



FIRST HALF 2020 FINANCIAL RESULTS

JULY 2020



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# ROVI response to COVID-19 pandemic

## ROVI priorities during COVID-19



Safeguard the health of our employees



Continue the supply of medicines to patients



Support society with resources and expertise

## ROVI status across the value chain

### Production & Commercial

- All manufacturing sites operating
- LMWH essential medicines for COVID-19
- Reduction of hospital activity

### R&D

- Continuation of Doria<sup>®</sup> approval process in Europe
- No delay in the registration of the Doria<sup>®</sup> dossier in USA

### Resources

- €2.5Mn booked to protect our employees' health

## H1 2020 financial results - Highlights



Operating revenue growth of 8% to €191.1Mn and EBITDA growth of 60% to €42.4Mn in H1 2020.



Sales of the heparin franchise increased by 23% to €104.0Mn in H1 2020.



Sales of Neparvis<sup>®</sup> increased by 43% to €13.8Mn in H1 2020.



Toll manufacturing sales increased by 31% to €34.8Mn in H1 2020.



For 2020, ROVI expects a mid-single-digit growth rate for the operating revenue.



## Milestone achieved

Moderna and ROVI announce collaboration for fill-finish manufacturing outside the United States of Moderna's COVID-19 vaccine candidate.

The Moderna logo, consisting of the word "moderna" in a red, lowercase, sans-serif font, with a blue dashed line underneath it.

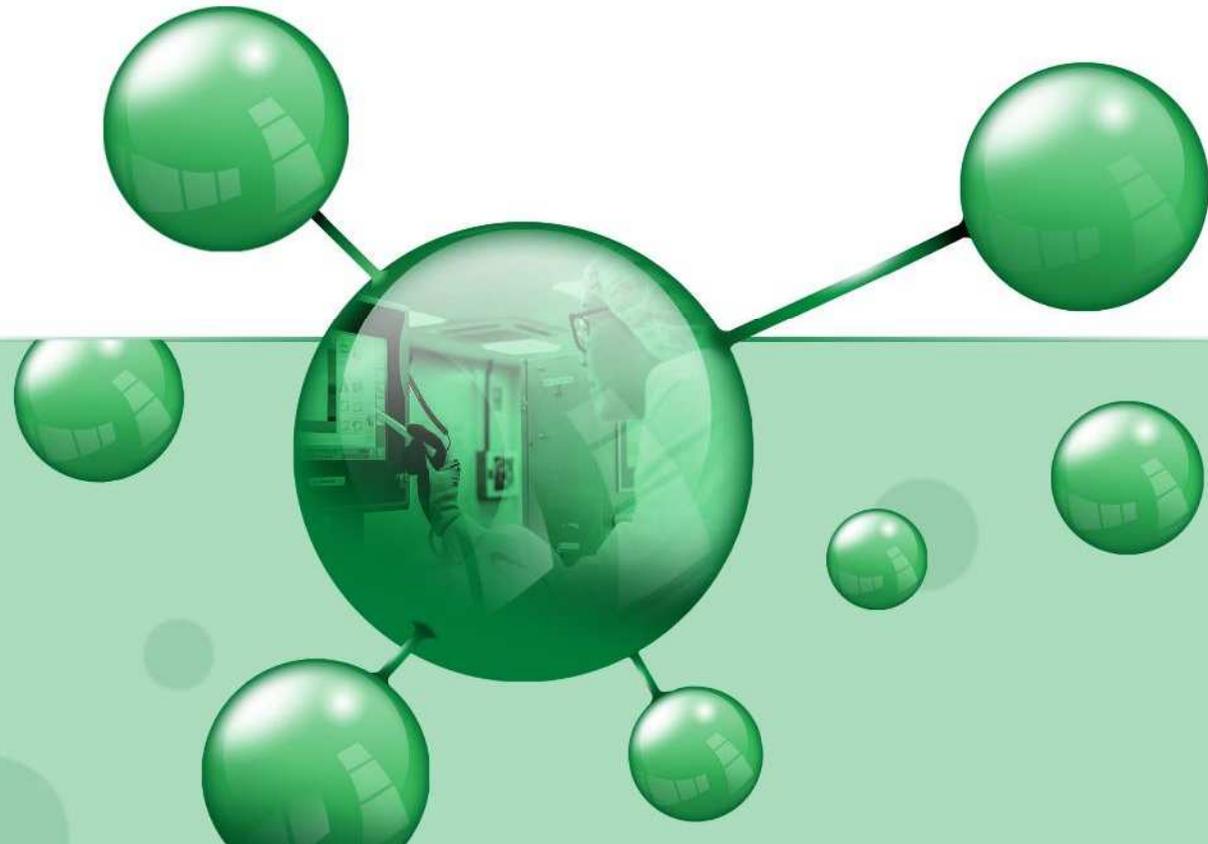
moderna®

**ROVI will provide vial filling and packaging capacity to support production of the vaccine candidate intended in principle to supply markets outside of the U.S. starting in early 2021.**



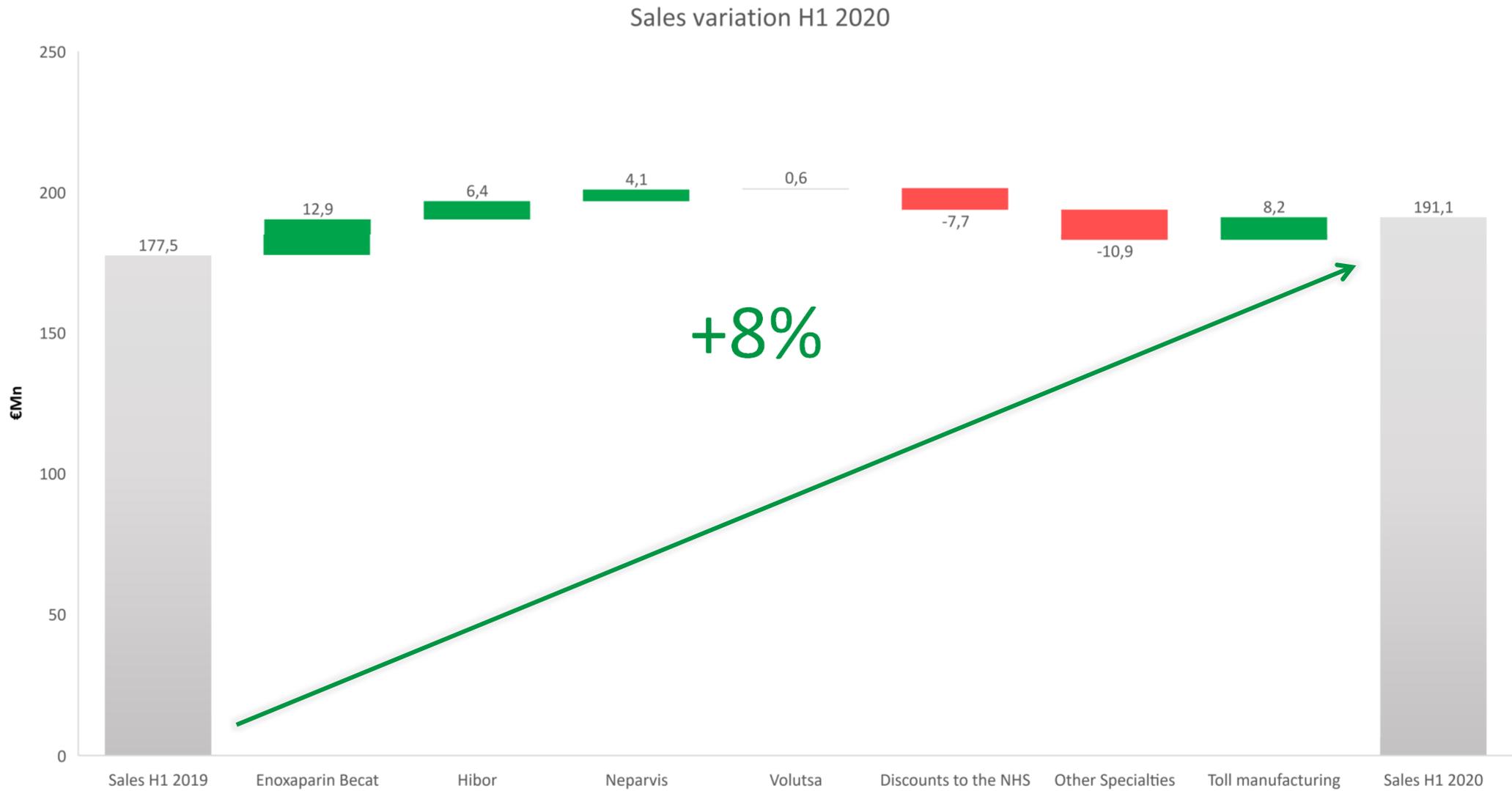
Juan López-Belmonte  
Chief Executive Officer

# Operating results



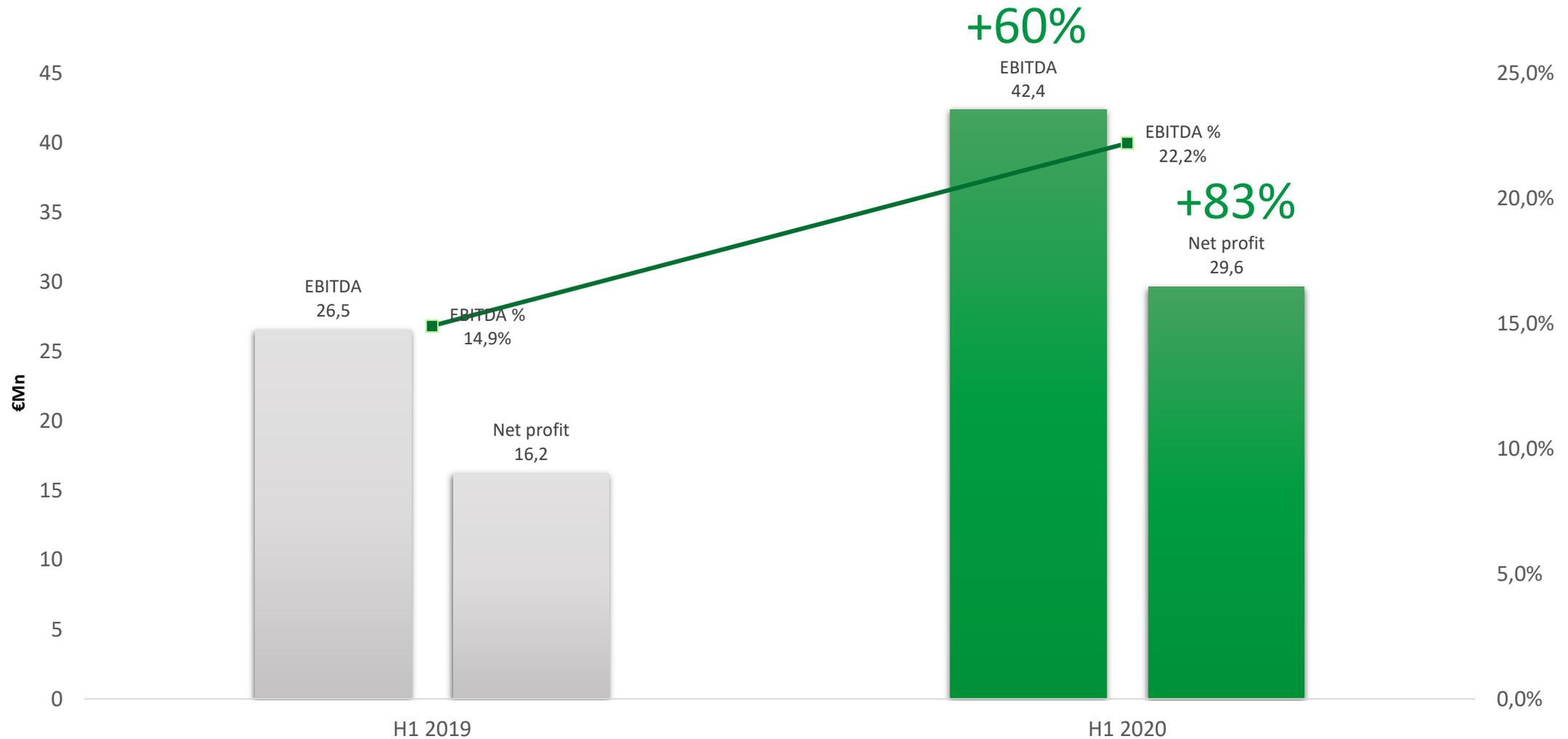


# Growth driven by specialty pharma and toll manufacturing businesses...





## ...with high profitability



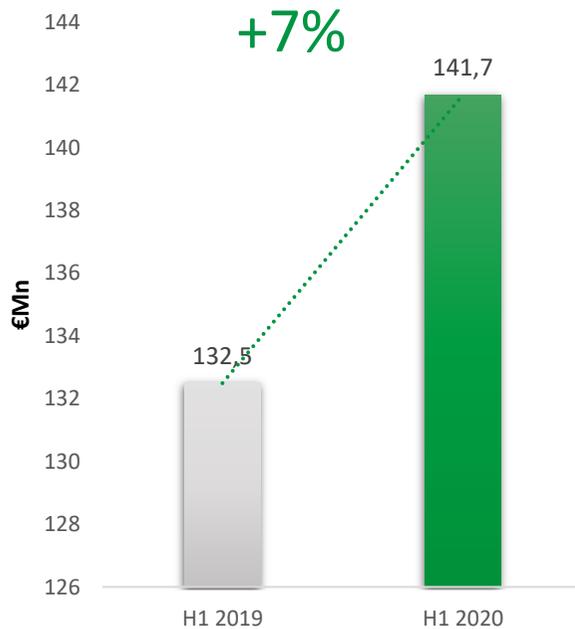
**EBITDA** increased to €42.4Mn in H1 2020, a rise of 60% compared to same period last year.

**Net profit** increased by 83%, from €16.2Mn in H1 2019 to €29.6Mn in H1 2020.

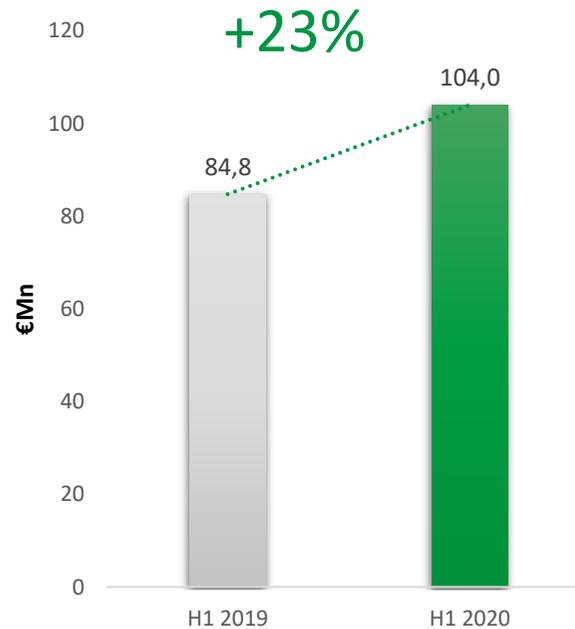


# Heparins, leading the specialty pharmaceutical business

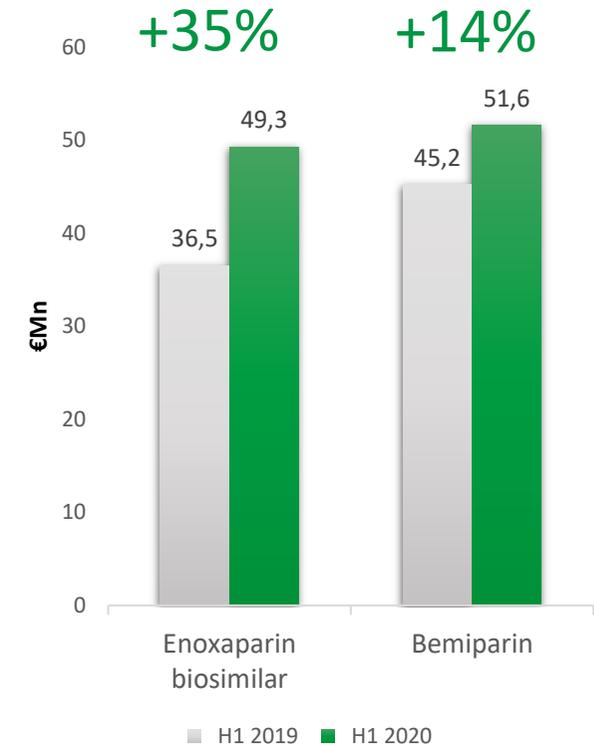
## Prescription-based sales



## Heparin franchise sales



## Sales LMWH



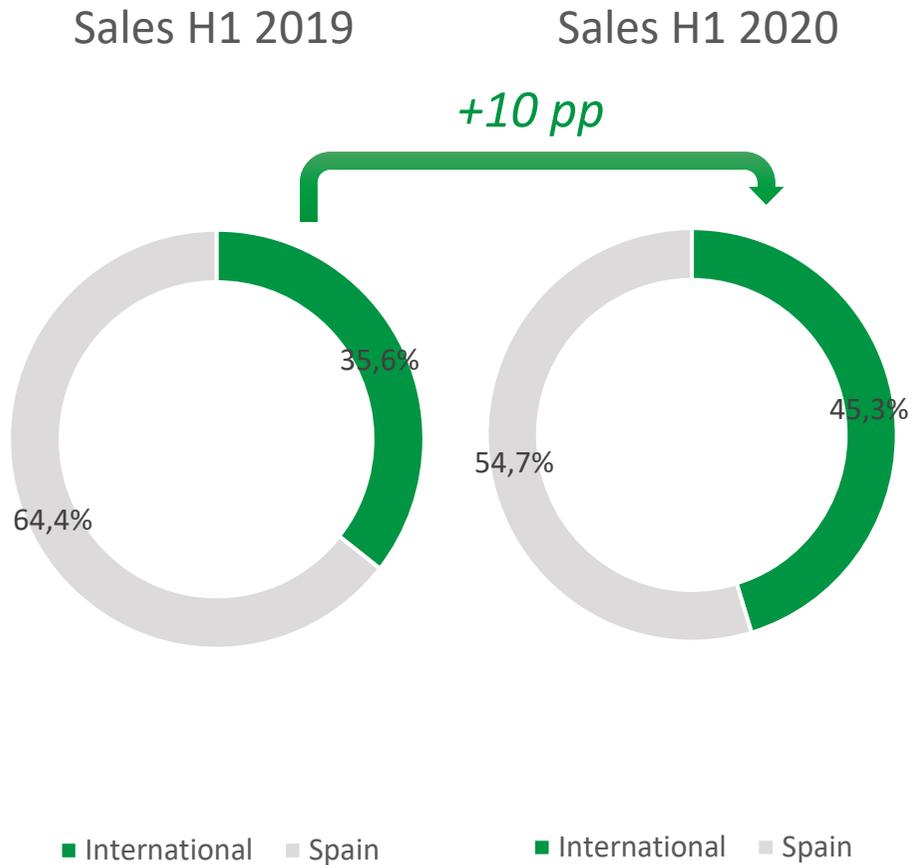
- Sales of **prescription-based pharmaceutical products** increased by **7%** to €141.7Mn in H1 2020.
- Sales of **heparin franchise** increased by 23% to €104.0Mn in H1 2020.
- **Heparin sales represented 54% of operating revenue** in H1 2020 compared to 48% in H1 2019.

# Well Positioned to Drive Long-Term Leadership in Low Molecular Weight Heparins (LMWH)

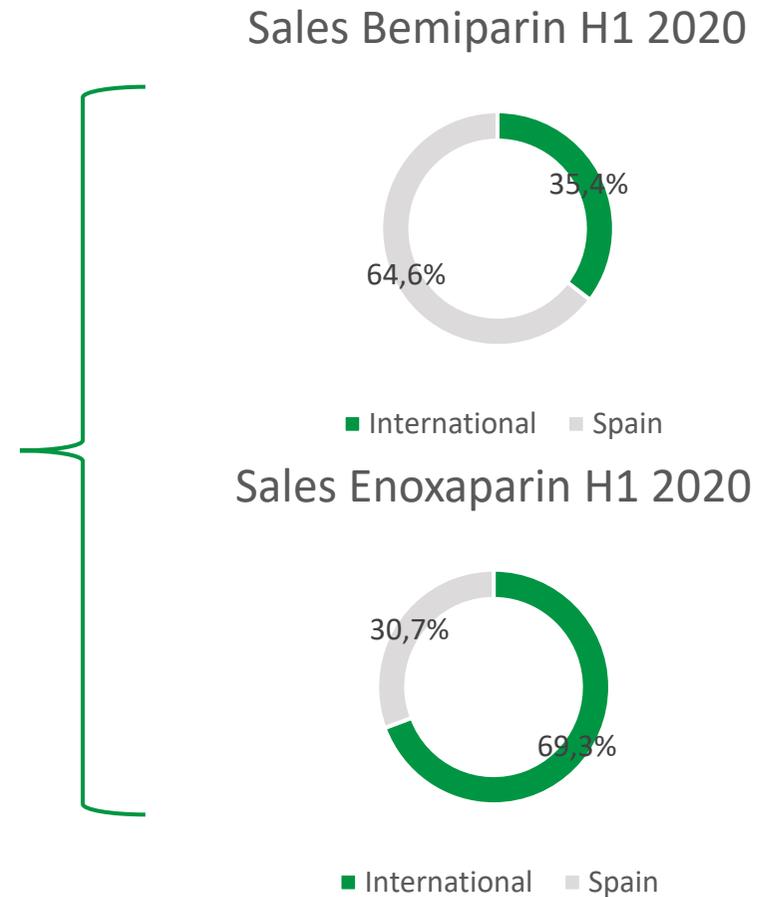


Sales of LMWH (Enoxaparin biosimilar and Bemiparin) increased by 24% to €101.0Mn in H1 2020.

## Total group sales



## Enoxaparin & Bemiparin international sales





# 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, Costa Rica, Finland and Sweden** in 2019.

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

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

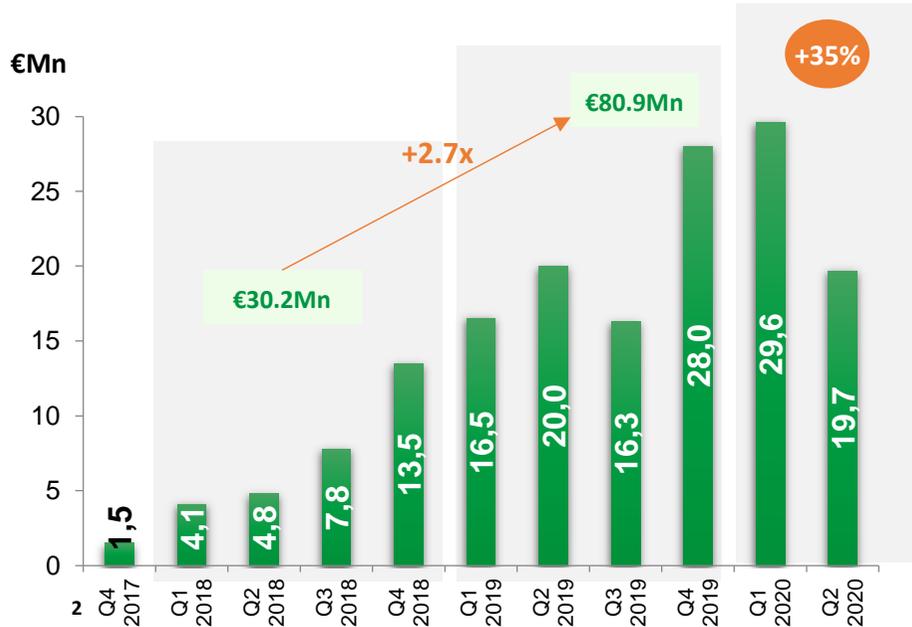
Approved in **26 countries** in Europe and 6 in the Rest of the World

Launched in **13 countries**

Pending approval in **70 countries**

## Enoxaparin Biosimilar Becat® Sales Ramp-up

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



## Stage I of Commercial Strategy

Focus on Europe...



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

ROVI will 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

## Stage II of Commercial Strategy

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

**€0.5bn** 2019 Market Sales<sup>3</sup>

**13.9%** 2019 Market Growth<sup>3</sup>

Already Signed Out-Licensed Agreements: **88 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 through Biogaran

2. Becat® 4Q 2017 sales include sales throughout September. As the product was launched that month, sales were negligible.

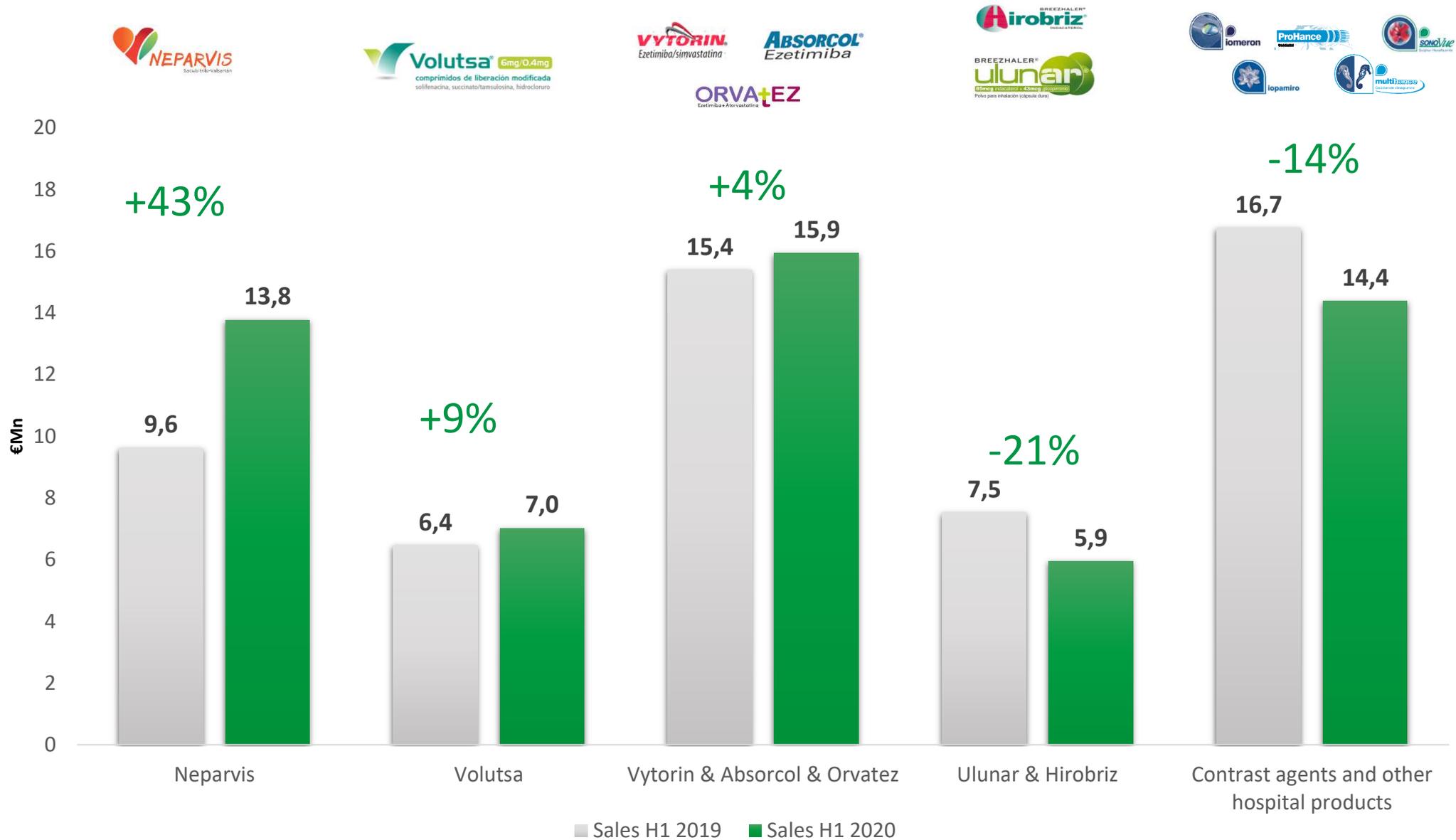
3. Estimates based on Sanofi-Aventis reported 2019 sales.

4. QuintilesIMS, 2015.

5. Technavio 2016 biosimilars report.



# Strong performance of the product portfolio





# Value added toll manufacturing services

## Toll manufacturing strategy

Our biosimilar of enoxaparin as a catalyst for the integration of industrial processes among all our manufacturing plants.

### ★ Packaging Excellence Centre in our Alcalá de Henares plant

State-of-the art installations

- 2 new high-speed lines
- 3 lines moved from Madrid plant
- In total, 13 packaging lines

### ★ New capacities for aseptic filling in our Madrid plants

Own products and for third parties

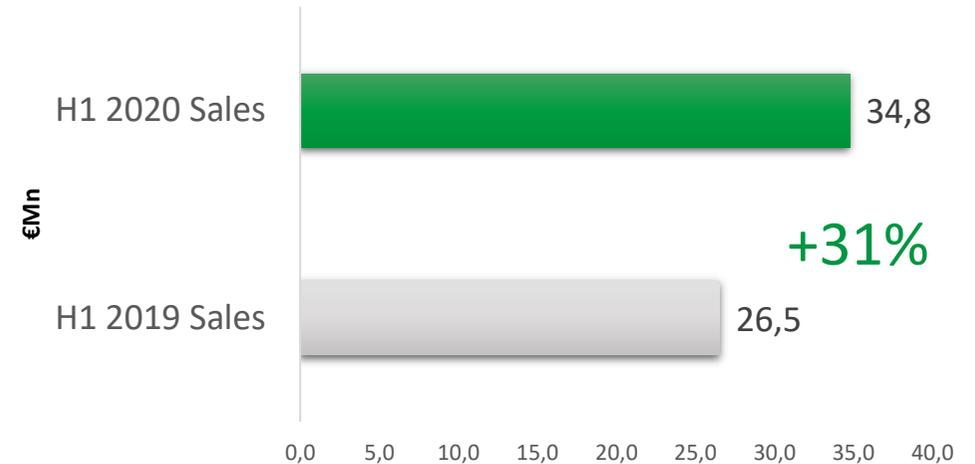
- 1 new filling line
- 1 new filling line for vials (Moderna)
- 1 new inspection line

### ★ Second heparin plant in Granada

Strategic growth in the LMWH field

- Active principle manufacturing
- Back-up facility
- Capacity x 2

## Toll manufacturing evolution



- Toll manufacturing sales increased by 31% to €34.8Mn in H1 2020.
- ROVI expects the toll manufacturing business to have increased by a high-double-digit percentage by the end of 2020.



- Thanks to Moderna's deal ROVI will incorporate 1 new filling line for vials.



# 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

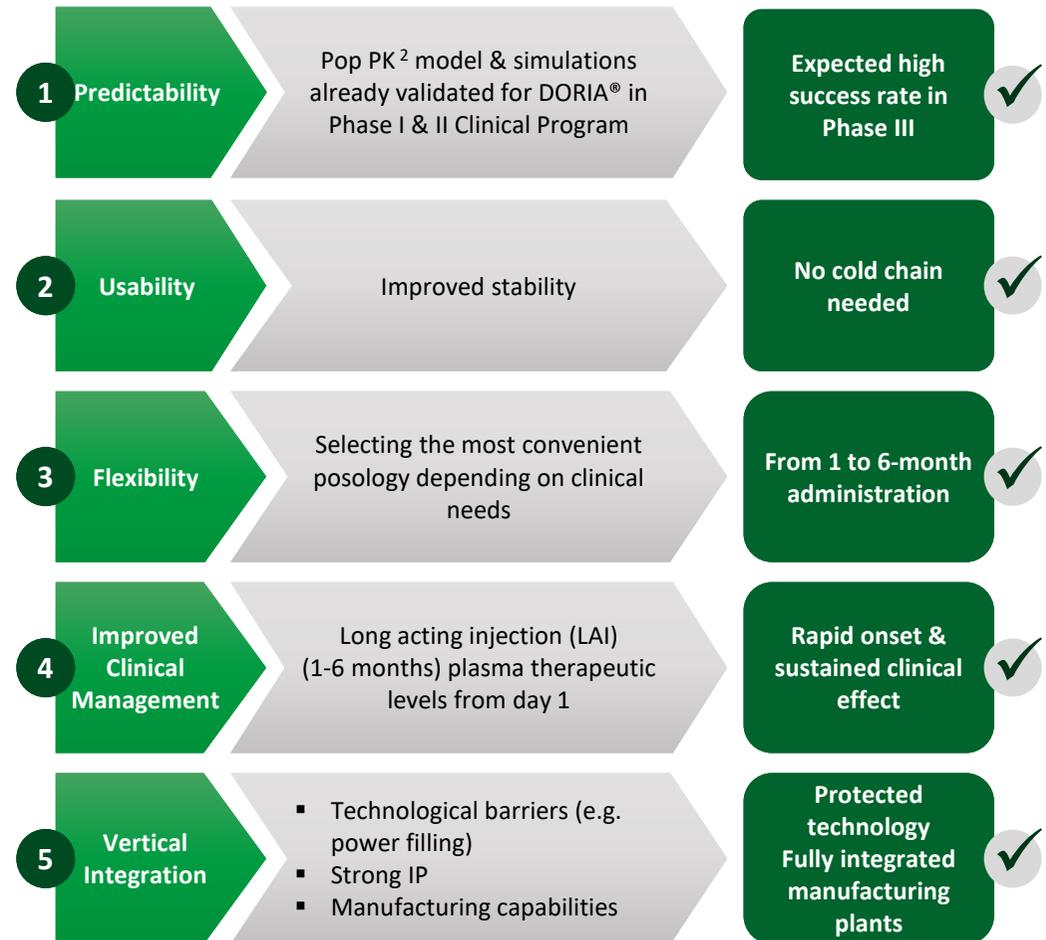
## 2 Candidates Currently in Clinical Trials

Product	Potential Indication	Current Situation				Key Milestones
		Non-Clinical	I	II	III	
DORIA <sup>®</sup> Risperidone, monthly	Schizophrenia	[Progress bar: ~90%]				In approval process in Europe and expected to be filed in USA in H2 2020
Letrozole ISM <sup>®</sup> Long acting Letrozole	Breast Cancer	[Progress bar: ~30%]				Phase I started in November 2017
Risperidone, quarterly	Schizophrenia	[Progress bar: ~10%]				

★ 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.



**THE KEY GROWTH LEVERS IN 2020**

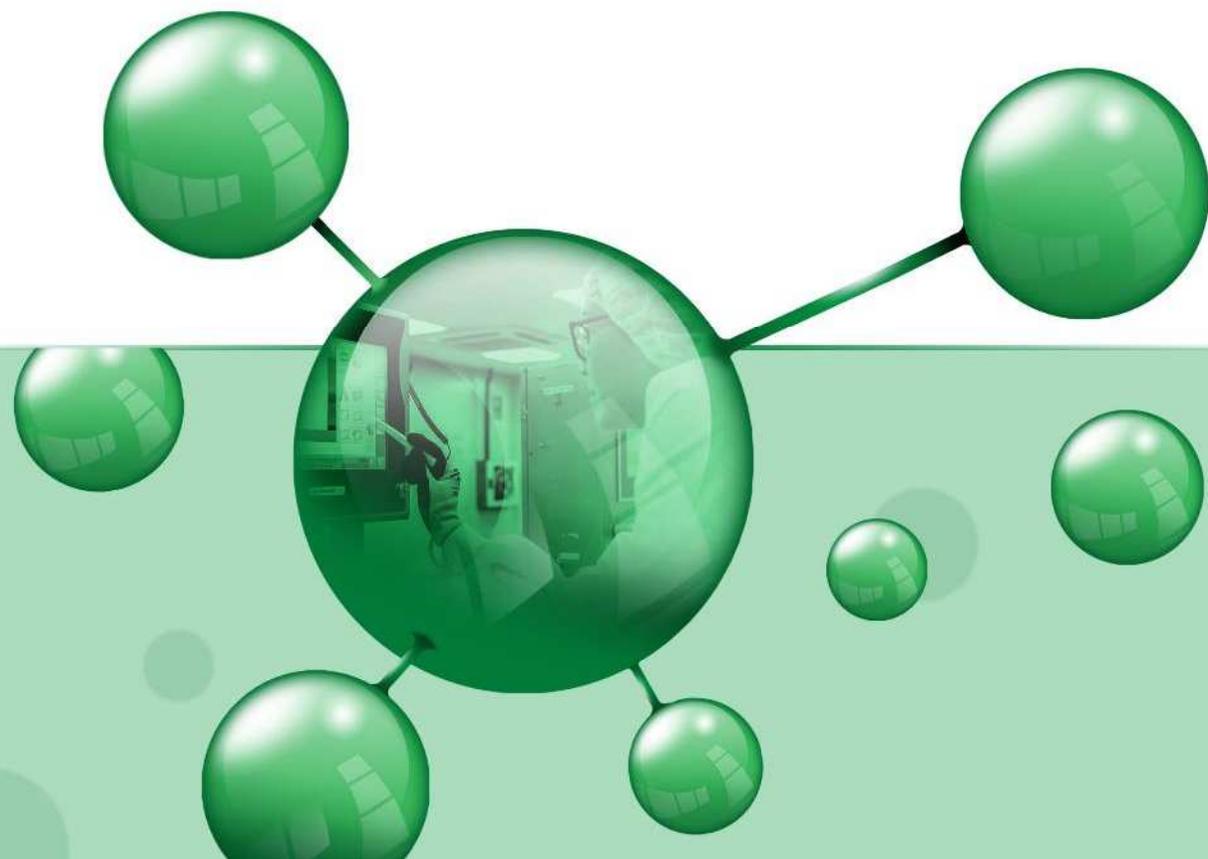
Specialty Pharma Business	Toll Manufacturing Services
<ul style="list-style-type: none"> <li>✓ Bemiparin</li> <li>✓ Biosimilar of Enoxaparin</li> <li>✓ Launches such as Neparvis and Volutsa</li> <li>✓ Existing portfolio of specialty pharmaceuticals</li> <li>✓ New acquisitions (Falithrom, Polaramine and sodium heparin)</li> </ul>	<ul style="list-style-type: none"> <li>✓ Spare capacity in the manufacturing plants</li> <li>✓ New customers to be acquired</li> </ul>

- Given the uncertainties associated to the development of the Covid-19 pandemic, it is not yet possible to make a precise assessment of the impact that the pandemic will have on 2020.
- The potential increase in the discounts to the National Health System as a result of the Covid-19 impact may affect attainment of these growth forecasts.



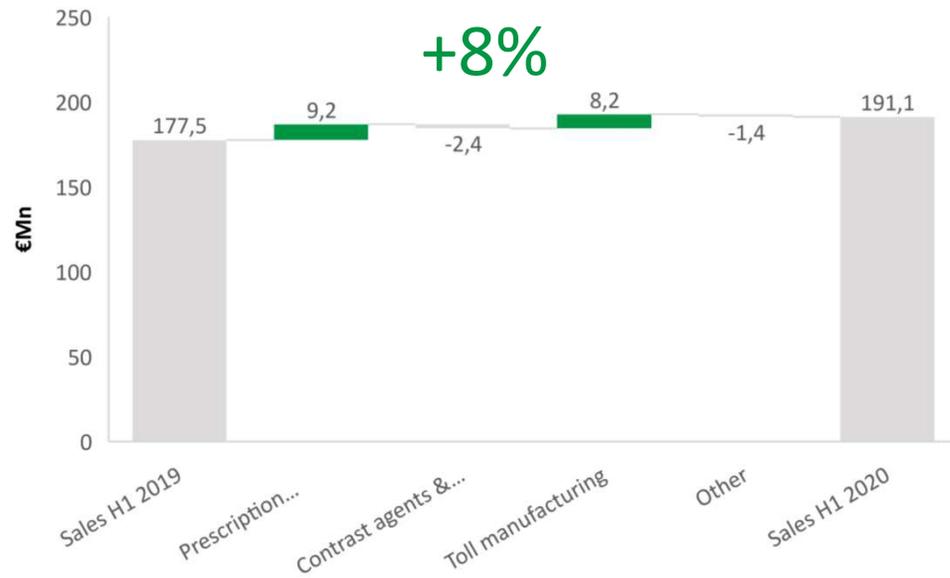
Javier López-Belmonte  
Chief Financial Officer

## Financial results

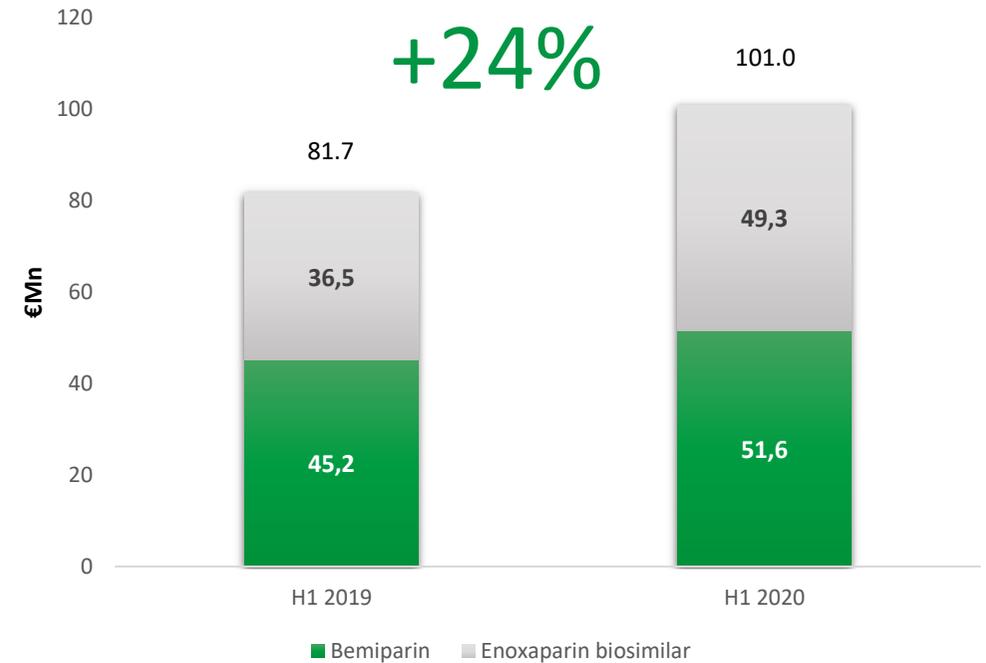


## Good revenue level with resilient sales growth

### Total operating revenue



### LMWH sales

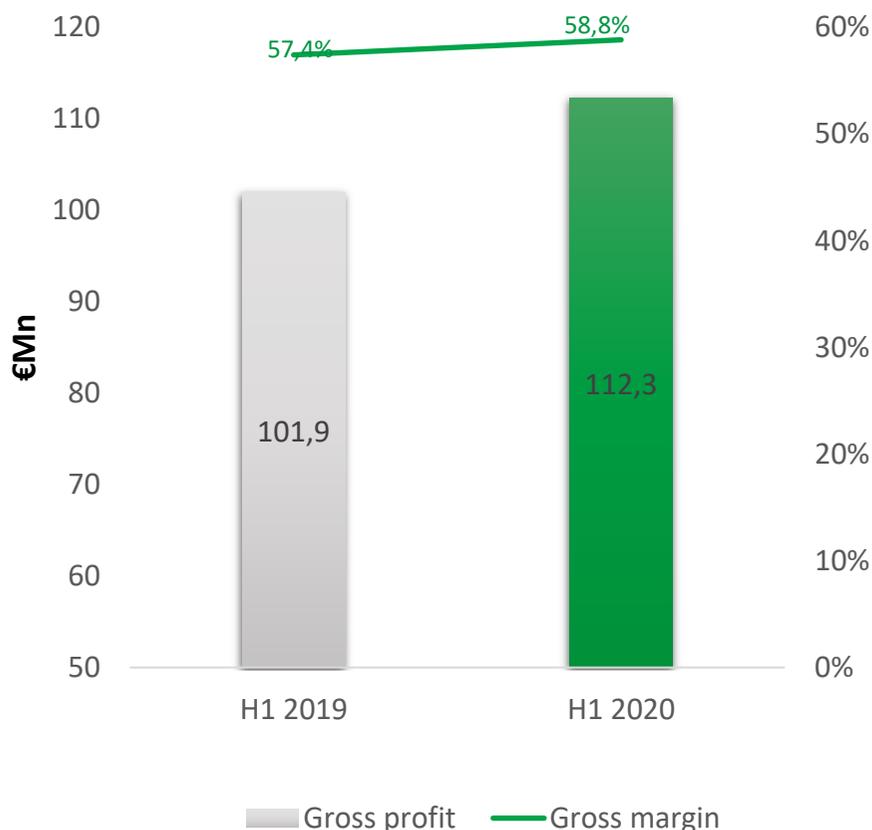


- **Operating revenue** increased by 8% to €191.1Mn, achieved on:
  - 7% growth in prescription-based products
  - 31% increase in toll manufacturing.
- Contrast agents and other hospital products decreased by 14%.
- Sales of **LMWH** increased by 24% to €101.0Mn in H1 2020.
  - **Enoxaparin biosimilar sales increased by 35%** to €49.3Mn and **Bemiparin sales increased by 14%**.

# Gross margin mainly impacted by the increase in toll manufacturing sales and the increase in heparin prices



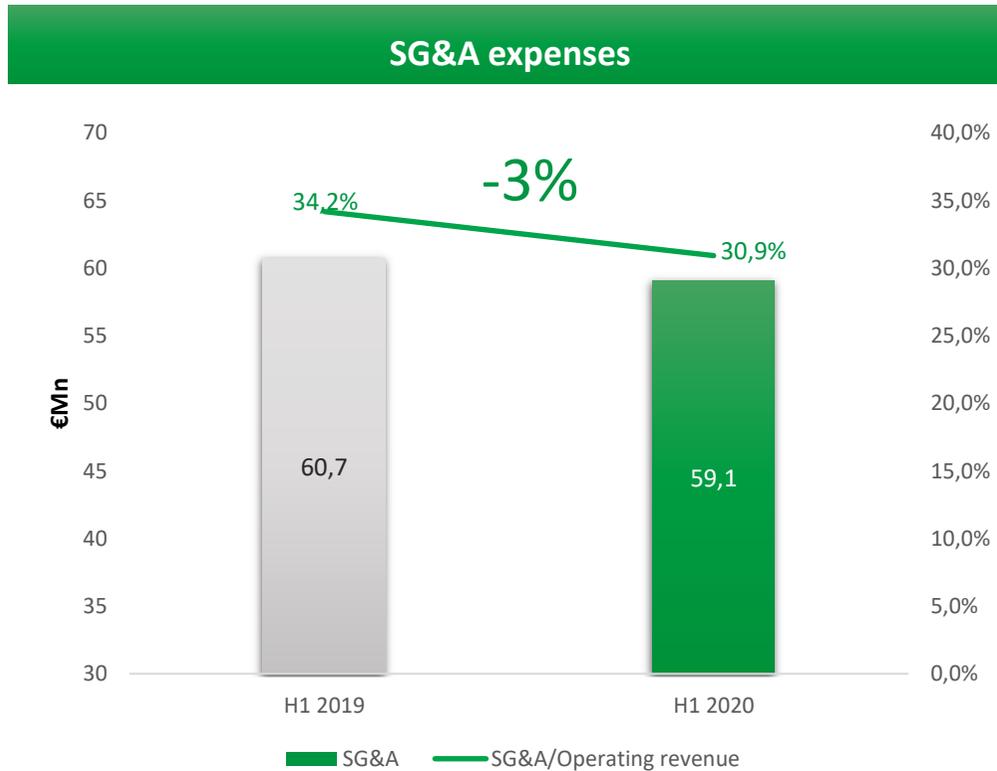
## Gross profit and Gross margin



## Gross margin impacts for the period

- Increase in **toll manufacturing** sales contributing with higher margins to group sales.
- Increase in **Bemiparin prices** in hospitals due to rises in both LMWH raw material prices and the demand for the product in hospitals to treat COVID-19.
- Improvement in **enoxaparin margins in Spain** counteracting the drop in the margin on international sales of enoxaparin.
- **End of the marketing of the Norgine B.V. product portfolio** with lower margins than the group.

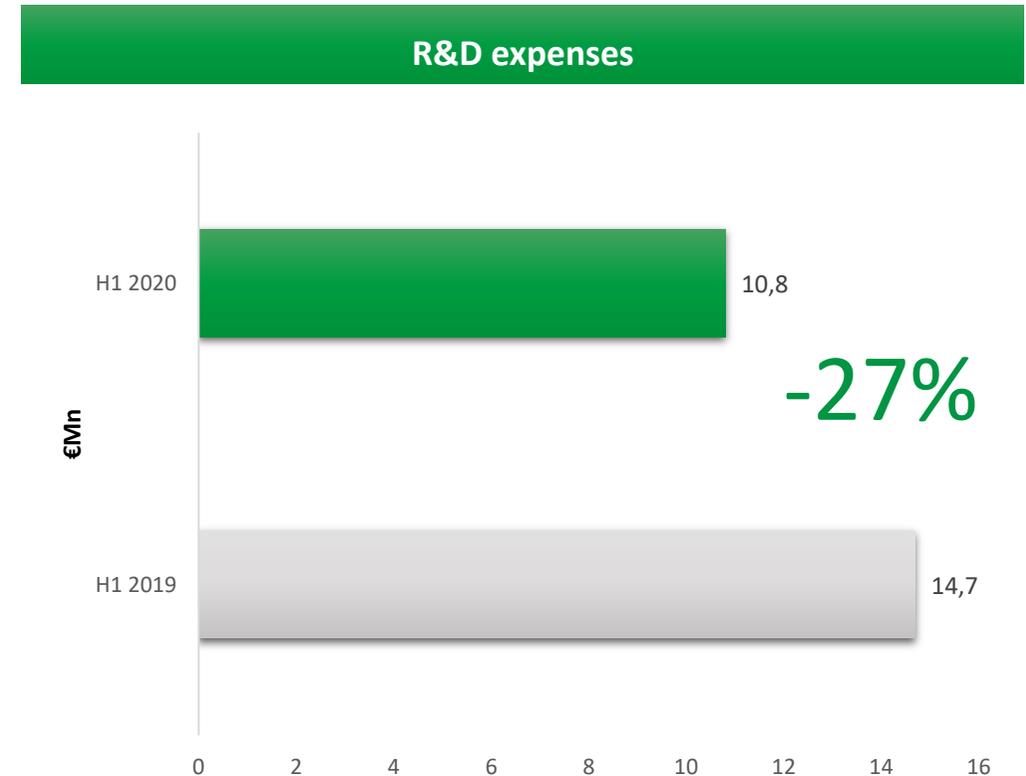
## Cost control along with commitment to R&D



**SG&A expenses** down 3% to €59.1Mn in H1 2020 mainly due to a drop in:

- Promotion expenses; and
- International subsidiaries expenses.

ROVI booked €2.5Mn in personnel and other expenses related to the **Covid-19 measures implemented**.



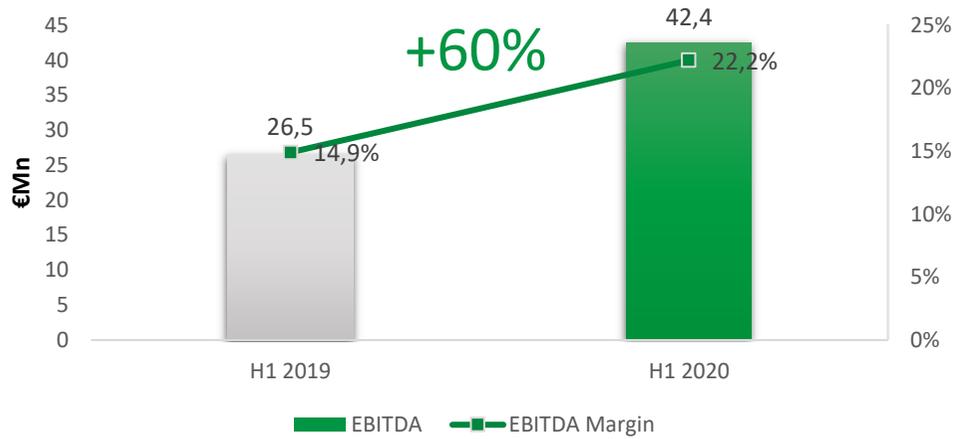
**R&D expenses** decreased 27% to €10.8Mn in H1 2020. These expenses are related to:

- Preparation of the Doria® registration dossier to be submitted to the FDA;
- Letrozole-ISM® Phase I trial; and
- Development of a new formulation of Risperidone-ISM® for a 3-monthly injection.

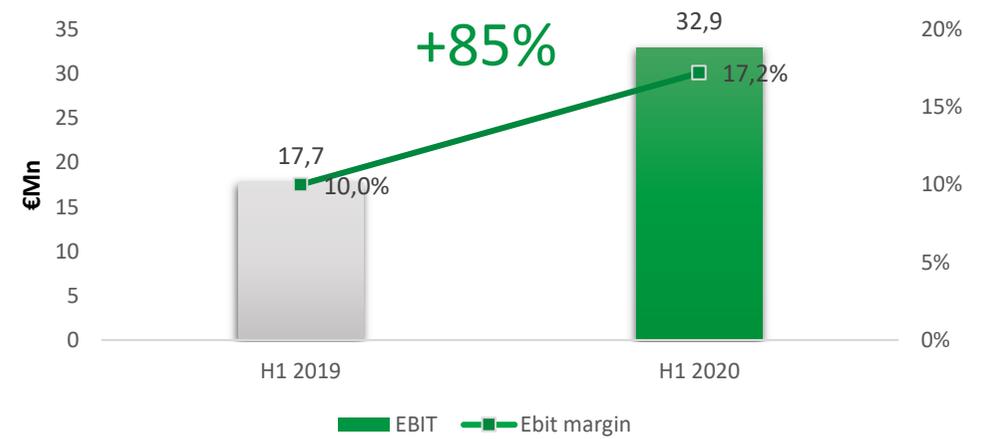


# EBITDA, EBIT & net profit analysis

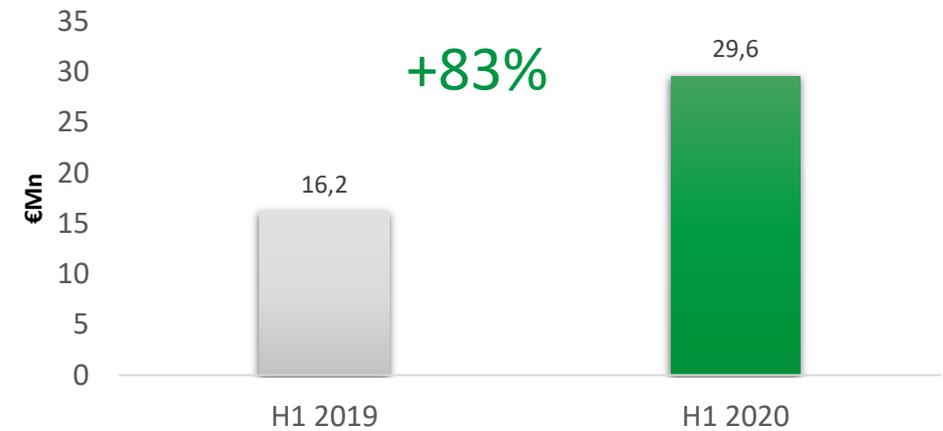
## EBITDA



## EBIT



## Net profit



## PRE-R&D analysis

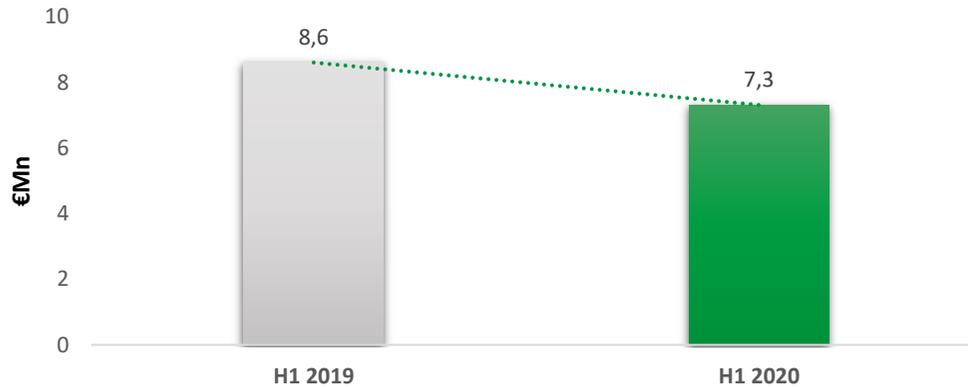


- **EBITDA “pre-R&D”** increased by 29%, from €41.2Mn in H1 2019 to €53.2Mn in H1 2020.
- **EBIT “pre-R&D”** increased by 34%, from €32.5Mn in H1 2019 to 43.6Mn in H1 2020.
- **Net profit “pre R&D”** increased by 32%, from €29.8Mn in H1 2019 to €39.3Mn in H1 2020.

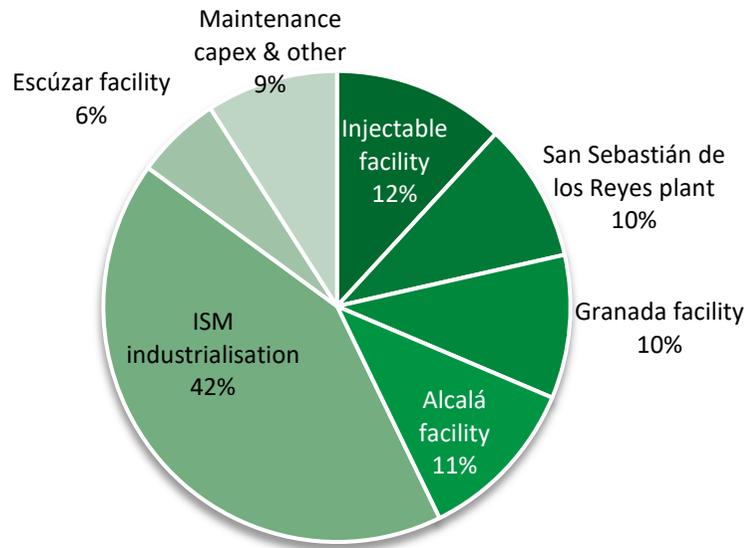
Note: EBITDA, EBIT and Net profit “pre-R&D” calculated excluding R&D expenses in H1 2020 and H1 2019

# Capital expenditure and Free Cash Flow

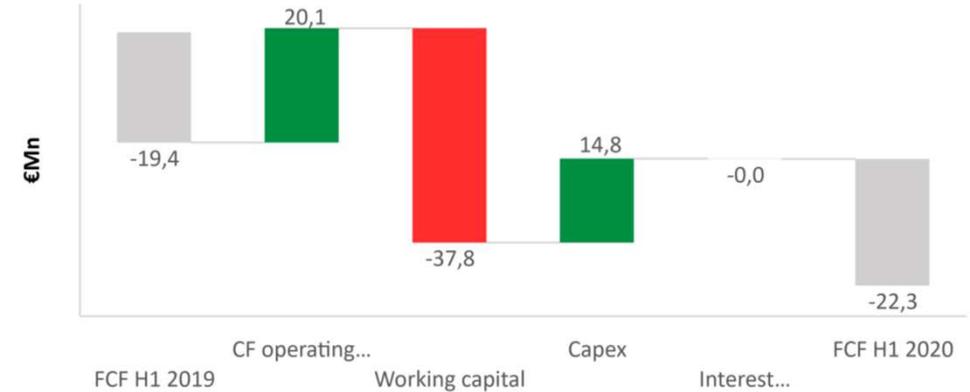
## Capex evolution



### CAPEX distribution H1 2020



## FCF evolution



FCF decreased to €-22.3Mn mainly due to:

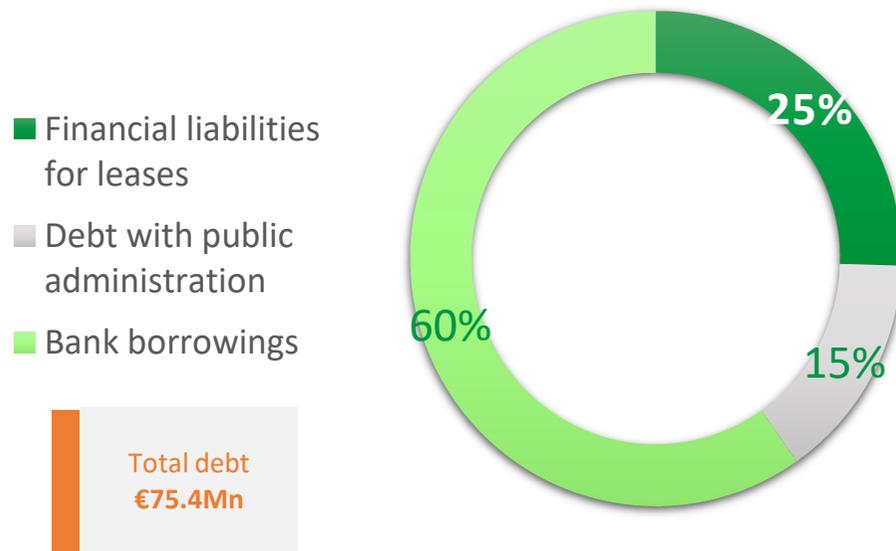
- Increase of €77.3Mn in the “inventories” line in the H1 2020 mainly as a result of higher heparin stock levels compared to an increase of €28.3Mn in the H1 2019;

This negative impact was partially offset by:

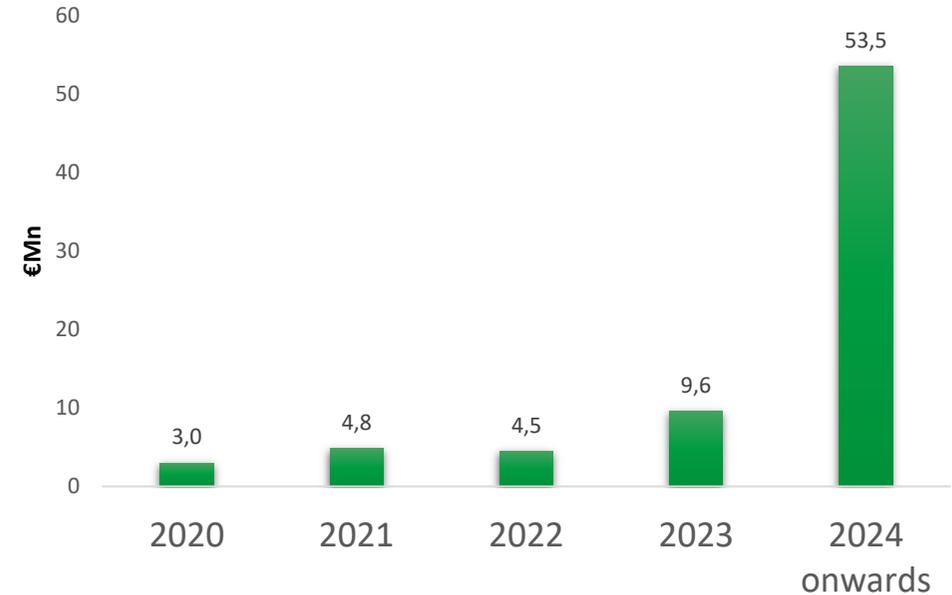
- Decrease of €14.8Mn in Capex mainly as a result of the acquisition of Polaramine® in the 1H 2019;
- Decrease of €5.8 Mn in the “trade and other receivables” item in H1 2020 compared to an increase of €9.6Mn in the H1 2019; and
- Increase of €15.4 Mn in profit before income tax.

# Debt analysis

## Debt breakdown by source (%)



## Debt maturities



- **Debt with public administration** represented **15% of total debt, with 0% interest rate.**
- **Net debt of €38.0Mn** as of 30 June 2020 vs €15.9Mn as of 31 December 2019.
- **Dividend:** ROVI expects to hold its Ordinary General Shareholders' Meeting in October 2020 and will propose the distribution of a dividend of 0.1751 euros per share, as announced to the Market in February 2020, when the company released its 2019 full year results.

# News-flow 2020



<b>Specialty Pharma</b>	Sales of biosimilar of Enoxaparin
	No additional products expected to be launched as a result of COVID-19 crisis.
	Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar in 70 countries outside Europe
<b>Toll manufacturing</b>	New contracts to be announced Evolution of Moderna's vaccine
<b>ISM<sup>®</sup> technology platform</b>	Risperidone ISM <sup>®</sup> expected to be filed in USA in H2 2020 Risperidone ISM <sup>®</sup> final Phase III data will be presented in scientific congresses
	Next steps of Letrozole ISM <sup>®</sup> to be discussed with regulatory authorities in 2020

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