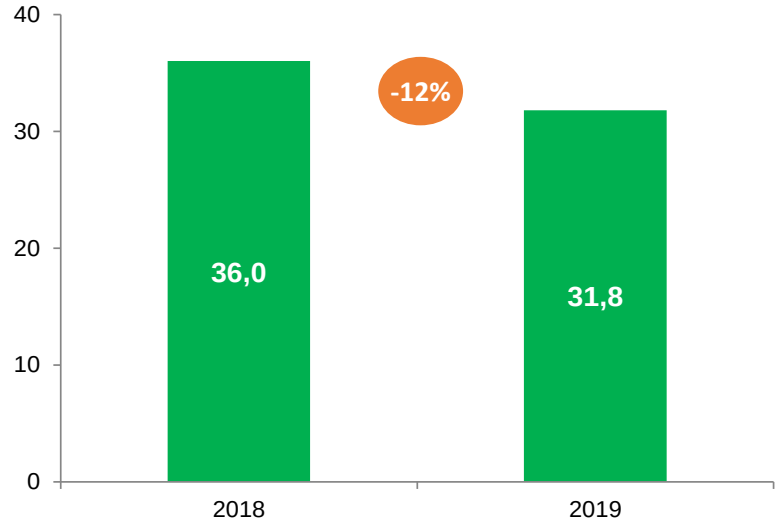



- Sales of **Neparvis**, a specialty product from Novartis launched in December 2016, **increased by 62% to €22.0Mn** in 2019, from €13.6Mn in 2018.
- Sales of **Volutsa**, launched in Spain in February 2015, **increased by 18%** to €13.3Mn in 2019.
- Sales of **Medicebran and Medikinet**, products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, decreased 22% to €5.8Mn in 2019.

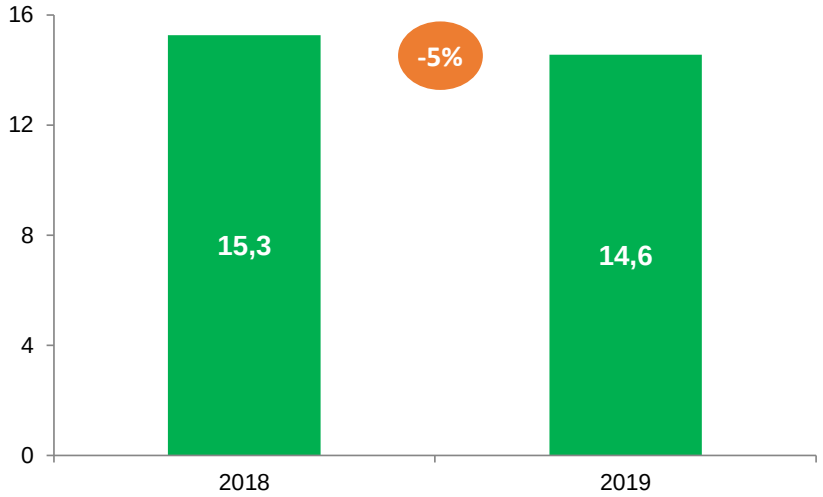
*Neparvis is a specialty product from Novartis indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction.*
*Volutsa is a specialty product from Astellas Pharma indicated for the treatment of moderate to severe storage symptoms and voiding symptoms 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)

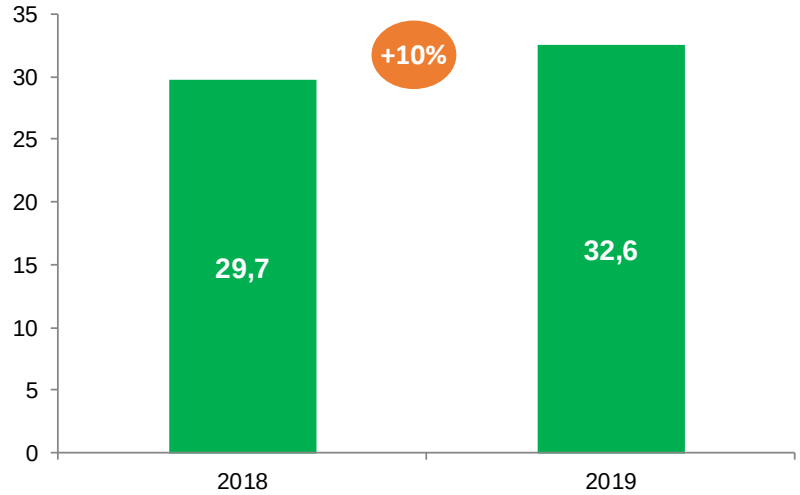
## Absorcol, Vytorin and Orvatez sales (€Mn)




## Hirobriz and Ulunar sales (€Mn)




## Contrast imaging agents sales (€Mn)

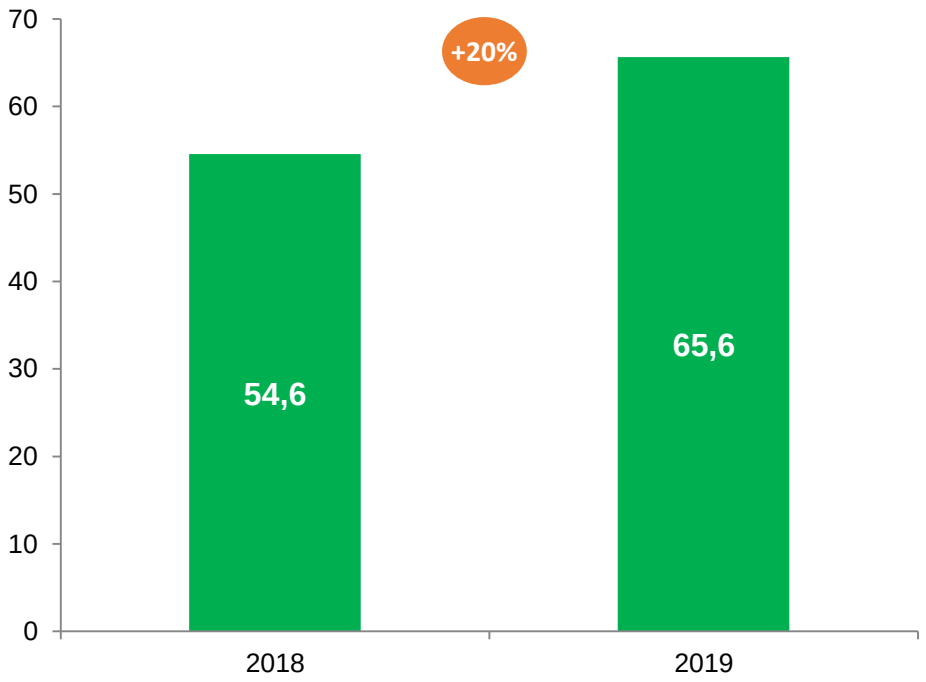



- Sales of **Vytorin®, Orvatez®** and **Absorcol®** decreased by 12% to €31.8Mn in 2019. In 2Q 2018, the active principle ezetimibe went out of patent and the price of Absorcol® was reduced. Likewise, generics formulated with ezetimibe and simvastatin were marketed in the same period, so the price of Vytorin® was reduced to be competitive.
- Sales of **Hirobriz and Ulunar**, both products for patients with COPD, launched in Spain in Q4 2014 decreased by 5% to €14.6Mn in 2019.
- **Contrast imaging agents and other hospital products** increased by 10% to €32.6Mn in 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 increased by 20% to 65.6 million euros in 2019 as a result of the redirection of our toll manufacturing activities strategy towards high-value-added products.
- In November 2019, the toll manufacturing management units, ROVI Contract Manufacturing and Frosst Ibérica, merged into a single entity, ROVI Pharma Industrial Services, which furnishes manufacturing services with the highest degree of quality and competitiveness. The total integration of the production processes is expected to allow the company to attain greater synergies and levels of efficiency in its industrial operations.
- Likewise, by the end of 2020, ROVI expects the toll manufacturing business to have increased by a low-double-digit percentage.

# 2 ISM® Platform Opens Up New Avenues of Growth for ROVI

## Overview

- Internally-developed and patented innovative drug-release technology, ISM®[1], 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

| Product | Potential Indication | Current Situation | | | | Key Milestones |
|---|---|---|---|---|---|---|
| | | Non-Clinical | I | II | III | |
| DORIA® Risperidone, monthly | Schizophrenia | | | | ■ | Positive results from Phase III. Filed in Europe. |
| Letrozole ISM® Long acting Letrozole | Breast Cancer | | | ■ | | Phase I started in November 2017 |
| Risperidone, quarterly | Schizophrenia | | ■ | | | |

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

★ Multiple FDA / GMP approved facilities to support the platform

## Key Company Highlights of ISM® Platform

| | | | |
|---|---|---|---|
| 1 | Predictability | Pop PK[2] 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)<br>▪ Strong IP<br>▪ Manufacturing capabilities | • Protected technology<br>• Fully integrated manufacturing plants ✓ |

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

# Guidance 2020

**2020 operating revenue growth rate**

**Mid-single-digit**

## THE KEY GROWTH LEVERS IN 2020

### Specialty Pharma Business

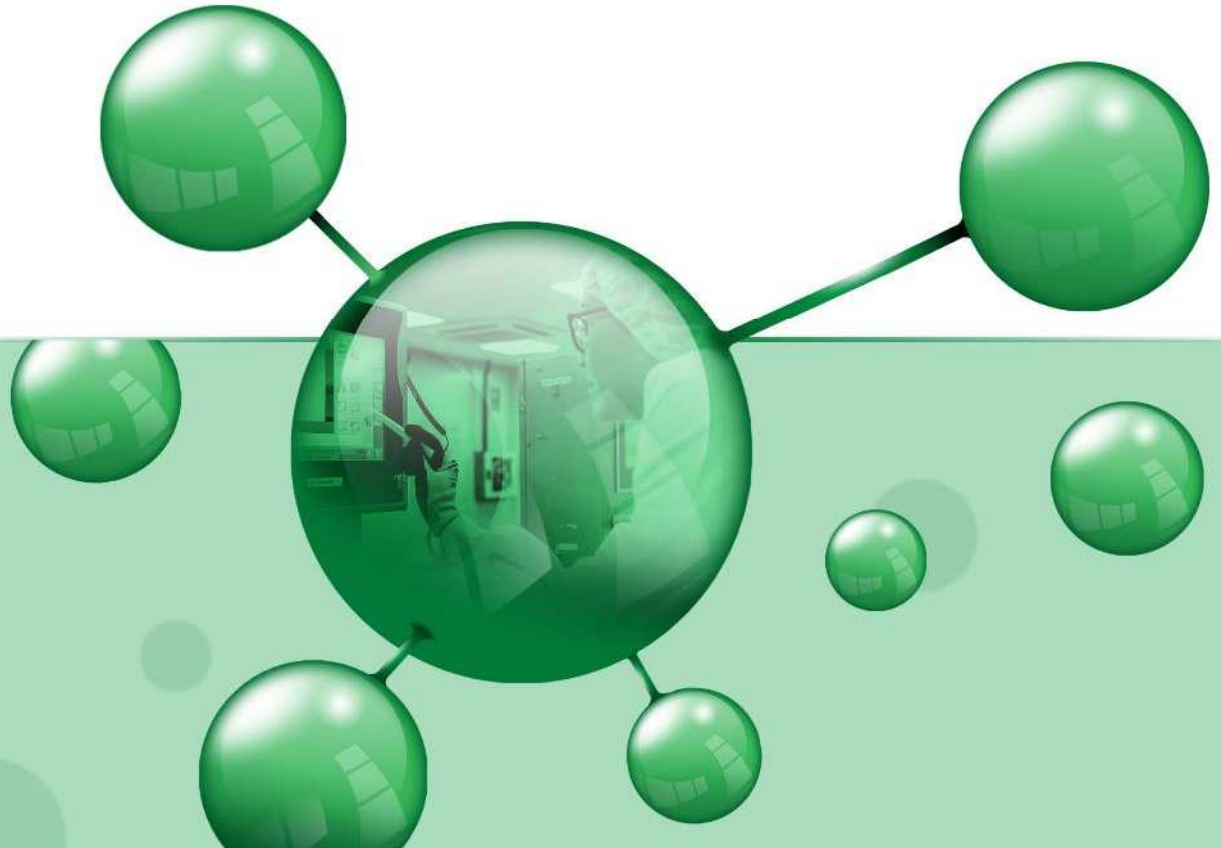
- ✓ Bemiparin
- ✓ Biosimilar of Enoxaparin
- ✓ Launches such as Neparvis and Volutsa
- ✓ Existing portfolio of specialty pharmaceuticals
- ✓ New acquisitions (Falithrom, Polaramine and sodium heparin)

### Toll Manufacturing Services

- ✓ Spare capacity in the manufacturing plants
- ✓ New customers to be acquired

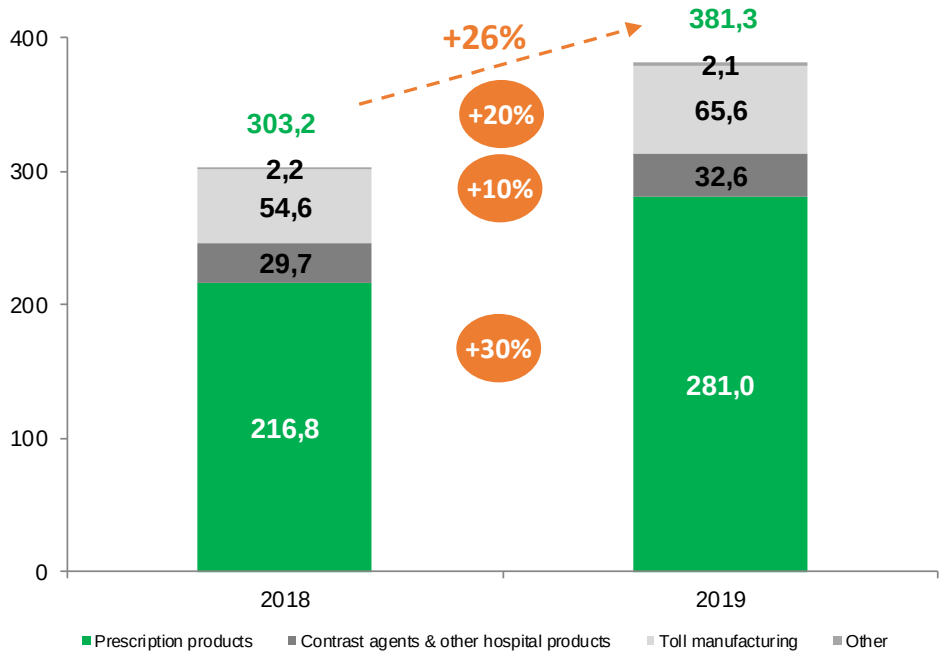
# Financial results

Javier López-Belmonte
Chief Financial Officer

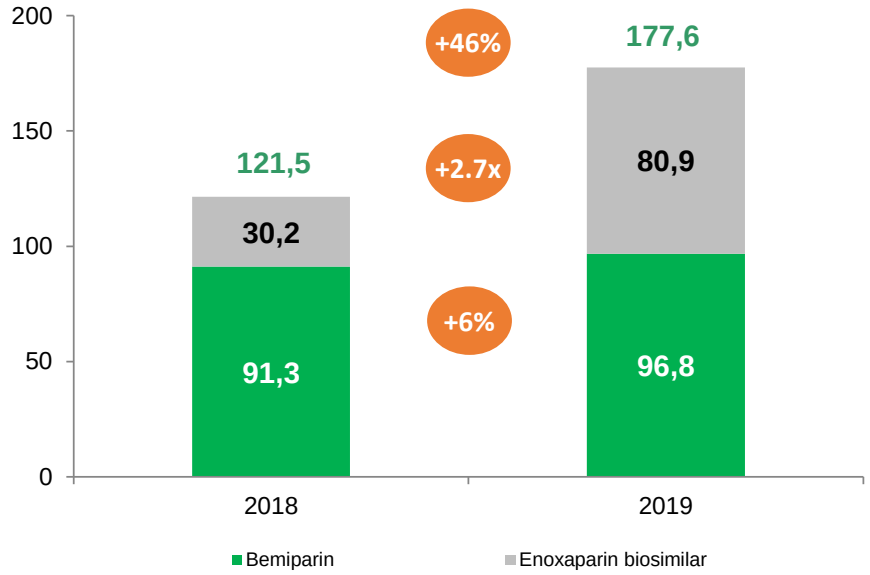


# Good revenue level with outstanding LMWH franchise growth

## Total operating revenue (€Mn)

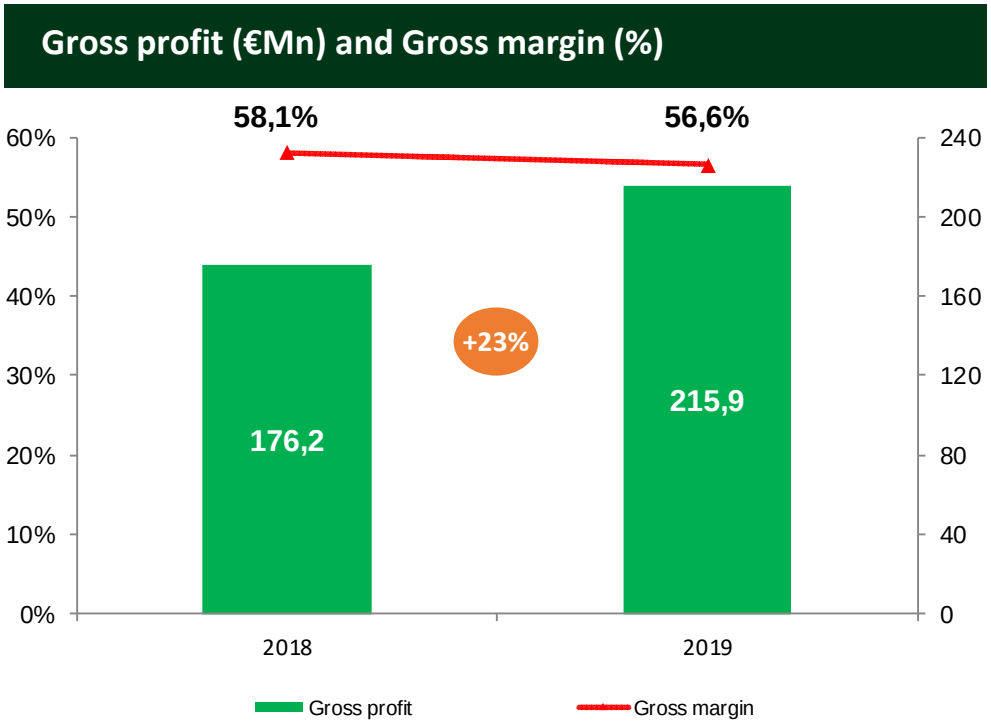



## LMWH franchise sales (€Mn)




- **Operating revenue** increased by 26% to €381.3Mn, achieved on:
  - 30% growth in prescription-based products;
  - 10% growth in contrast agents and other hospital products;
  - 20% increase in toll manufacturing; and
  - OTC and other revenues decreased by 3%.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** increased by 46% to €177.6Mn in 2019, representing 47% of operating revenue in 2019 vs 40% in 2018.
  - **Enoxaparin biosimilar sales increased 2.7 times to €80.9Mn** and Bemiparin sales increased by 6%.

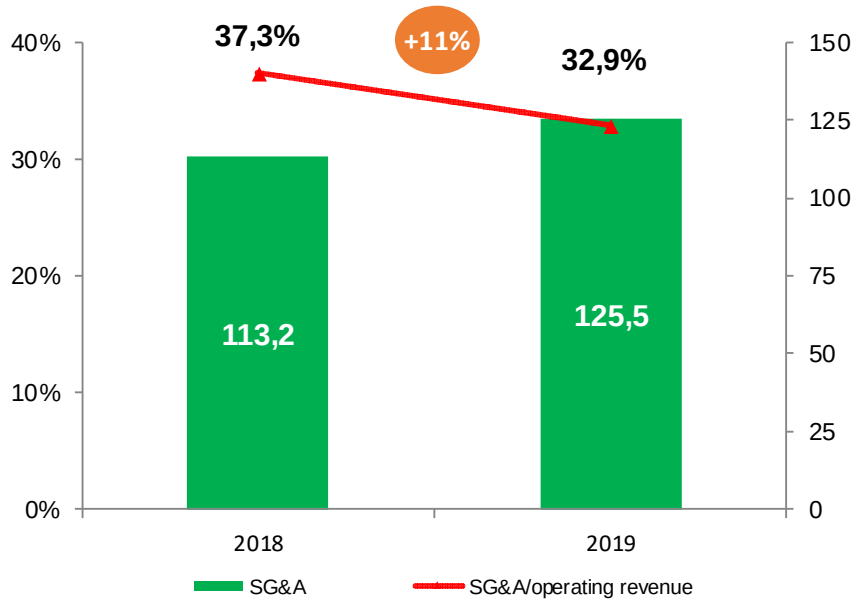
# Gross margin impacted by the increase of enoxaparin biosimilar sales and the increase of LMWH raw material prices



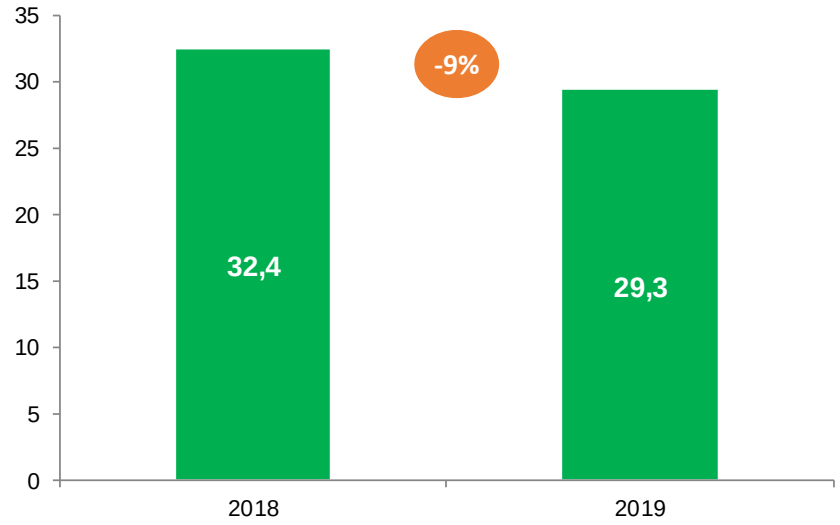

- **Gross profit** increased by 23% to €215.9Mn in 2019, the gross margin showing a decrease of 1.5 percentage points from 58.1% in 2018 to 56.6%, mainly due to:
  - the increase of Enoxaparin biosimilar sales, which added lower margins in 2019 after the launch of the product in five new markets; and
  - the increase in the LMWH raw material prices (due to the African swine fever), which, in 2019, were running around 44% over 2018 prices.
- ROVI expects this upward trend in low-molecular-weight heparin raw material prices to increase during 2020. This, together with the uncertainty about the potential impact of the new coronavirus, makes the impact of these issues on the 2020 gross margin unpredictable at the present date.

# Cost control along with commitment to R&D

## SG&A expenses (€Mn)



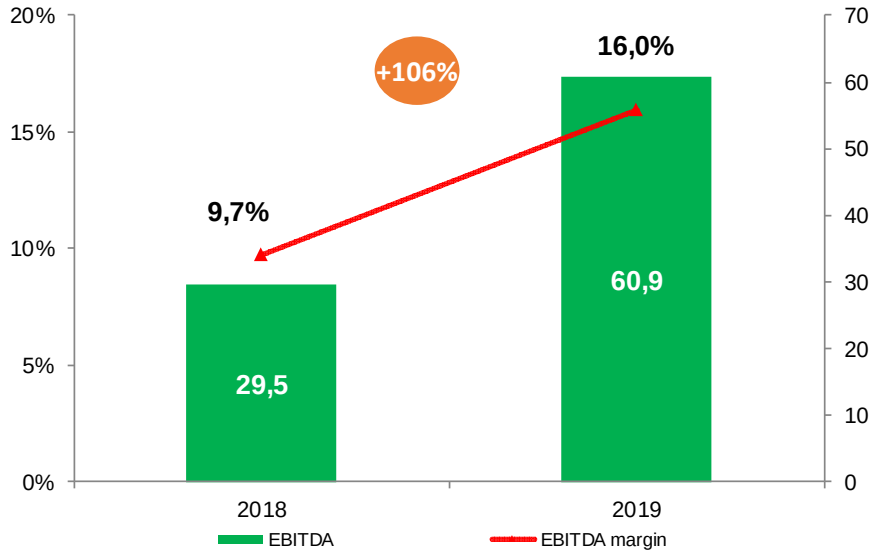

## R&D expenses (€Mn)



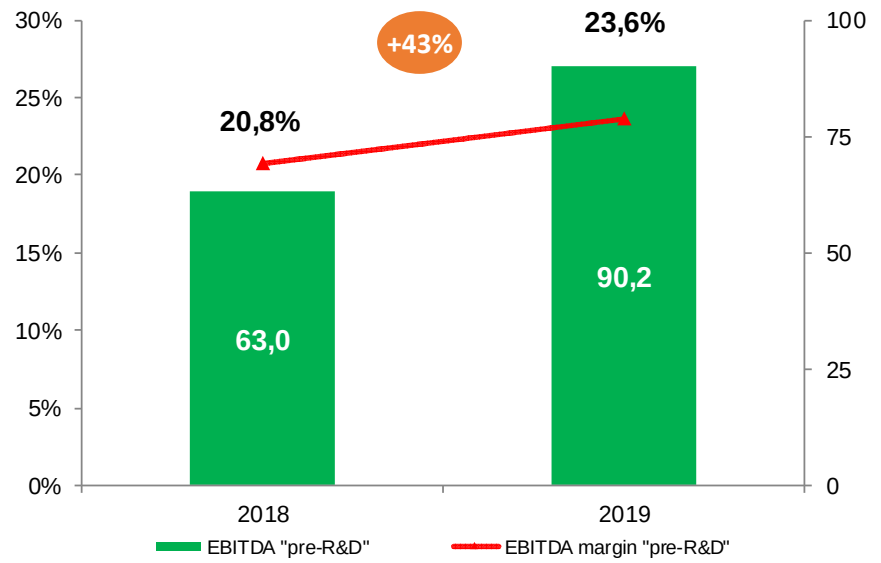

- **SG&A expenses rose 11%** to €125.5Mn in 2019 mainly due to:
  - international subsidiaries expenses, which amounted to €9.0Mn compared to €7.4Mn in 2018;
  - the increase of 1.6 million euros in marketing expenses related to the enoxaparin biosimilar promotion in Spain; and
  - a larger volume of enoxaparin biosimilar production.
  - In 2020, expenses related to international subsidiaries are expected to be around 10 million euros.
- **R&D expenses decreased 9%** to €29.3Mn in 2019. These expenses are related to the development of the Risperidone-ISM® Phase III trial and the Letrozole-ISM® Phase I trial.

# EBITDA

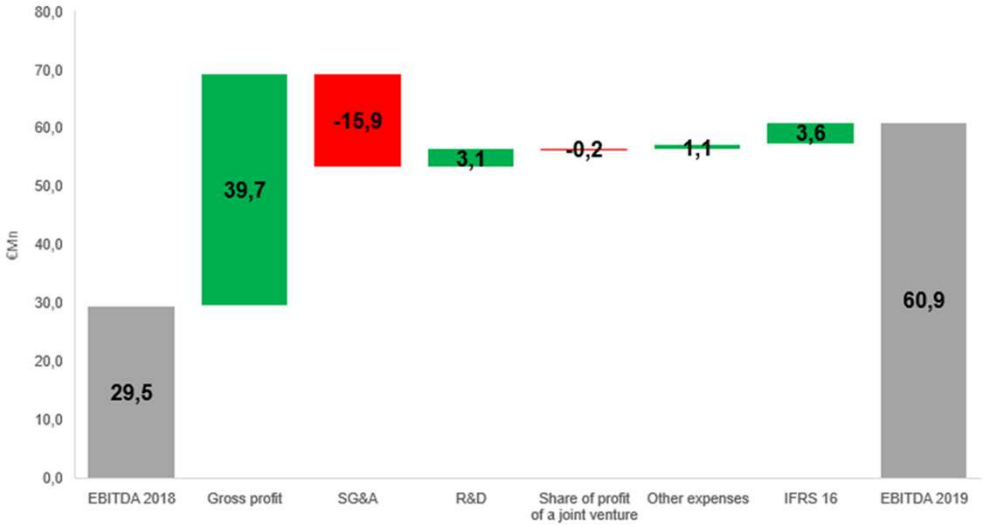
## EBITDA (€Mn) and EBITDA margin (%)




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




## 2019 EBITDA impacts (€Mn)

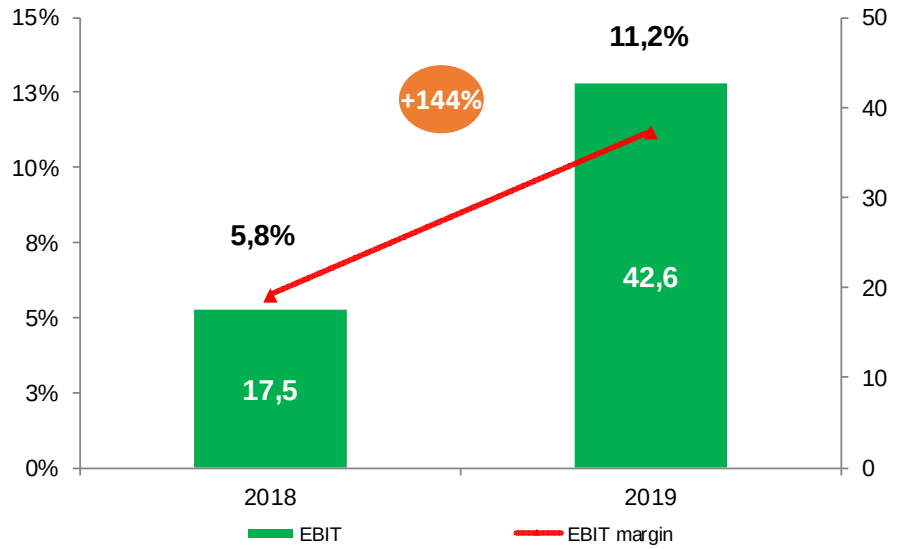



- In 2018, EBITDA was affected by non-recurring expenses of €1.1Mn, linked to a substantial change to Frosst Ibérica employees working conditions.
- **EBITDA** increased by 106% to €60.9Mn in 2019, reflecting a 6.2 pp rise in the EBITDA margin, which was up to 16.0% in 2019 from 9.7% in 2018.
- **EBITDA "pre-R&D"** (w/o R&D and non recurring expenses) increased by 43% to €90.2Mn in 2019, reflecting a 2.9 pp rise in the EBITDA margin to 23.6% in 2019. Likewise,
  - recognising the same amount of R&D expenses in 2019 as in 2018 and excluding the impact of the non recurring expenses in 2018, EBITDA would have increased by 89% to €57.8Mn, reflecting a 5.1 pp rise in the EBITDA margin to 15.2% in 2019.

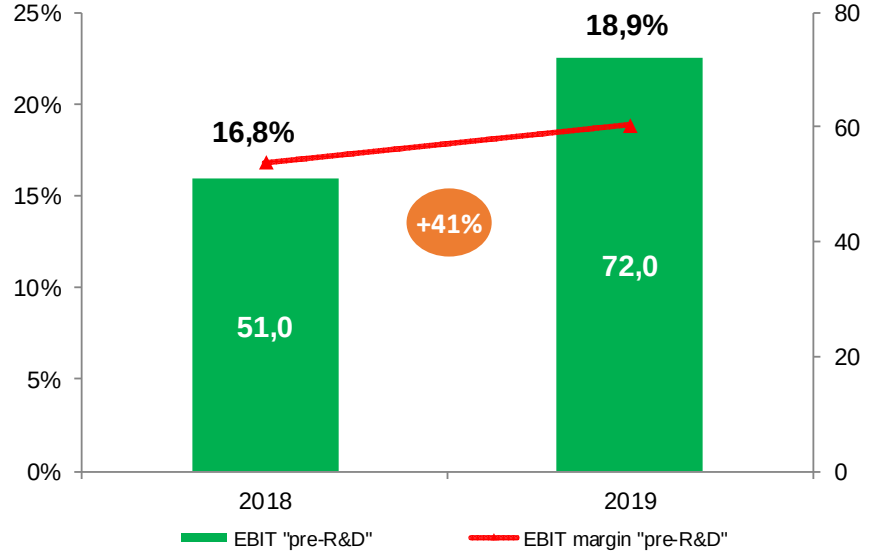
Note: EBITDA "pre-R&D" calculated excluding R&D expenses in 2019 and 2018 and the impact of non recurring expenses in 2018

# EBIT

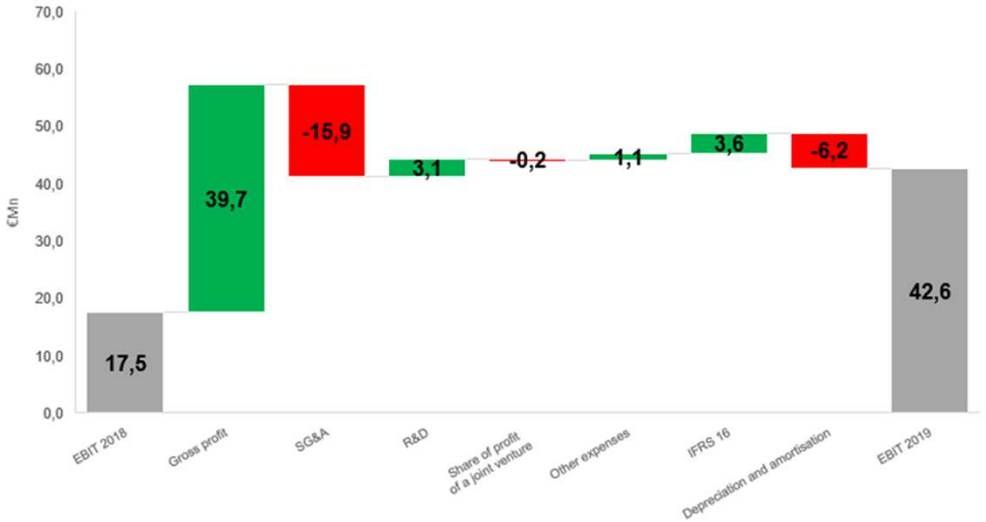
## EBIT (€Mn) and EBIT margin (%)




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




## 2019 EBIT impacts (€Mn)

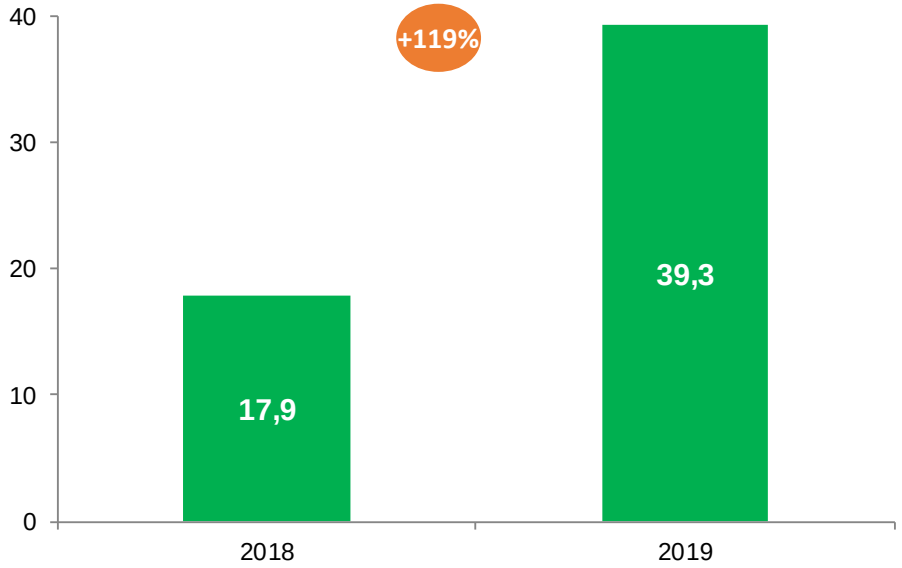



- As a result of the IFRS 16 application and the new PP&E and intangible assets purchases made during the last twelve months**, depreciation and amortisation** expenses increased by 51% to €18.2Mn in 2019.
- **EBIT** increased to €42.6Mn in 2019, reflecting a 5.4 pp rise in the EBIT margin, which was up to 11.2% in 2019.
- **EBIT "pre-R&D"** (w/o R&D and non recurring expenses) increased by 41%, from €51.0Mn in 2018 to €72.0Mn in 2019, reflecting a 2.1 pp rise in the EBIT margin to 18.9% in 2019. Likewise,
  - recognising the same amount of R&D expenses in 2019 as in 2018 and excluding the impact of the non recurring expenses in 2018, EBIT would have increased by 113% to €39.6Mn, reflecting a 4.3 pp rise in the EBIT margin.

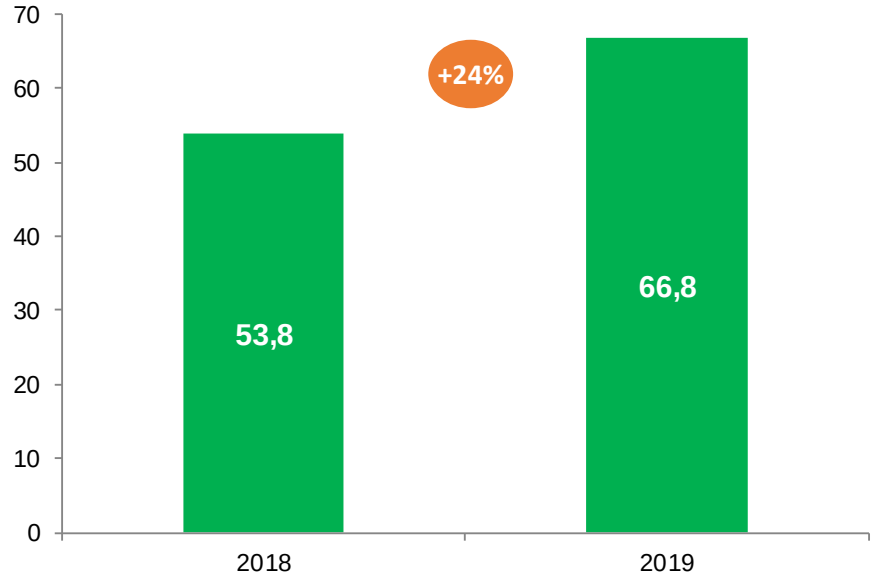
Note: EBIT "pre-R&D" calculated excluding R&D expenses in 2019 and 2018 and the impact of non recurring expenses in 2018

# Net profit

## Net profit (€Mn)




## Net profit "pre-R&D" (€Mn)

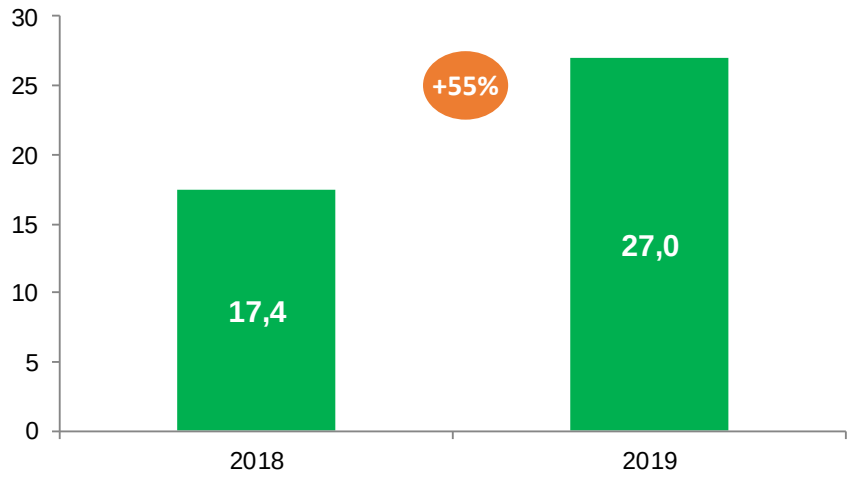



- **Net profit** increased to €39.3Mn in 2019, a 119% rise compared to 2018.
- **Net profit "pre R&D"** (w/o R&D and non recurring expenses) increased by 24%, from €53.8Mn in 2018 to €66.8Mn in 2019. Likewise,
  - recognising the same amount of R&D expenses in 2019 as in 2018 and excluding the impact of the non recurring expenses in 2018, net profit would have increased by 91% to €36.4Mn.
- The **effective tax rate** was 6.2% in 2019 (negative income tax of €2.6Mn), compared to -7.3% in 2018 (positive income tax of €1.2Mn), mainly due to the decrease in R&D expenses in 2019 in comparison with the previous year, which led to lower research and development tax credits.
- As of 31 December 2019, **negative tax bases** amounted to €34.9Mn, of which €8.3Mn will be used in the 2019 income tax.

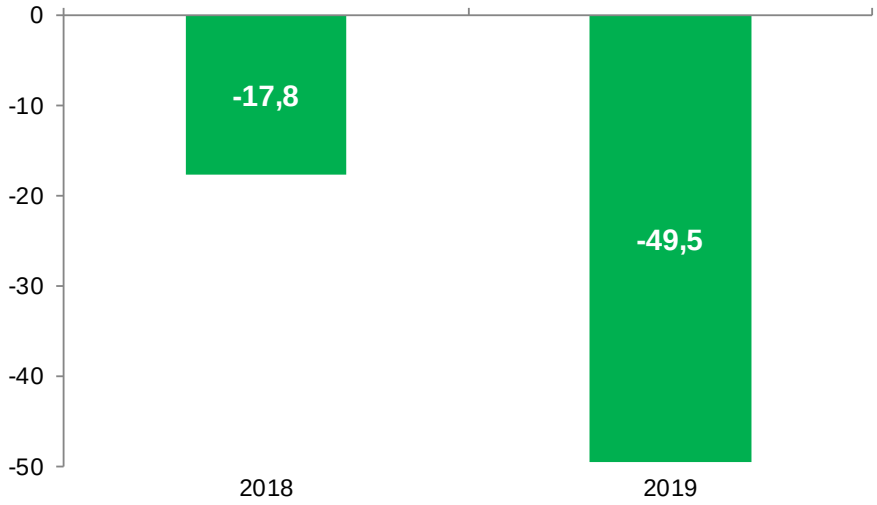
Note: Net profit "pre-R&D" calculated excluding R&D expenses in 2019 and 2018 and the impact of non recurring expenses in 2018. Same effective tax rate as the reported net profit.

# Capital expenditure and Free Cash Flow

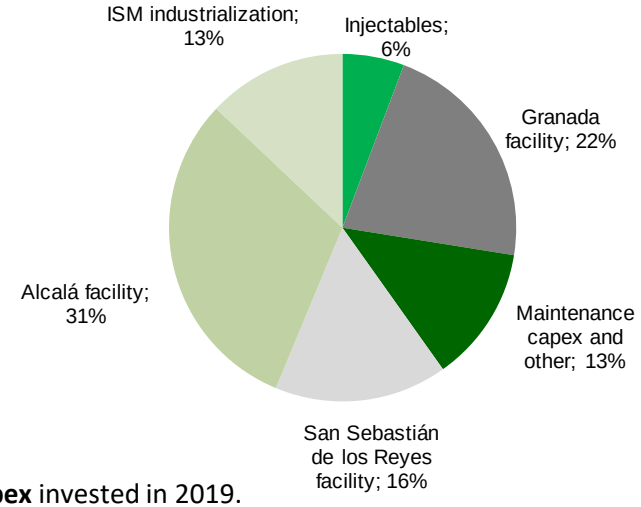
## Capex evolution (€Mn)




## Free Cash Flow (€Mn)




## Capex breakdown (%)

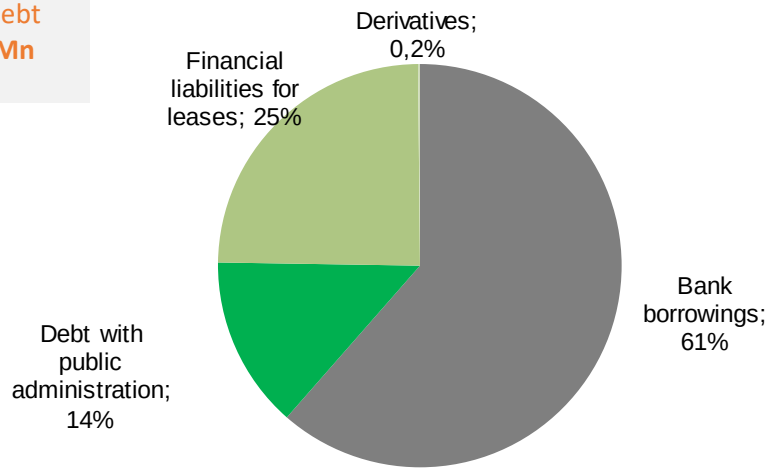



- €27.0Mn of **capex** invested in 2019.
  - €1.6Mn of investment capex related to the injectable plant;
  - €5.9Mn of investment capex related to the Granada facility;
  - €8.3Mn of investment capex related to the Alcalá de Henares facility;
  - €4.3Mn of investment capex related to the San Sebastián de los Reyes facility;
  - €3.5Mn of investment capex related to the ISM® industrialization; and
  - €3.4Mn of maintenance capex and other capex
- €13.5Mn invested in 2019 for the acquisition of Polaramine®.
- **FCF** decreased to €-49.5Mn mainly due to:
  - €14.1Mn increase in capex mainly because of the acquisition of Polaramine®;
  - €67.2Mn increase in "inventories" in 2019 vs €21.3Mn increase in 2018;
  - €20.4Mn increase in "trade and other receivables" in 2019 vs €9.6Mn increase in 2018;
  - €24.0Mn increase in "trade and other payables" in 2019 vs €6.5Mn increase in 2018; and
  - €25.2Mn increase in profit before income tax.

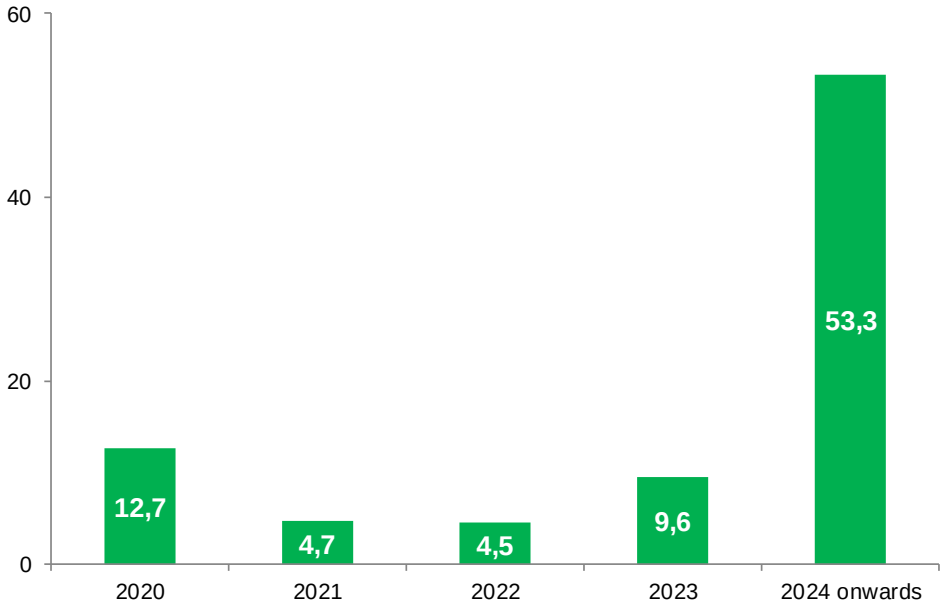
# Financial debt

## Debt breakdown by source (%)

Total debt
**€84.8Mn**




## Debt maturities by year (€Mn)




- **Debt with public administration** represented 14% of total debt, with 0% interest rate.
- **Gross cash position of €68.9Mn** as of 31 December 2019 vs €97.0Mn as of 31 December 2018.
- **Net debt of €15.9Mn** as of 31 December 2019 vs net cash of €62.8Mn as of 31 December 2018.
- ROVI will pay a **dividend** of 0.1751 euros per share with dividend rights on 2019 earnings if the Shareholders General Meeting approves the application of the 2019 profit, under proposal of ROVI's Board of Directors. This proposed dividend would mean an increase of 119% compared to the dividend on 2018 earnings (€0.0798/share) and represents a 25% pay out.

# News-flow 2020

| | |
|---|---|
| **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 71 countries outside Europe |
| **Toll manufacturing** | New contracts to be announced |
| **ISM® technology platform** | Risperidone ISM® expected to be filed in USA in H2 2020<br>Risperidone ISM® final Phase III data will be presented in scientific congresses |
| | Next steps of Letrozole ISM® to be discussed with regulatory authorities in 2020 |

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