



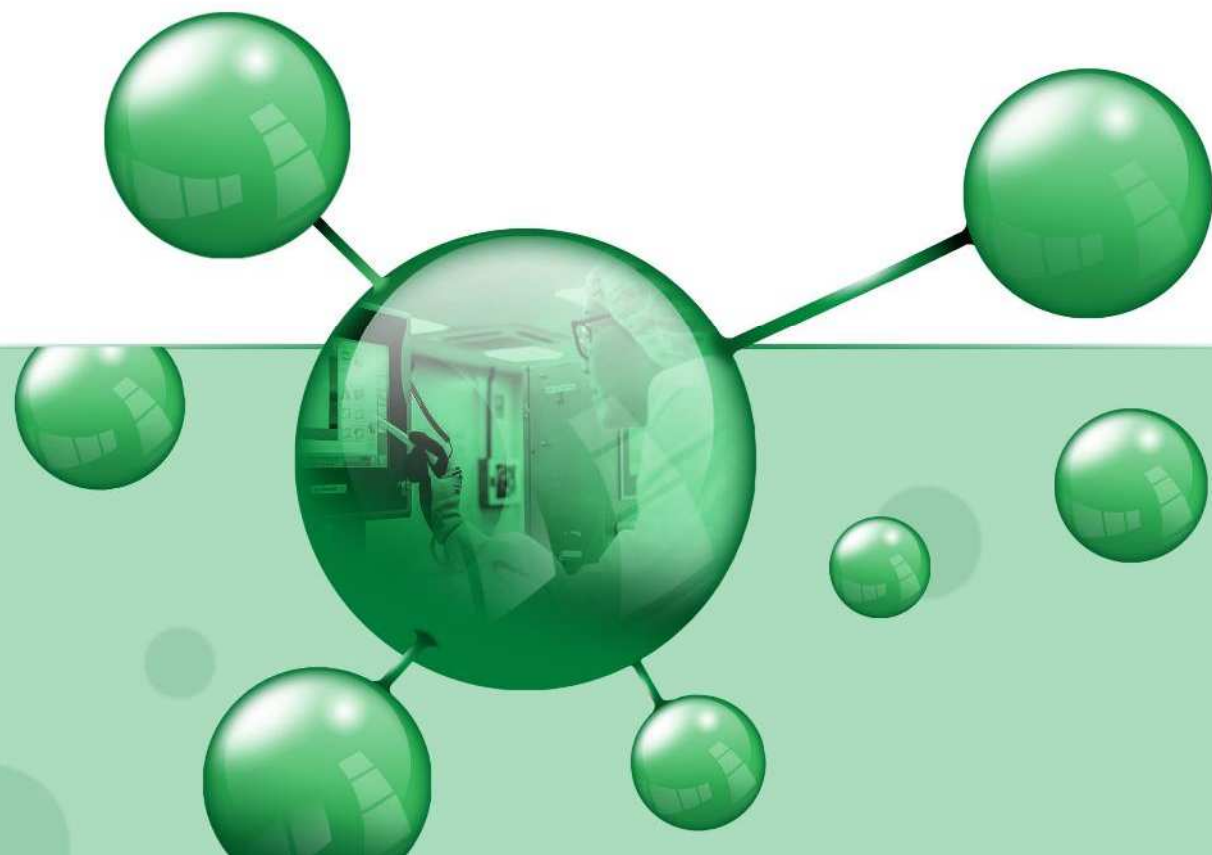
FIRST NINE MONTHS OF 2019 FINANCIAL  
RESULTS  
NOVEMBER 2019



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# Operating results





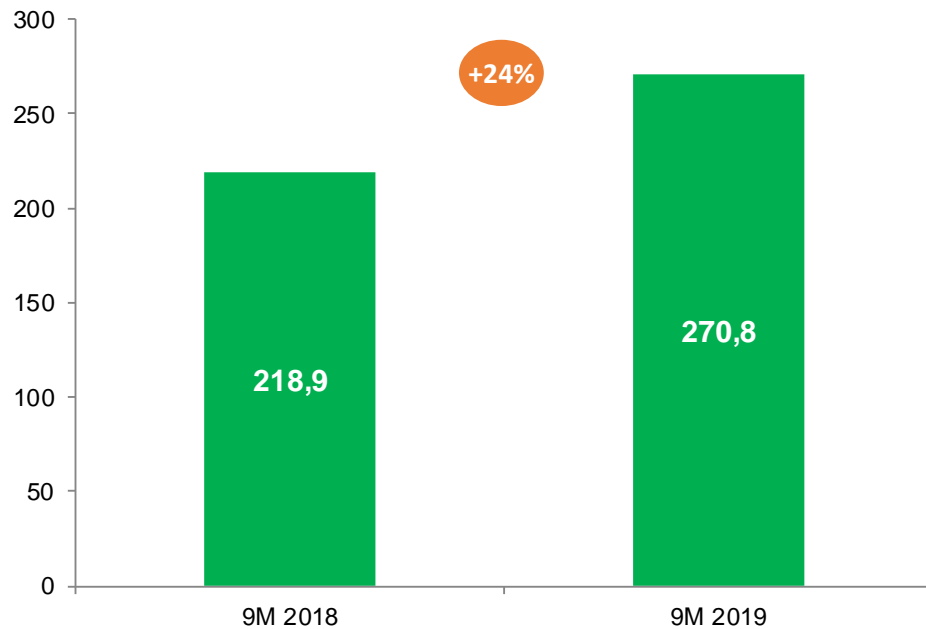
## 9M 2019 financial results - Highlights

- **Operating revenue** increased by 24% to €270.8Mn in 9M 2019, driven by the strength of the specialty pharmaceutical business, where sales rose 25%, strongly outperforming the market, and by the toll manufacturing business, which grew by 18%. Total revenue increased by 23% to €271.6Mn in 9M 2019.
- **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 44% to €122.6Mn in 9M 2019. **LMWH sales represented 45%** of operating revenue in 9M 2019 compared to 39% in 9M 2018. **Sales of the Enoxaparin biosimilar** amounted to **€52.9Mn** in 9M 2019 and **positive performance of Bemiparin in Spain (+11%** to €55.1Mn).
- Sales of **Neparvis**, launched in December 2016, increased 63% to €15.2Mn in 9M 2019.
- On July 5, 2019, ROVI informed about **the conclusion of the PRISMA-3 and BORIS studies**, thus completing the Clinical Trial Program that will support the application for the marketing authorisation for Doria® for the treatment of schizophrenia in the European Union and United States, in a first phase, and, subsequently, in other countries.
- **Preliminary data of the Letrozole ISM® phase I clinical trial (the LISA-1 study) confirm that this ISM® formulation provides a prolonged release of letrozole which produces a sustained suppression of oestrogenic hormones.**
- 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 September 30, 2019 were:
  - Recognition of assets under the “Property, plant and equipment” caption (non-current assets) for an amount of €21.7Mn.
  - Increase in debt under the captions “Financial liabilities for non-current and current leases” of €18.3Mn and €3.6Mn, respectively.
  - Lower operating expenses and, consequently, an increase of EBITDA of €2.6Mn, since operating lease payments were recognized under the SG&A caption.
  - Higher expense for the depreciation of the right-of-use asset of €2.5Mn.
  - An increase of €0.2Mn in the finance costs of the lease liabilities.
- **EBITDA** increased by 83%, from €25.9Mn in 9M 2018 to €47.5Mn in 9M 2019, reflecting a 5.7 pp rise in the EBITDA margin to 17.6% in 9M 2019.
- **Net profit** increased by 96%, from €15.7Mn in 9M 2018 to €30.7Mn in 9M 2019.

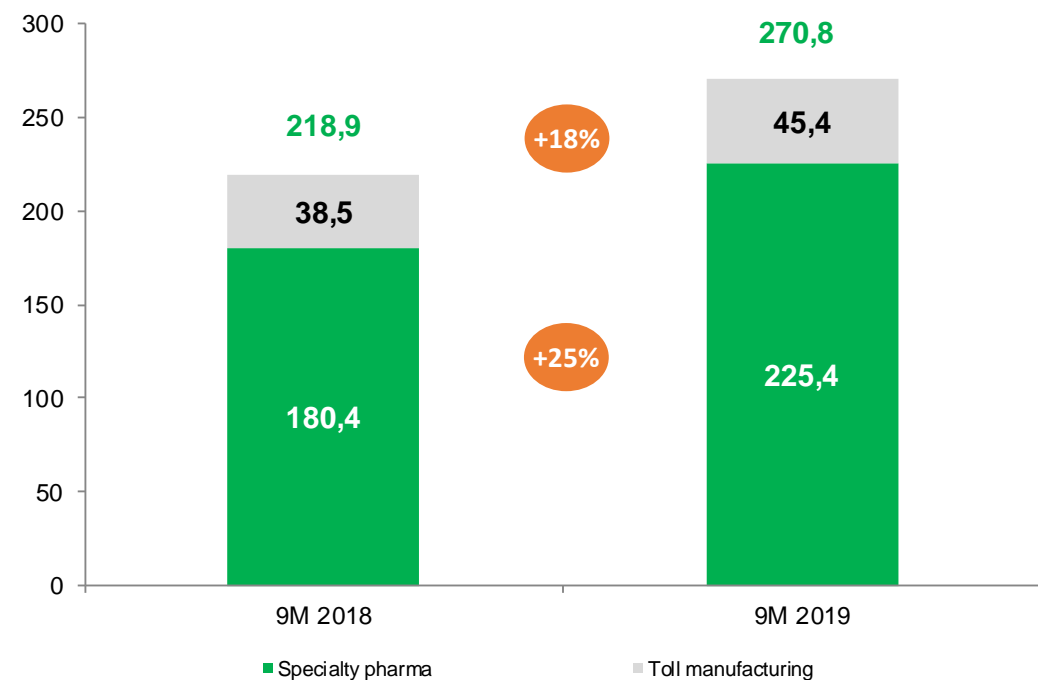


# Growth driven by specialty pharma and toll manufacturing businesses...

Total operating revenue (€Mn)



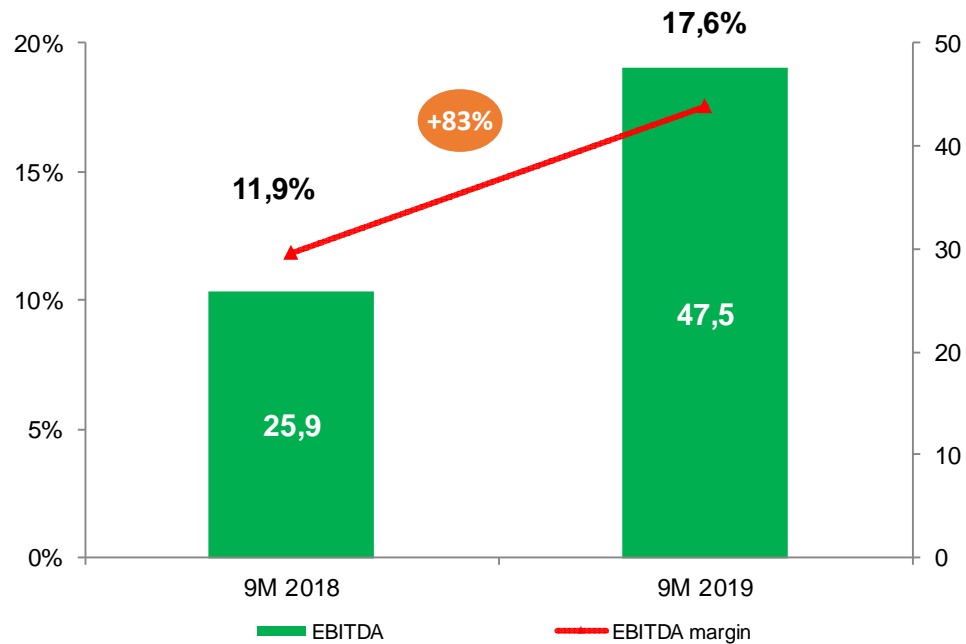
Operating revenue growth by category (€Mn)



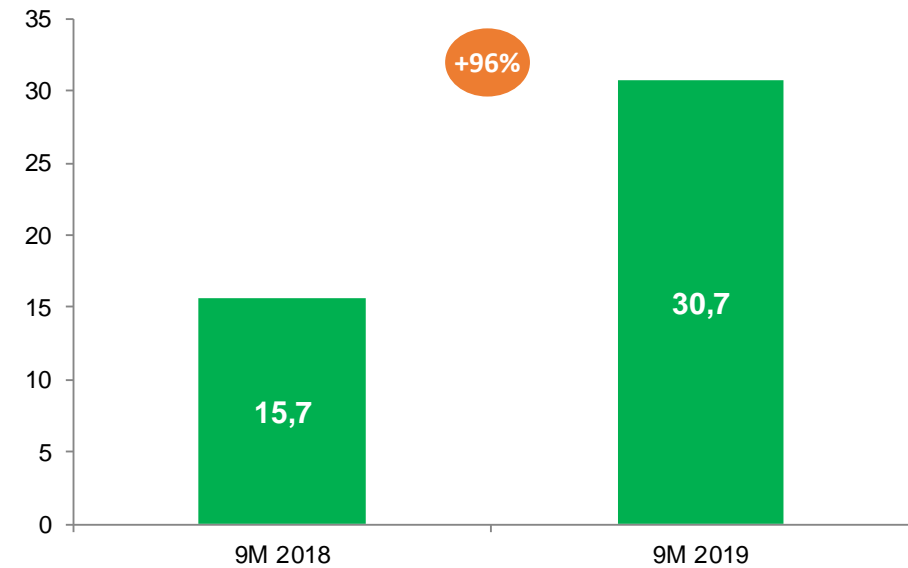
- **Operating revenue increased by 24%** to €270.8Mn in 9M 2019 driven by the strength of:
  - the specialty pharmaceutical business, where sales rose 25%; and
  - the toll manufacturing business, which grew by 18%.
- ROVI forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in the first nine months of 2019, which, according to the Ministry of Health, Consumption and Social Welfare, showed a growth rate of 2.9%.

## ...with high profitability

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



### Net profit (€Mn)

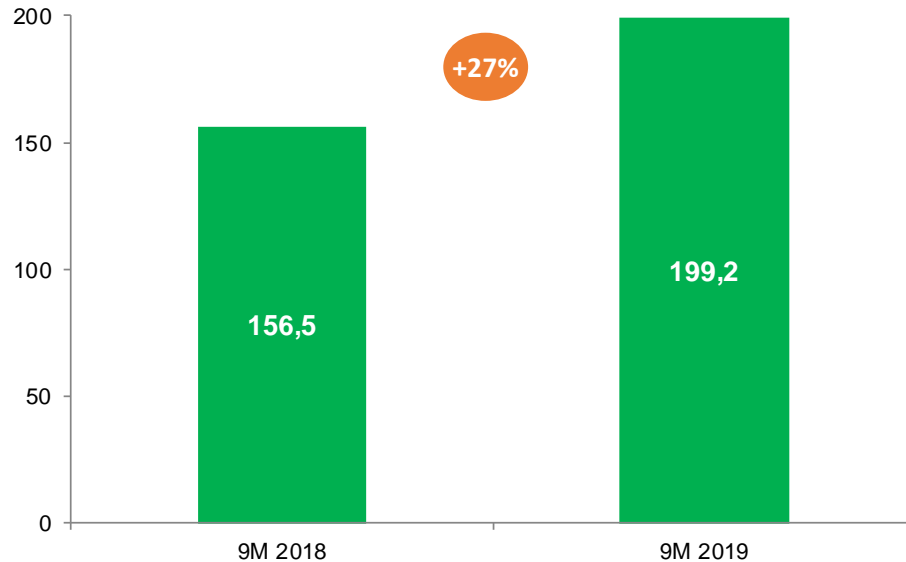


- In 9M 2018, EBITDA was affected by non-recurring expenses of €1.1Mn.
- As a result of the IFRS 16 application, EBITDA was positively impacted by €2.6Mn in 9M 2019.
- **EBITDA increased by 83%**, from €25.9Mn in 9M 2018 to €47.5Mn in 9M 2019, reflecting a 5.7 percentage point rise in the EBITDA margin to 17.6% in 9M 2019.
- **Net profit** increased by 96%, from €15.7Mn in 9M 2018 to €30.7Mn in 9M 2019.

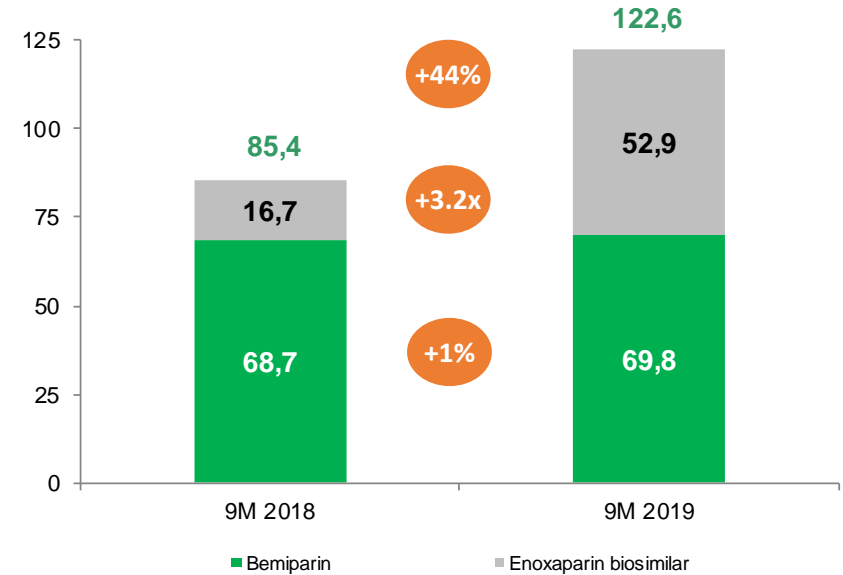


# LMWH, leading the specialty pharmaceutical business

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

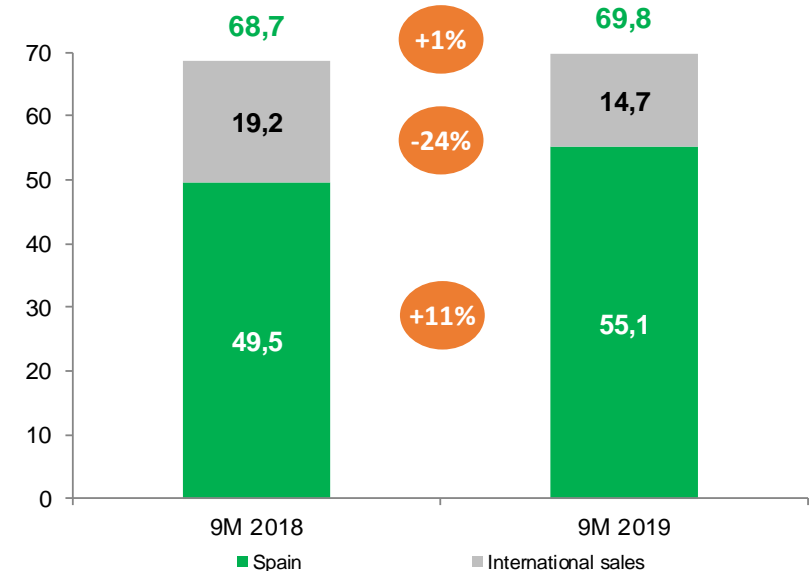


## LMWH franchise sales (€Mn)



- Sales of **prescription-based pharmaceutical products increased by 27%** to €199.2Mn in 9M 2019.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** (Enoxaparin biosimilar and Bemiparin) **increased by 44%** to €122.6Mn in 9M 2019.
- **LMWH sales represented 45% of operating revenue in 9M 2019 compared to 39% in 9M 2018.**
  - Sales of the **Enoxaparin biosimilar** amounted to **€52.9Mn** in 9M 2019.
  - **Bemiparin total sales increased by 1%** to €69.8Mn in 9M 2019:
    - Sales in **Spain increased 11%** to €55.1Mn.
    - **International sales decreased by 24%** to €14.7Mn. ROVI expects international Bemiparin sales to remain stable in 2019.

## 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<sup>1</sup>, Austria, Latvia and Estonia** in 2018; and in **Portugal, Poland and Costa Rica** in 9M 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.

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

Directly Marketed in  
**Germany, UK, Italy, Spain & Portugal**

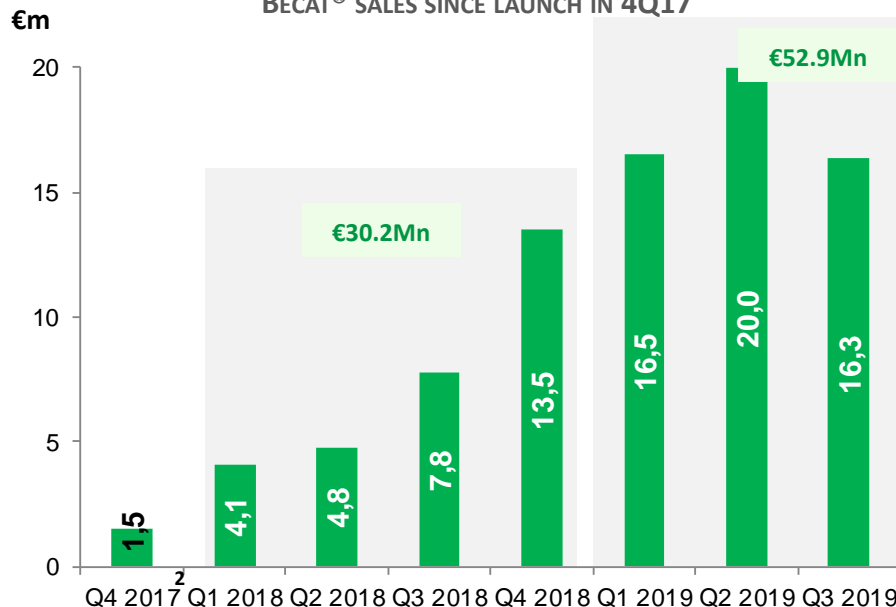
Approved; To Be Directly Marketed  
**2 Countries**

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

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

### Enoxaparin Biosimilar Becat® Sales Ramp-up

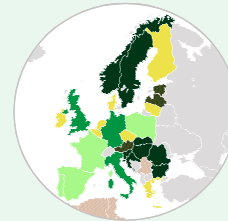
VERY POSITIVE EVOLUTION OF ENOXAPARIN BIOSIMILAR BECAT® SALES SINCE LAUNCH IN 4Q17



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

Focus on Europe...



...the largest enoxaparin market with **€0.9bn** sales<sup>3</sup>

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



...which account for **c.75%** of the European market<sup>4</sup>

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

**50-70%** Market Share<sup>5</sup>

...of the reference product market

In Europe, there are only ...

**2 other** Authorized Biosimilars

...already in the market

### Stage II of Commercial Strategy

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

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

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

Already Signed Out-Licensed Agreements: **89 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.

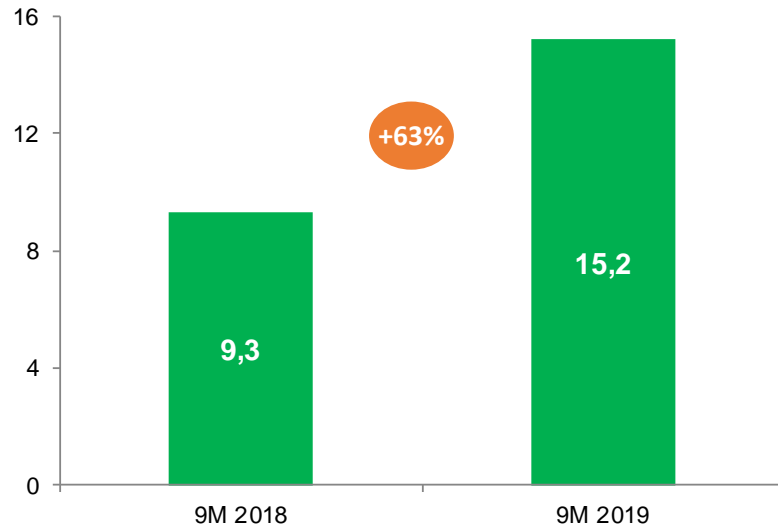
4. QuintilesIMS, 2015.  
5. Technavio 2016 biosimilars report.



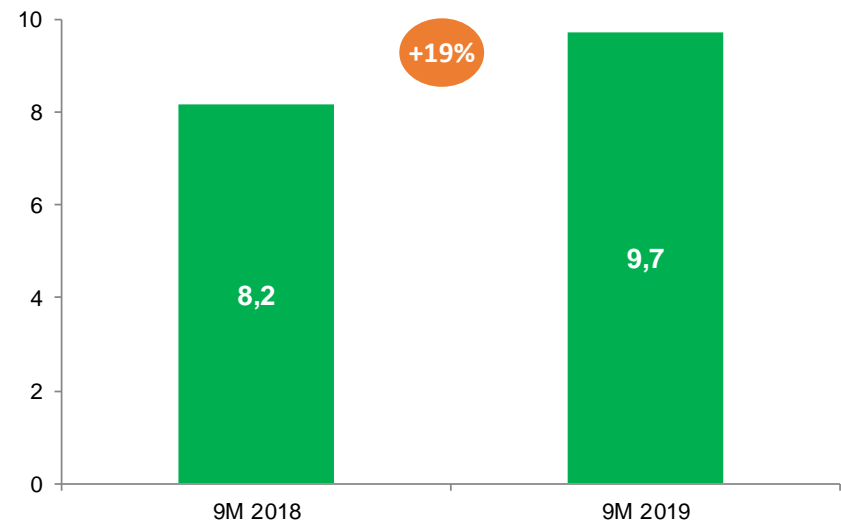


## Strong performance of the product portfolio (1/2)

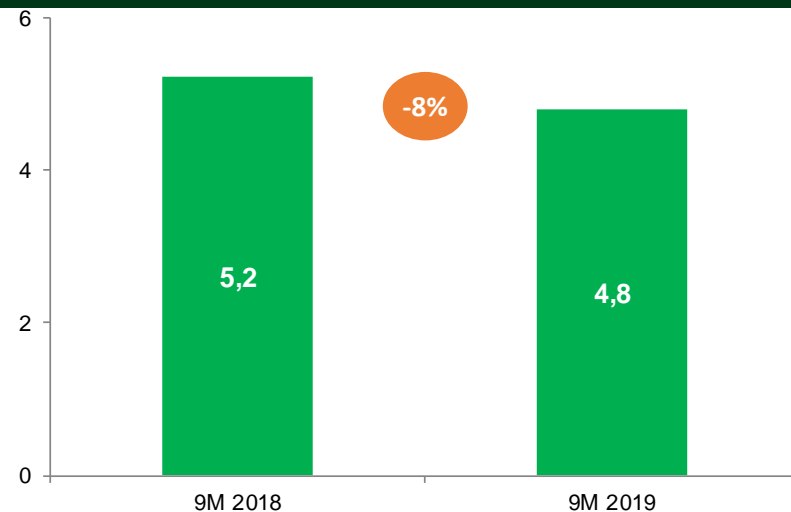
### Neparvis sales (€Mn)



### Volutsa sales (€Mn)



### Medicebran and Medikinet sales (€Mn)



- Sales of **Neparvis**, a specialty product from Novartis launched in December 2016, **increased by 63% to €15.2Mn** in 9M 2019, from €9.3Mn in 9M 2018.
- Sales of **Volutsa**, launched in Spain in February 2015, **increased by 19%** to €9.7Mn in 9M 2019.
- Sales of **Medicebran and Medikinet**, products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, decreased 8% to €4.8Mn in 9M 2019.

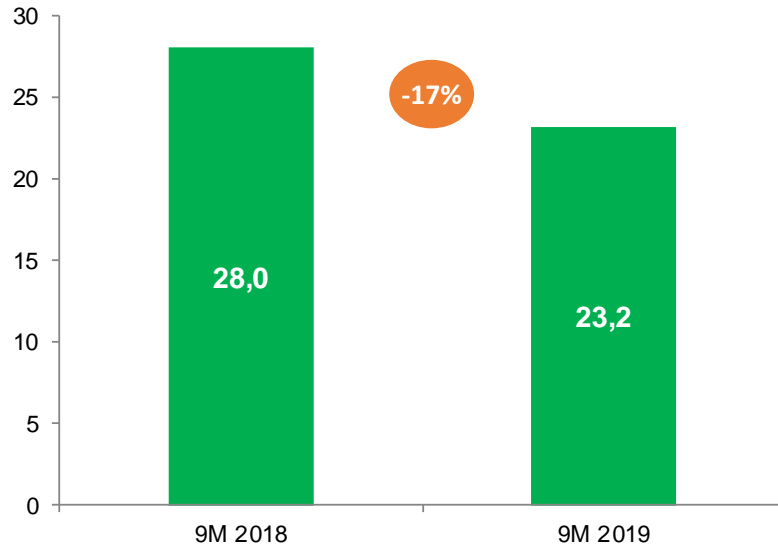
*Neparvis is a specialty product from Novartis indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction.*

*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.*

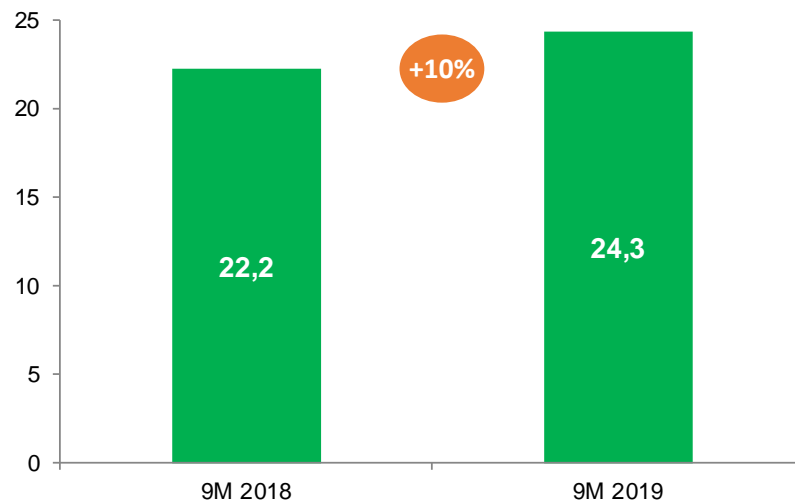
*Medicebran and Medikinet are specialty products from Medice indicated for the treatment of ADHD in children and teenagers.*

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

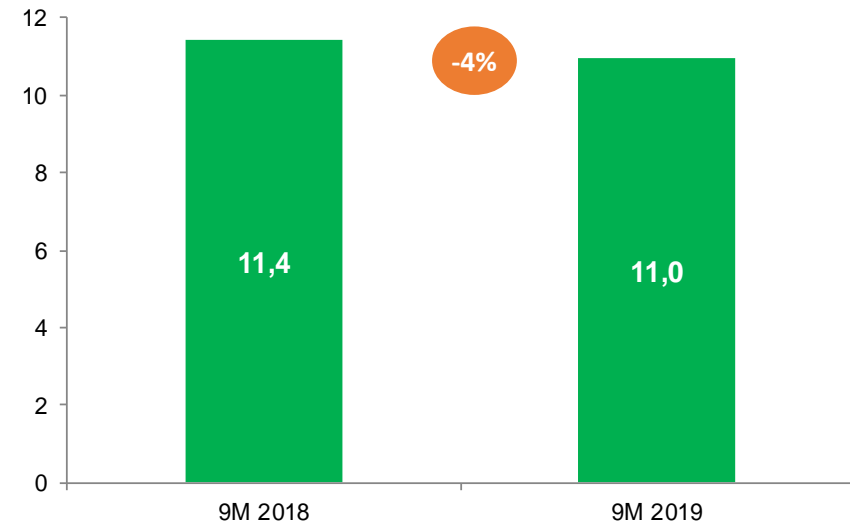
### Absorcol, Vytorin and Orvatez sales (€Mn)



### Contrast imaging agents sales (€Mn)



### Hirobriz and Ulunar sales (€Mn)



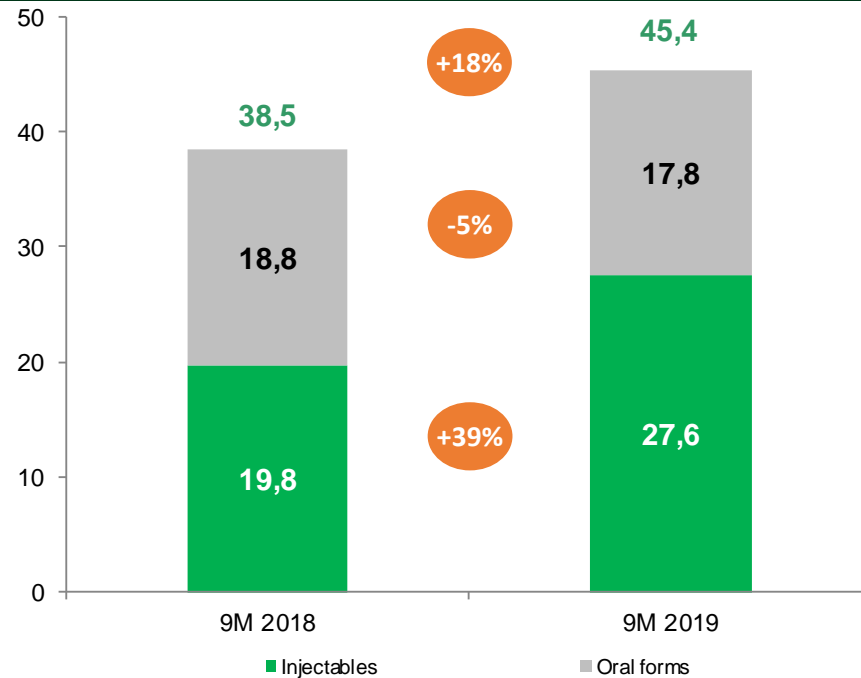
- Sales of **Vytorin**<sup>®</sup>, **Orvatez**<sup>®</sup> and **Absorcol**<sup>®</sup> decreased by 17% to €23.2Mn in 9M 2019. In 2Q 2018, the active principle ezetimibe went out of patent and the price of Absorcol<sup>®</sup> was reduced. Likewise, generics formulated with ezetimibe and simvastatin were marketed in the same period, so the price of Vytorin<sup>®</sup> was reduced to be competitive.
- Sales of **Hirobriz** and **Ulunar**, both products for patients with COPD, launched in Spain in Q4 2014 decreased by 4% to €11.0Mn in 9M 2019.
- **Contrast imaging agents and other hospital products** increased by 10% to €24.3Mn in 9M 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 18% to €45.4Mn in 9M 2019 because of the good performance of the injectable business, where revenue increased by 39% to €27.6Mn as a result of higher volumes manufactured for some customers.
- Frosst Ibérica plant sales decreased by 5% to €17.8Mn in 9M 2019 compared to the same period of the previous year.
- By the end of 2019, ROVI expects the toll manufacturing business to have increased by a low-double-digit percentage.



# ISM<sup>®</sup> Platform Opens Up New Avenues of Growth for ROVI

## Overview

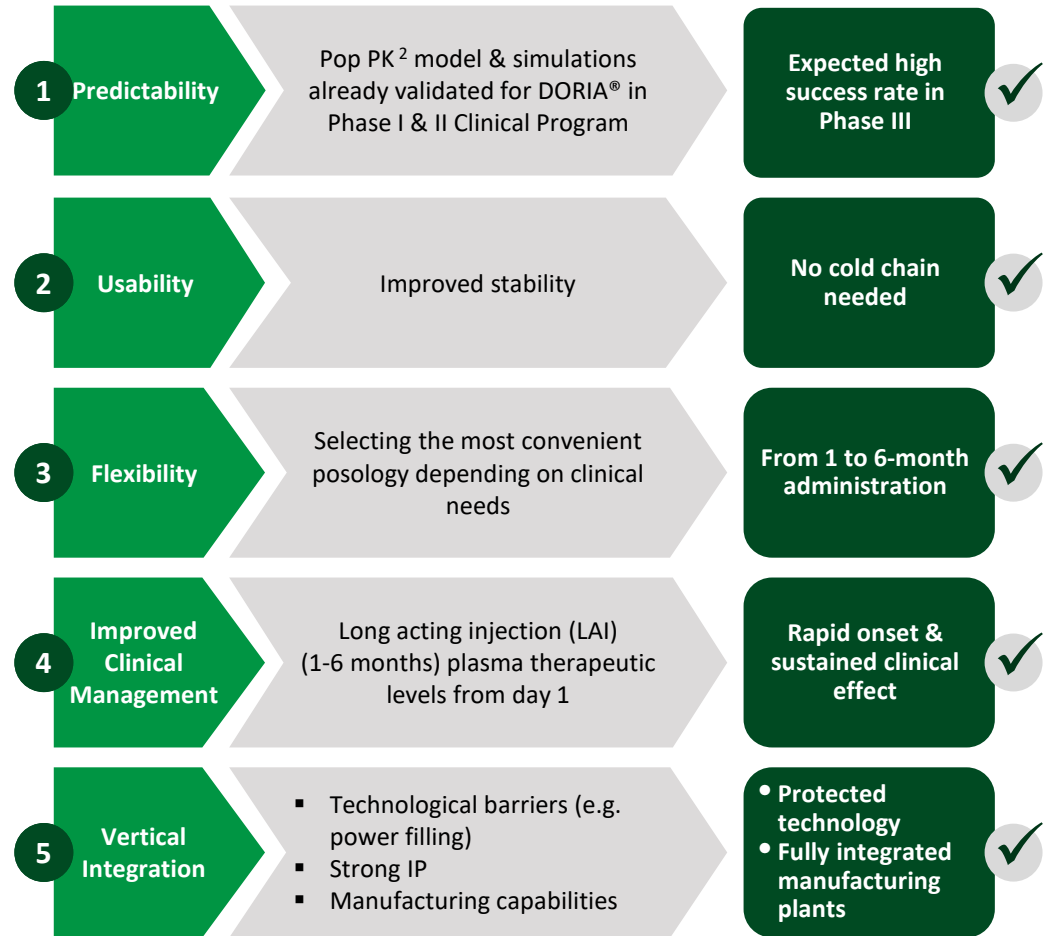
- Internally-developed and patented innovative drug-release technology, ISM<sup>®1</sup>, which allows for the **sustained release of compounds administered by injection**
  - Based on **two separate syringes respectively containing (a) the drug and polymer** (solid state) and (b) **the solvent** (liquid state)
- Potential wide applicability of ISM<sup>®</sup> technology to new chronic therapeutic areas, including **psychiatry** and **oncology**
  - 505(b)(2) path of approval** for candidates leveraging ISM<sup>®</sup> technology

## 2 Candidates Currently in Clinical Trials

Product	Potential Indication	Current Situation				Key Milestones
		Pre-Clinical	I	II	III	
DORIA <sup>®</sup> Risperidone, monthly	Schizophrenia	[Progress bar: Pre-Clinical, I, II, III]				Positive results from Phase III
Letrozole ISM <sup>®</sup> Long acting Letrozole	Breast Cancer	[Progress bar: Pre-Clinical, I]				Phase I started in November 2017

- ★ 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<sup>®</sup> Platform



1. ISM<sup>®</sup> stands for *In Situ Microparticles*<sup>®</sup>.  
 2. PK stands for pharmacokinetic.



# DORIA®: Positive Results from Phase 3 study

## Phase III clinical trial

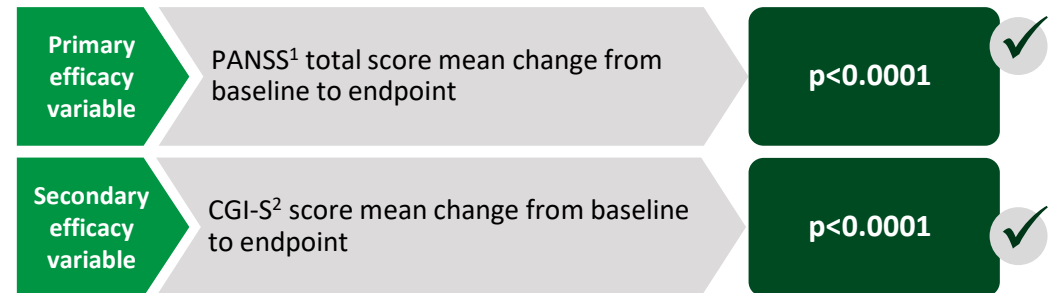
- It is double-blind (+ open-label extension), parallel, multicentre (31 sites/ 2 countries)
- The objectives of Phase III are:
  - Evaluate the efficacy and safety of DORIA® compared to placebo in the treatment of subjects with acute exacerbation of schizophrenia
  - Health Resources Utilization (HRU), 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]

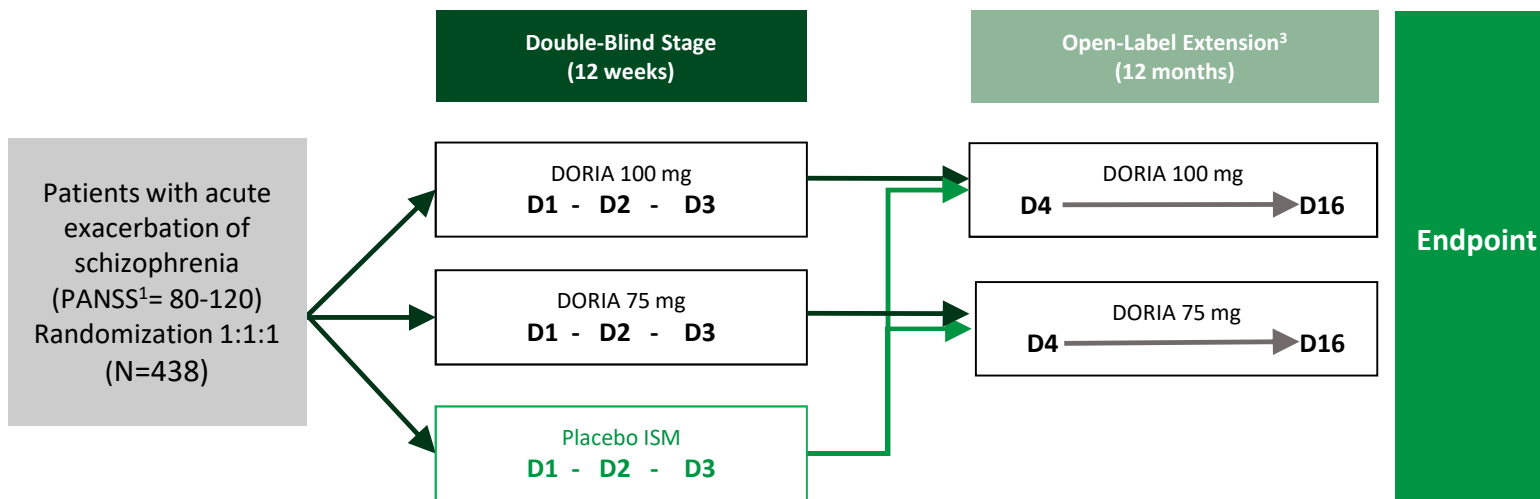
## Main efficacy variables achieved

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 results to be presented in scientific congresses
- Filing in Europe expected for Q1 2020 and in USA expected for 2020
- Open-Label Extension stage to be completed by January 2020
- The Boris study results will be used to support the registration of Doria®. The main objective of this study is to assess the comparative bioavailability of Risperidone ISM® with oral risperidone.

<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]



**2020 operating revenue growth rate**

**Mid-single-digit**

## THE KEY GROWTH LEVERS IN 2020

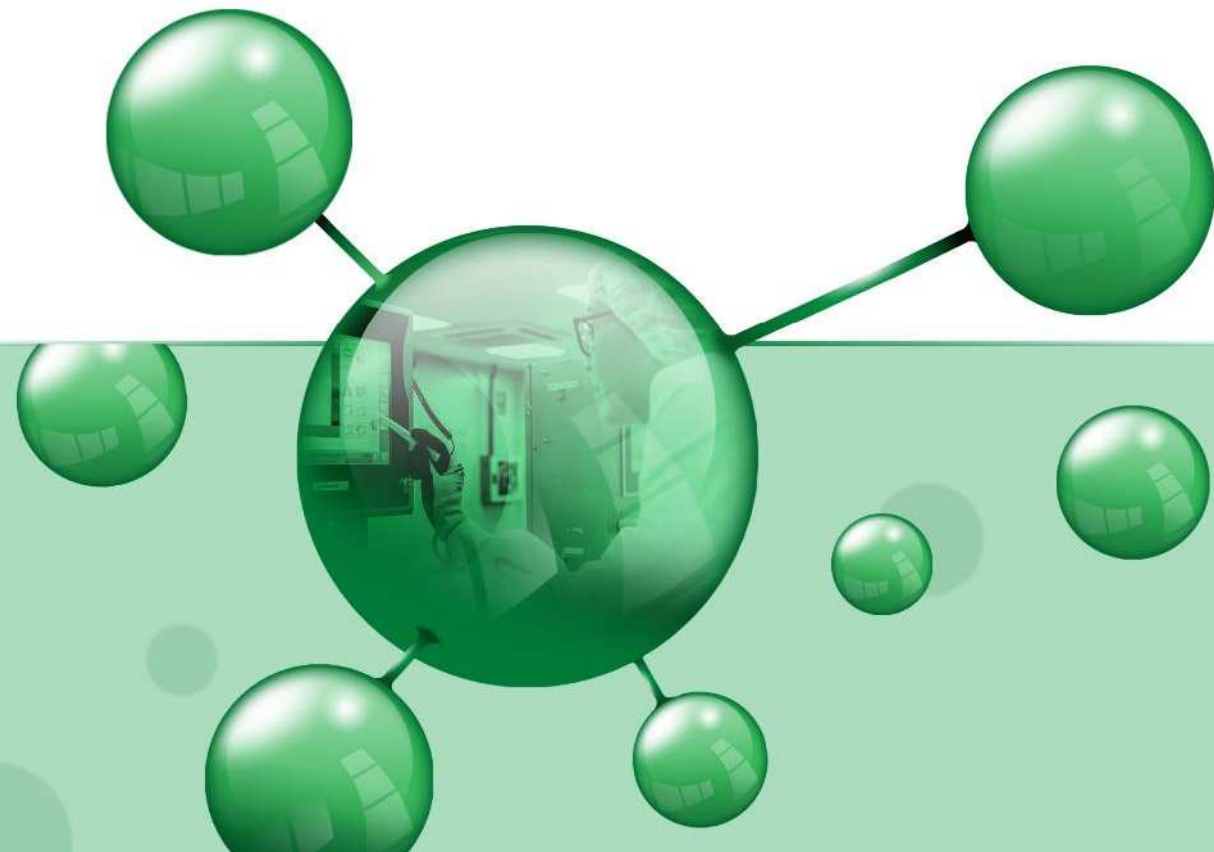
### Specialty Pharma Business

- ✓ Bemiparin
- ✓ Biosimilar of Enoxaparin
- ✓ Latest launches such as Neparvis and Volutsa
- ✓ Existing portfolio of specialty pharmaceuticals
- ✓ New acquisitions (Falithrom and Polaramine)

### Toll Manufacturing Services

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

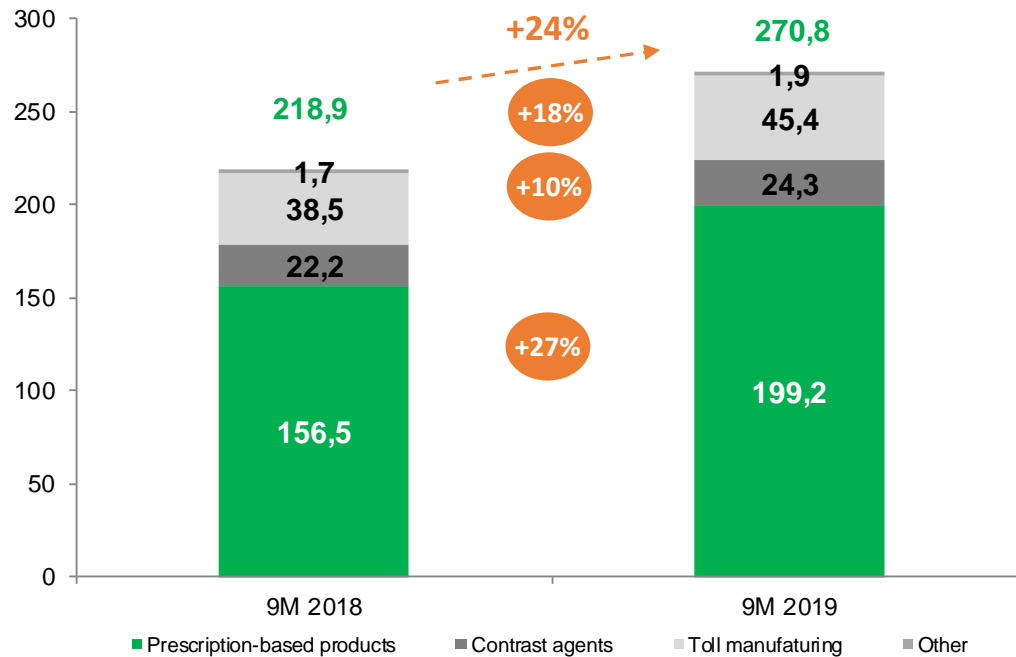
# Financial results



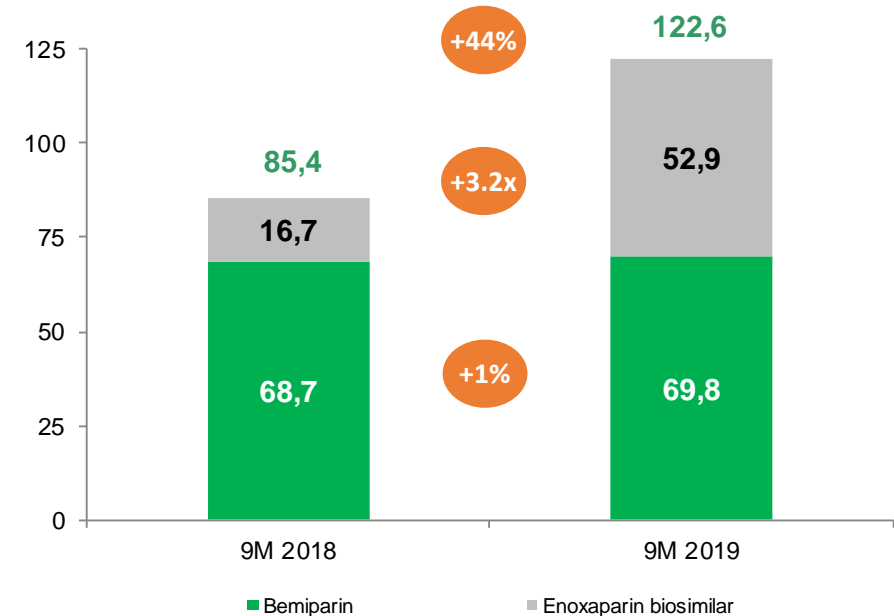


# Good revenue level with outstanding LMWH franchise growth

## Total operating revenue (€Mn)



## LMWH franchise sales (€Mn)

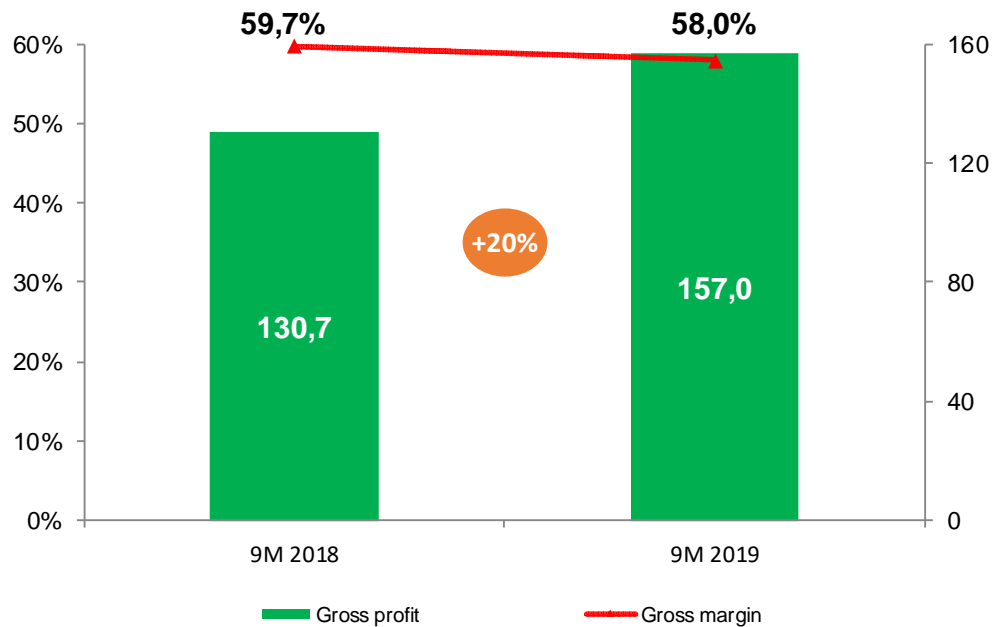


- **Operating revenue** increased by 24% to €270.8Mn, achieved on:
  - 27% growth in prescription-based products;
  - 10% growth in contrast agents and other hospital products;
  - 18% increase in toll manufacturing; and
  - OTC and other revenues increased by 8%.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** increased by 44% to €122.6Mn in 9M 2019, representing 45% of operating revenue in 9M 2019 vs 39% in 9M 2018.
  - **Enoxaparin biosimilar sales increased 3.2 times to €52.9Mn** and Bemiparin sales increased by 1%.



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

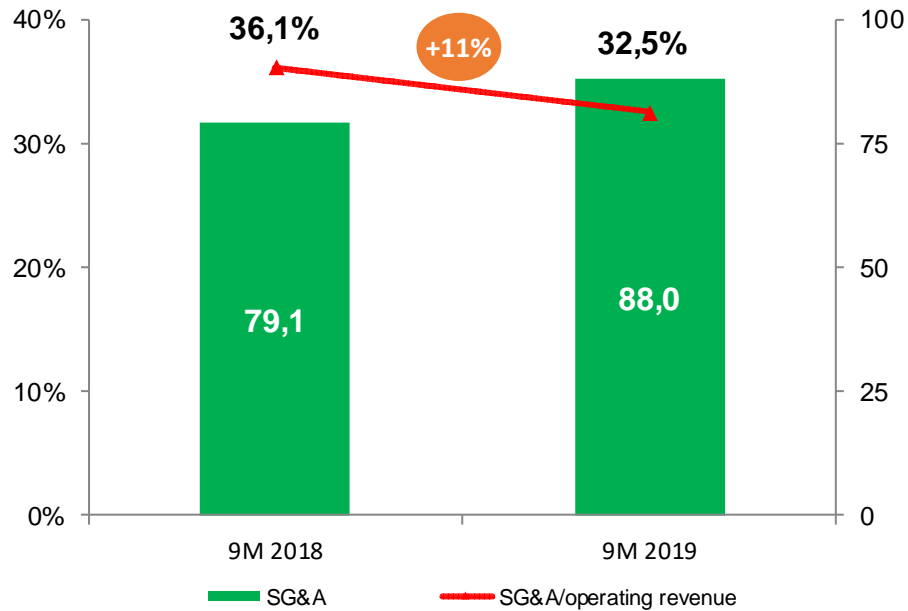
## Gross profit (€Mn) and Gross margin (%)



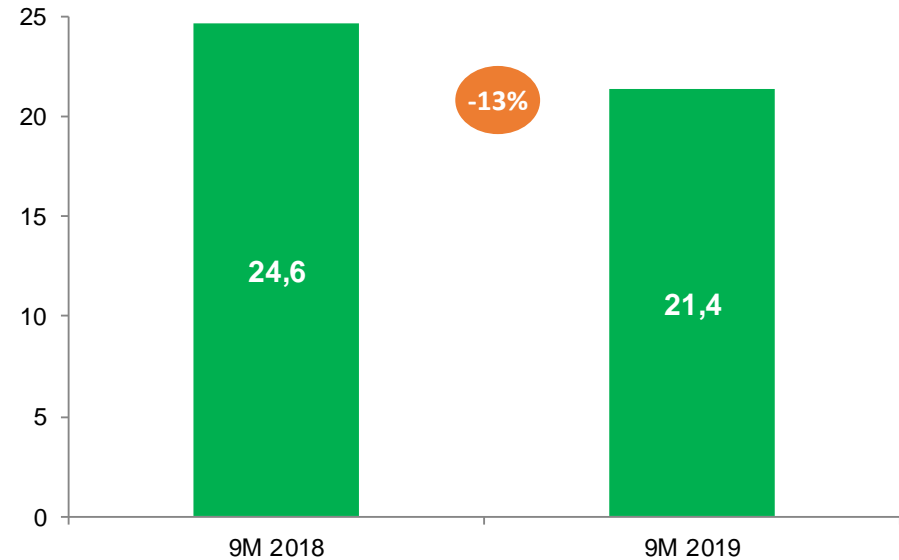
- **Gross profit** increased by 20% to €157.0Mn in 9M 2019, the gross margin showing a decrease of 1.7 percentage points from 59.7% in 9M 2018 to 58.0%, mainly due to:
  - the increase of Enoxaparin biosimilar sales, which added lower margins in the first half of 2019 after the launch of the product in six new markets; and
  - the increase in the LMWH raw material prices, which, in the first nine months of 2019, were running around 39% over 9M 2018 prices. ROVI expects this rising trend to continue during 2019.

# Cost control along with commitment to R&D

## SG&A expenses (€Mn)



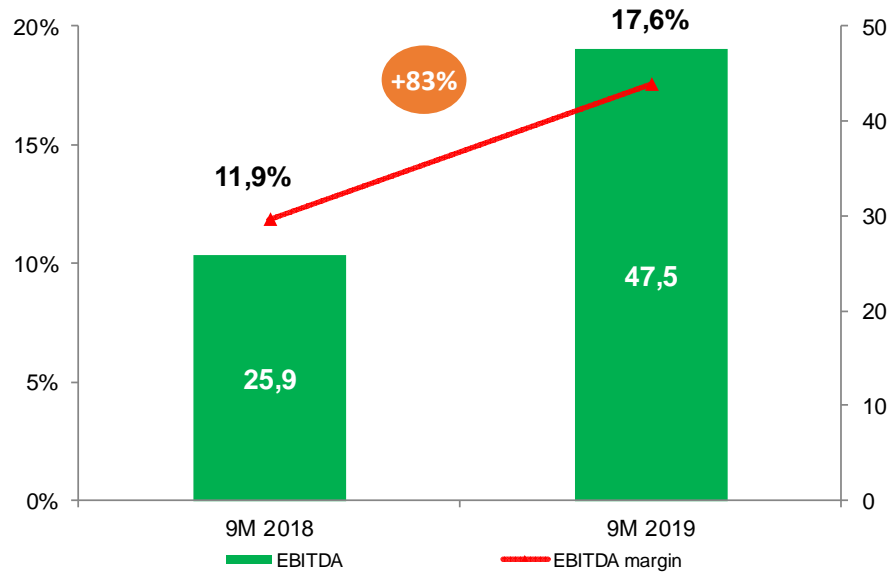
## R&D expenses (€Mn)



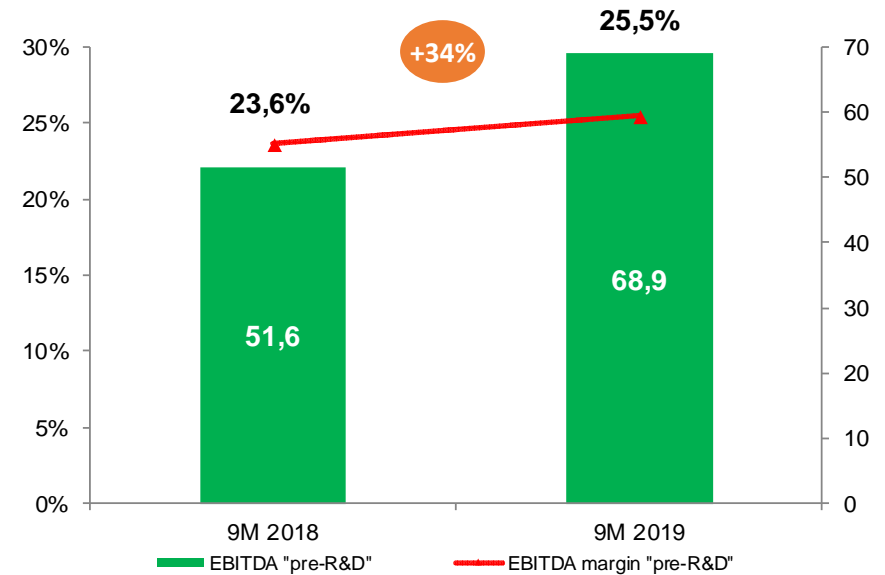
- **SG&A expenses rose 11%** to €88.0Mn in 9M 2019 mainly due to:
  - international subsidiaries expenses, which amounted to €6.5Mn compared to €4.7Mn in 9M 2018; and
  - a larger volume of enoxaparin biosimilar production.
  - In 2019, expenses related to international subsidiaries are expected to be around 9 million euros.
- **R&D expenses decreased 13%** to €21.4Mn in 9M 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

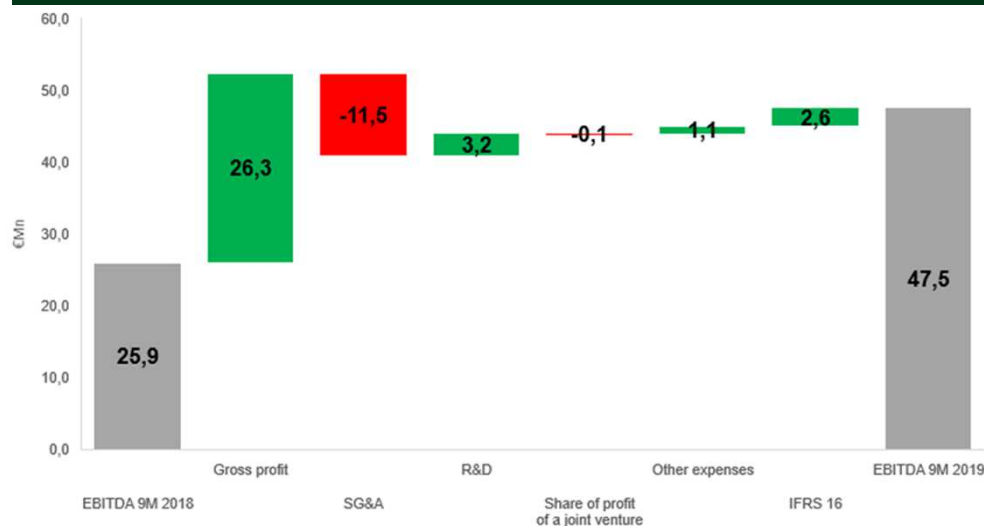
## EBITDA (€Mn) and EBITDA margin (%)



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



## 9M 2019 EBITDA impacts (€Mn)

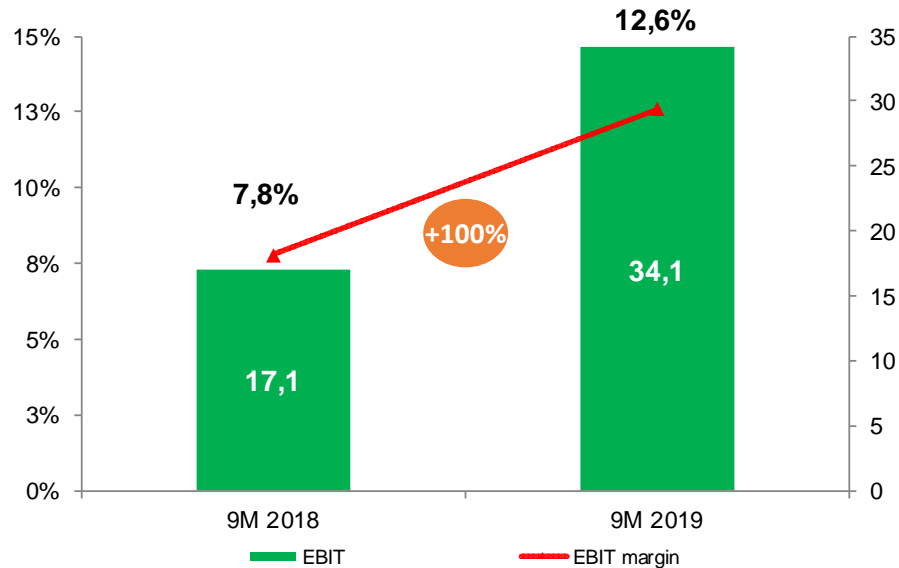


- In 9M 2018, EBITDA was affected by non-recurring expenses of €1.1Mn, linked to a substantial change to Frosst Ibérica employees working conditions.
- **EBITDA** increased by 83% to €47.5Mn in 9M 2019, reflecting a 5.7 pp rise in the EBITDA margin, which was up to 17.6% in 9M 2019 from 11.9% in 9M 2018.
- **EBITDA "pre-R&D"** (w/o R&D and non recurring expenses) increased by 34% to €68.9Mn in 9M 2019, reflecting a 1.9 pp rise in the EBITDA margin to 25.5% in 9M 2019. Likewise,
  - recognising the same amount of R&D expenses in 9M 2019 as in 9M 2018 and excluding the impact of the non recurring expenses in 9M 2018, EBITDA would have increased by 64% to €44.3Mn, reflecting a 4.0 pp rise in the EBITDA margin to 16.4% in 9M 2019.

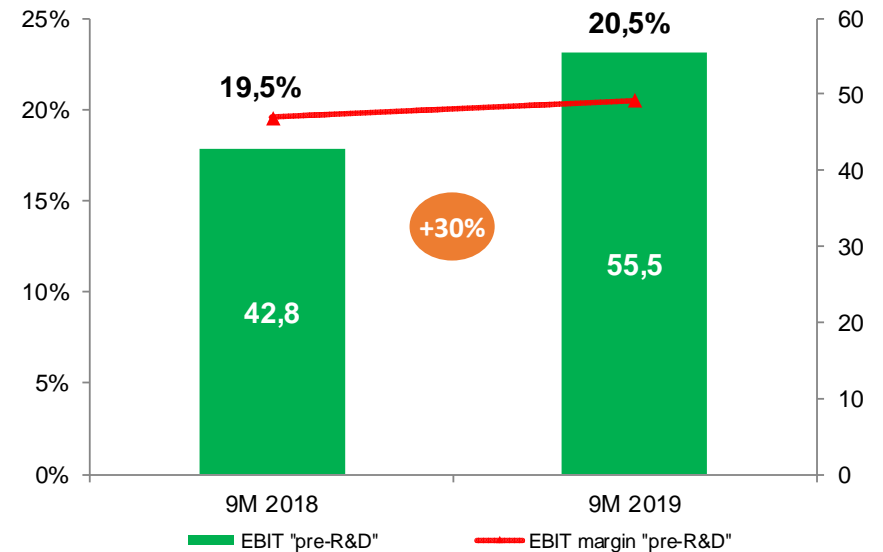
Note: EBITDA "pre-R&D" calculated excluding R&D expenses in 9M 2019 and 9M 2018 and the impact of non recurring expenses in 9M 2018

# EBIT

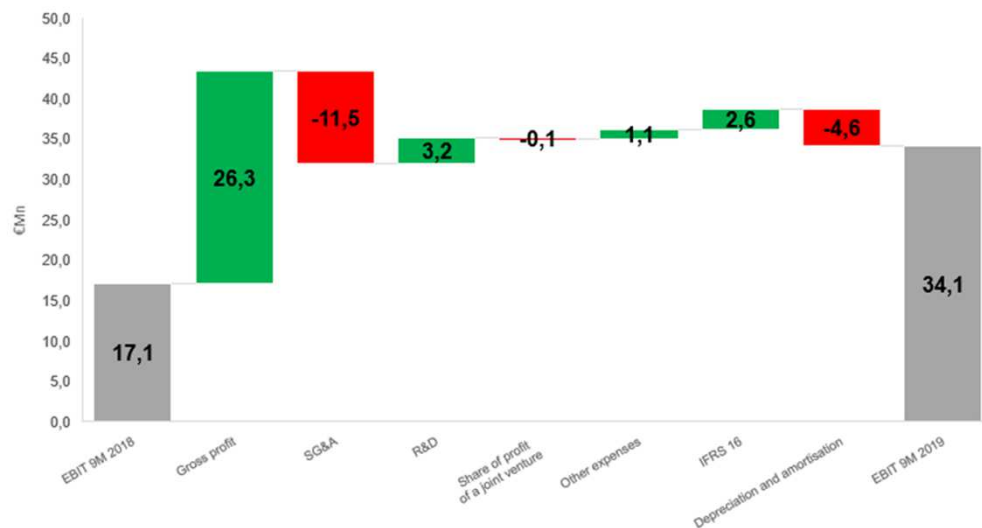
## EBIT (€Mn) and EBIT margin (%)



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



## 9M 2019 EBIT impacts (€Mn)

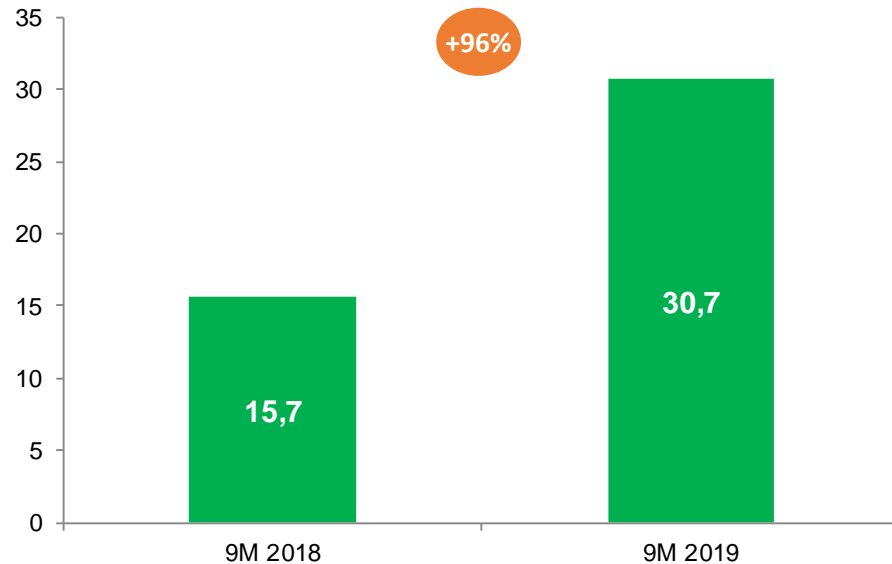


- As a result of the IFRS 16 application and the new PP&E and intangible assets purchases made during the last twelve months, **depreciation and amortisation** expenses increased by 51% to €13.4Mn in 9M 2019.
- **EBIT** increased to €34.1Mn in 9M 2019, reflecting a 4.8 pp rise in the EBIT margin, which was up to 12.6% in 9M 2019.
- **EBIT "pre-R&D"** (w/o R&D and non recurring expenses) increased by 30%, from €42.8Mn in 9M 2018 to €55.5Mn in 9M 2019, reflecting a 1 pp rise in the EBIT margin to 20.5% in 9M 2019. Likewise,
  - recognising the same amount of R&D expenses in 9M 2019 as in 9M 2018 and excluding the impact of the non recurring expenses in 9M 2018, EBIT would have increased by 70% to €30.9Mn, reflecting a 3.1 pp rise in the EBIT margin.

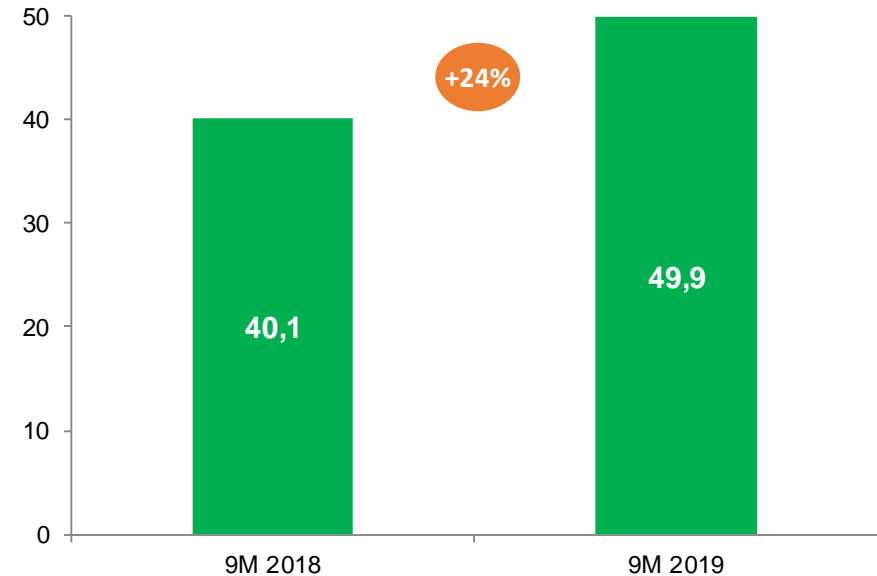
Note: EBIT "pre-R&D" calculated excluding R&D expenses in 9M 2019 and 9M 2018 and the impact of non recurring expenses in 9M 2018

# Net profit

## Net profit (€Mn)



## Net profit “pre-R&D” (€Mn)

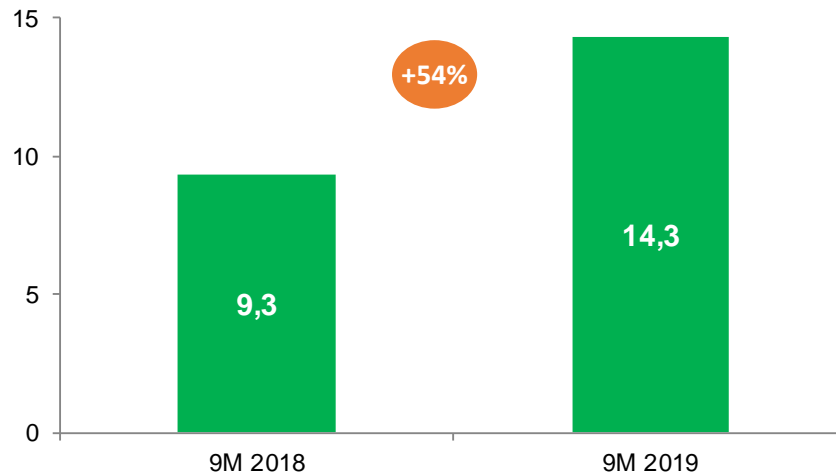


- **Net profit** increased to €30.7Mn in 9M 2019, a 96% rise compared to 9M 2018.
- **Net profit “pre R&D”** (w/o R&D and non recurring expenses) increased by 24%, from €40.1Mn in 9M 2018 to €49.9Mn in 9M 2019. Likewise,
  - recognising the same amount of R&D expenses in 9M 2019 as in 9M 2018 and excluding the impact of the non recurring expenses in 9M 2018, net profit would have increased by 67% to €27.8Mn.
- The **effective tax rate** was 10.3% in 9M 2019, compared to 4.7% in 9M 2018, mainly due to the decrease in R&D expenses in 9M 2019, compared to 9M 2018, which led to lower R&D tax credits.
- As of 30 September 2019, **negative tax bases** amounted to €34.9Mn, of which €1.7Mn will be used in 9M 2019.

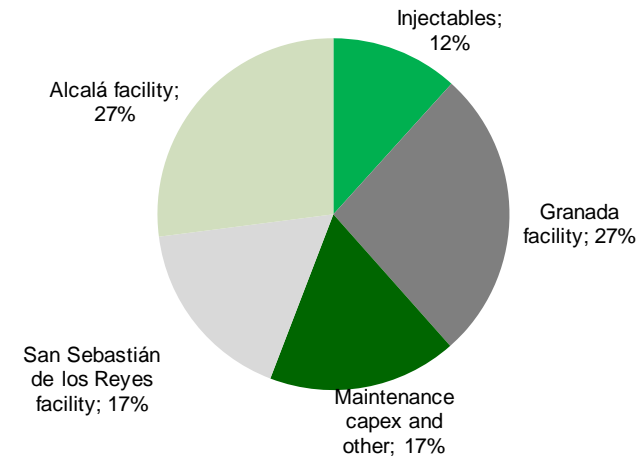
Note: Net profit “pre-R&D” calculated excluding R&D expenses in 9M 2019 and 9M 2018 and the impact of non recurring expenses in 9M 2018. Same effective tax rate as the reported net profit.

# Capital expenditure and Free Cash Flow

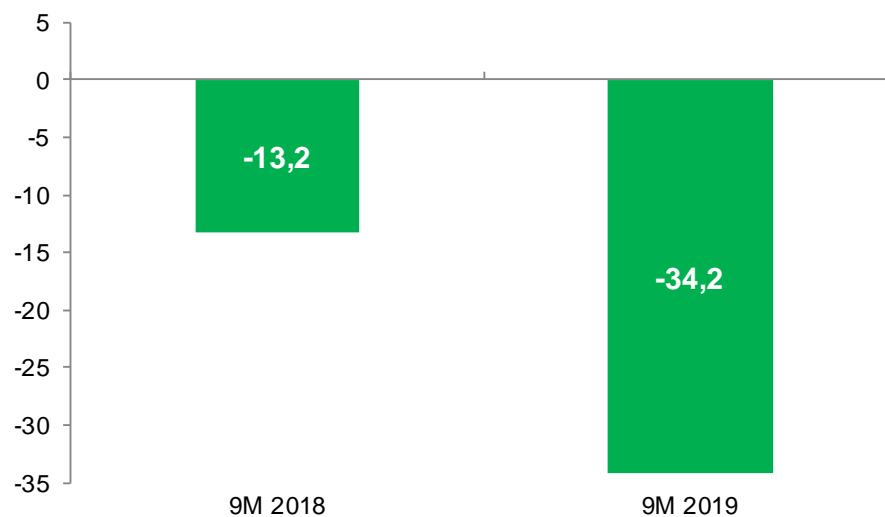
## Capex evolution (€Mn)



## Capex breakdown (%)



## Free Cash Flow (€Mn)

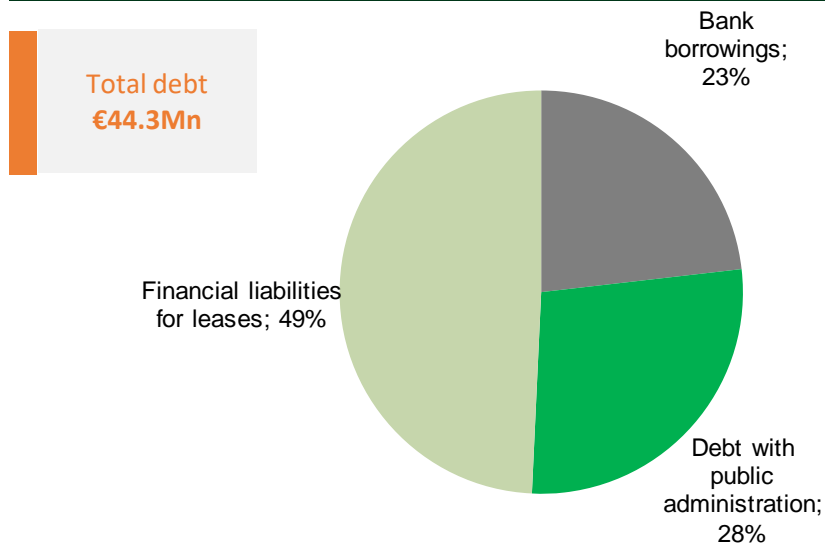


- €14.3Mn of **capex** invested in 9M 2019.
  - €1.7Mn of investment capex related to the injectable plant;
  - €3.8Mn of investment capex related to the Granada facility;
  - €3.9Mn of investment capex related to the Alcalá de Henares facility;
  - €2.5Mn of investment capex related to the San Sebastián de los Reyes facility;
  - €2.5Mn of maintenance capex and other capex
- €13.5Mn invested in 9M 2019 for the acquisition of Polaramine®.
- **FCF** decreased to €-34.2Mn mainly due to:
  - €18.5Mn increase in capex mainly because of the acquisition of Polaramine®;
  - €54.7Mn increase in "inventories" in 9M 2019 vs €27.7Mn increase in 9M 2018;
  - €11.7Mn increase in "trade and other receivables" in 9M 2019 vs €10.1Mn increase in 9M 2018;
  - €12.2Mn increase in "trade and other payables" in 9M 2019 vs €7.0Mn increase in 9M 2018; and
  - €17.8Mn increase in profit before income tax.

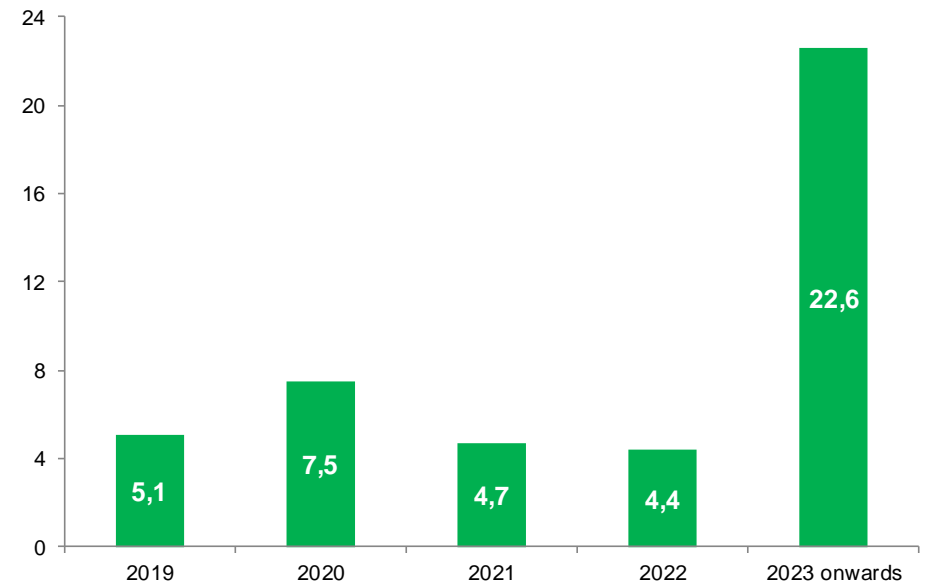


# Financial debt

## Debt breakdown by source (%)



## Debt maturities by year (€Mn)



- **Debt with public administration** represented 28% of total debt, with 0% interest rate.
- **Gross cash position of €44.5Mn** as of 30 September 2019 vs €97.0Mn as of 31 December 2018.
- **Net cash of €0.2Mn** as of 30 September 2019 vs €62.8Mn as of 31 December 2018.
- ROVI paid a **gross dividend of 0.0798 euros** per share on 2018 earnings and it represented a 25% pay-out.



# News-flow 2019-2020



<b>Specialty Pharma</b>	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 83 countries outside Europe
<b>Toll manufacturing</b>	New contracts to be announced
<b>ISM<sup>®</sup> technology platform</b>	Risperidone ISM <sup>®</sup> final Phase III data will be presented in scientific congresses
	Letrozole ISM <sup>®</sup> Phase I ongoing. Next steps to be discussed with regulatory authorities in 2020

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