



FIRST HALF 2019 FINANCIAL RESULTS

JULY 2019

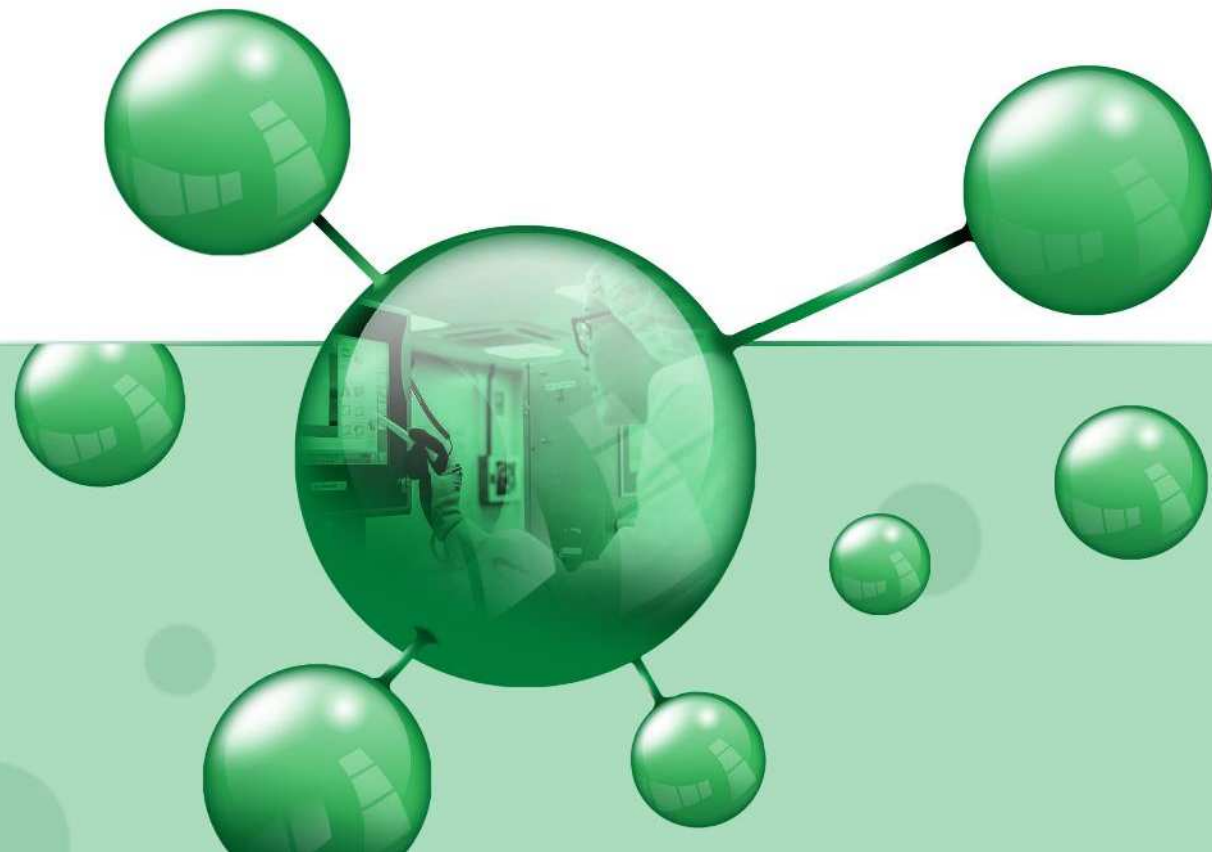


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Operating results

Juan López-Belmonte
Chief Executive Officer





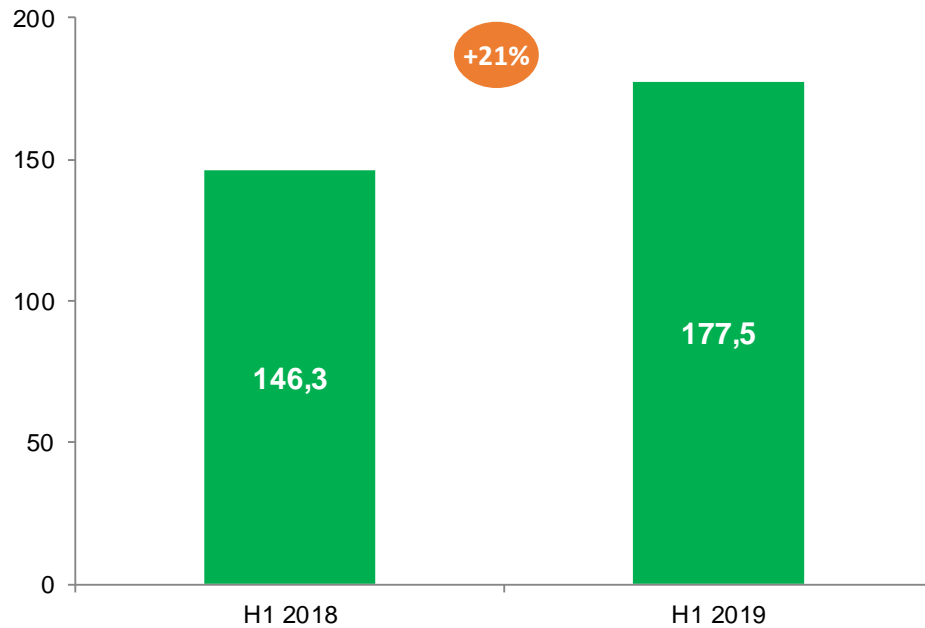
First Half 2019 financial results - Highlights

- **Operating revenue** increased by 21% to €177.5Mn in H1 2019, driven by the strength of the specialty pharmaceutical business, where sales rose 22%, strongly outperforming the market, and by the toll manufacturing business, which grew by 15%. Total revenue increased by 21% to €177.9Mn in H1 2019.
- For the second time this year, ROVI is upgrading its operating revenue guidance for the full year 2019, from low-double-digit growth rate to high-double-digit growth rate.
- 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.**
- All the EU countries (26 countries) where ROVI had applied for the national registration of the Enoxaparin biosimilar had approved such registration.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** increased by 43% to €81.7Mn in H1 2019. **LMWH sales represented 46%** of operating revenue in H1 2019 compared to 39% in H1 2018. **Sales of the Enoxaparin biosimilar** amounted to **€36.5Mn** in H1 2019 and **positive performance of Bemiparin in Spain (+5%** to €35.5Mn).
- Sales of **Neparvis**, launched in December 2016, increased 63% to €9.6Mn in H1 2019.
- 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 June 30, 2019 were:
 - Recognition of assets under the “Property, plant and equipment” caption (non-current assets) for an amount of €22.8Mn.
 - Increase in debt under the captions “Financial liabilities for non-current and current leases” of €19.1Mn and €3.7Mn, respectively.
 - Lower operating expenses and, consequently, an increase of EBITDA of €1.6Mn, since operating lease payments were recognized under the SG&A caption.
 - Higher expense for the depreciation of the right-of-use asset of €1.5Mn.
 - An increase of €0.1Mn in the finance costs of the lease liabilities.
- **EBITDA** increased by 99%, from €13.3Mn in H1 2018 to €26.5Mn in H1 2019, reflecting a 5.8 pp rise in the EBITDA margin to 14.9% in H1 2019.
- **Net profit** increased by 114%, from €7.6Mn in H1 2018 to €16.2Mn in H1 2019.

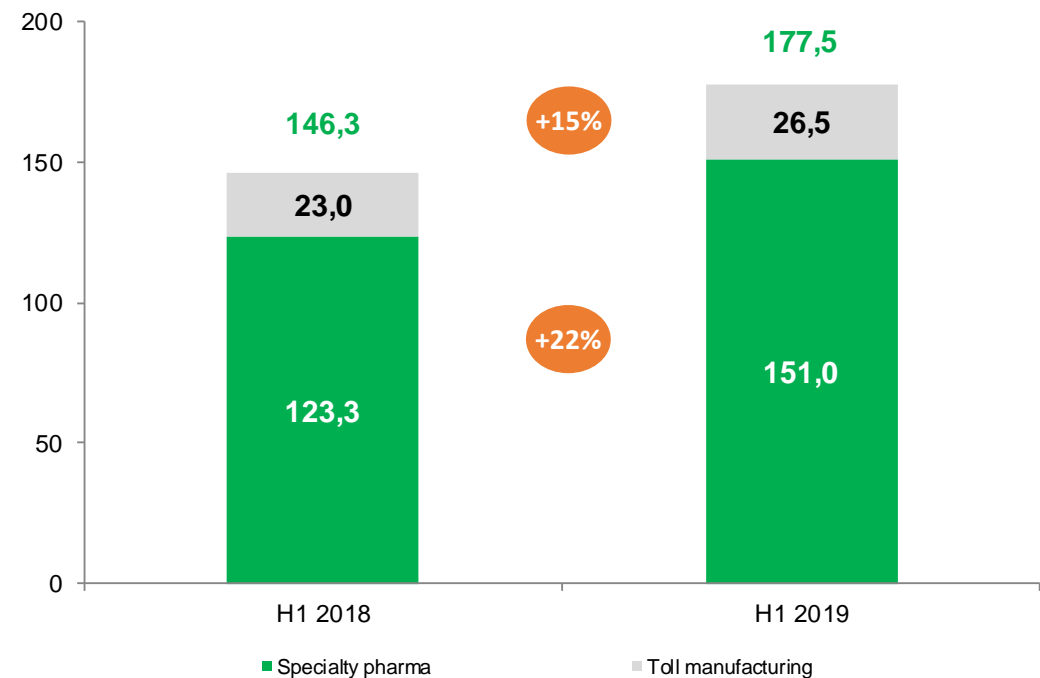


Growth driven by specialty pharma and toll manufacturing businesses...

Total operating revenue (€Mn)



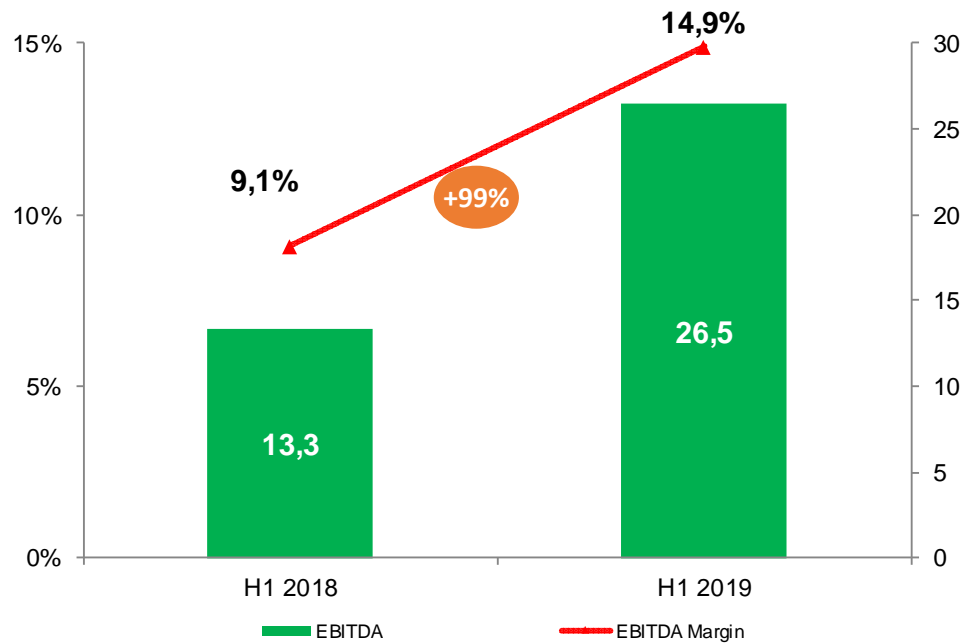
Operating revenue growth by category (€Mn)



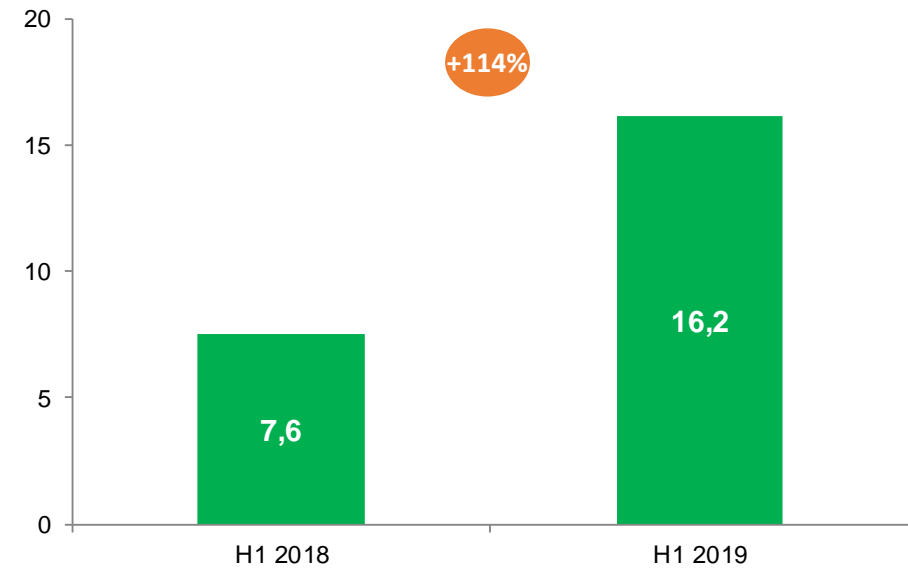
- **Operating revenue increased by 21%** to €177.5Mn in H1 2019 driven by the strength of:
 - the specialty pharmaceutical business, where sales rose 22%; and
 - the toll manufacturing business, which grew by 15%.
- ROVI forecasts that it will continue to grow at a higher rate than Spanish pharmaceutical market expenditure in the first five 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)

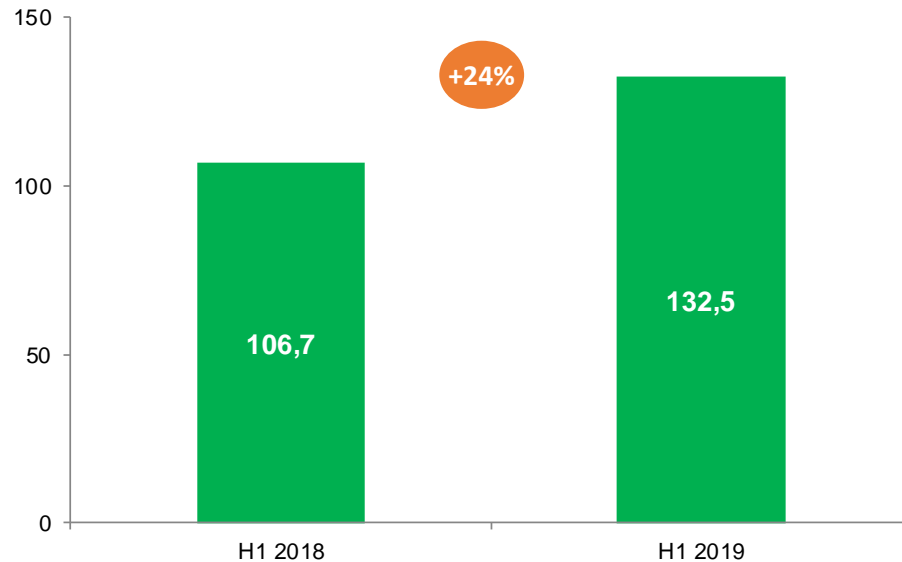


- In H1 2018, EBITDA was affected by non-recurring expenses of €2.6Mn.
- As a result of the IFRS 16 application, EBITDA was positively impacted by €1.6Mn in H1 2019.
- **EBITDA increased by 99%**, from €13.3Mn in H1 2018 to €26.5Mn in H1 2019, reflecting a 5.8 percentage point rise in the EBITDA margin to 14.9% in H1 2019.
- **Net profit increased by 114%**, from €7.6Mn in H1 2018 to €16.2Mn in H1 2019.

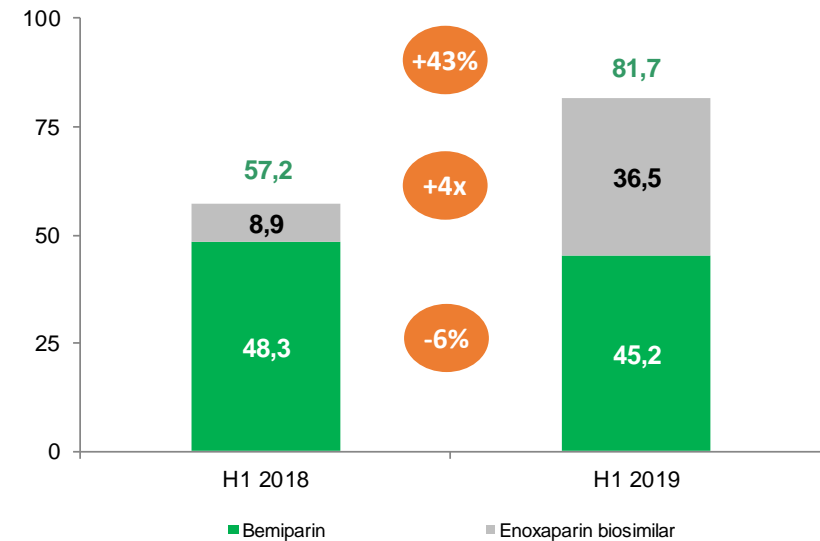


LMWH, leading the specialty pharmaceutical business

Prescription-based pharma products sales (€Mn)

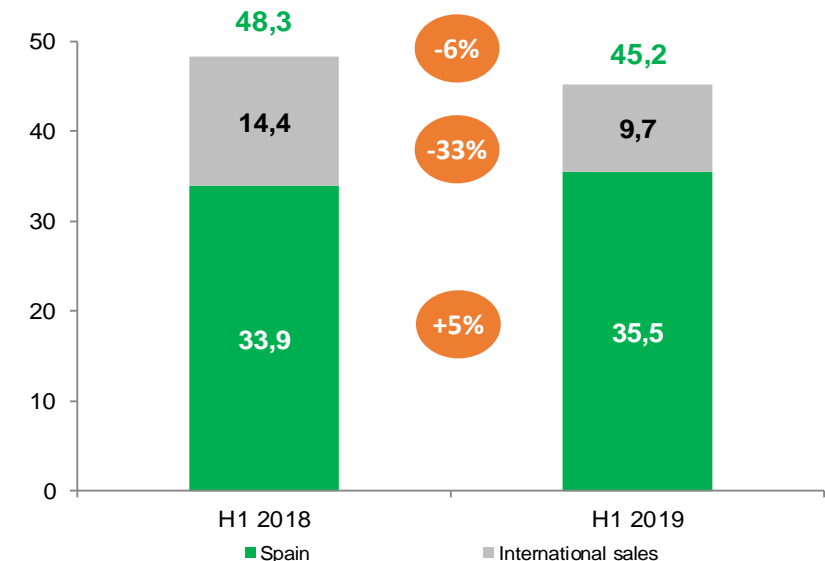


LMWH franchise sales (€Mn)



- Sales of **prescription-based pharmaceutical products** increased by **24%** to €132.5Mn in H1 2019.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** (Enoxaparin biosimilar and Bempiparin) increased by **43%** to €81.7Mn in H1 2019.
- **LMWH sales represented 46% of operating revenue in H1 2019 compared to 39% in H1 2018.**
 - Sales of the **Enoxaparin biosimilar** amounted to **€36.5Mn** in H1 2019.
 - **Bempiparin total sales decreased by 6%** to €45.2Mn in H1 2019:
 - Sales in **Spain increased 5%** to €35.5Mn.
 - **International sales decreased by 33%** to €9.7Mn. This significant decrease was specifically linked to H1 2019 and ROVI expects international Bempiparin sales to remain stable in 2019.

Bempiparin 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, France¹, Austria, Latvia and Estonia** in 2018; and in **Portugal** and **Costa Rica** in H1 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
Germany, UK, Italy, Spain & Portugal

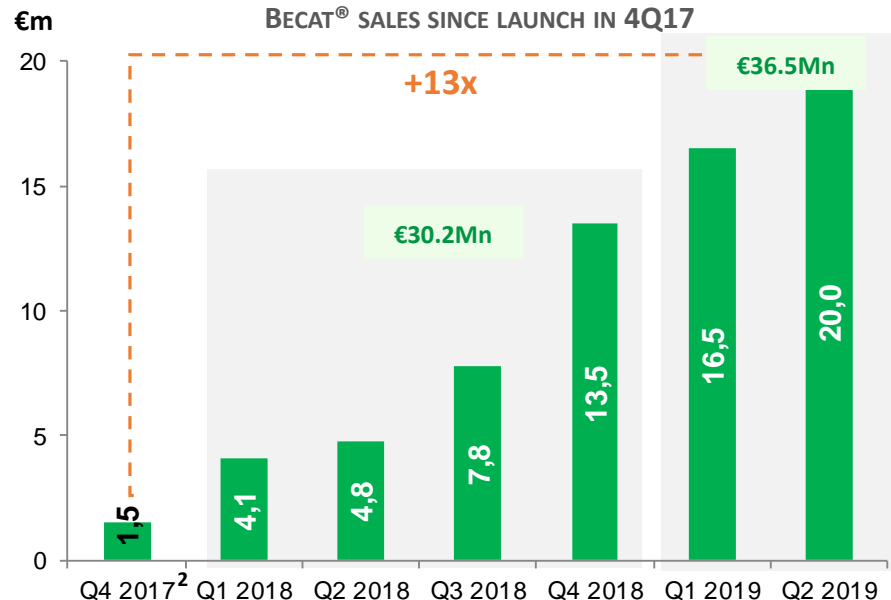
Approved; To Be Directly Marketed
2 Countries

Approved; To Be Out-Licensed
19 Countries

Pending Approval; To Be Out-Licensed
85 Countries

Enoxaparin Biosimilar Becat® Sales Ramp-up

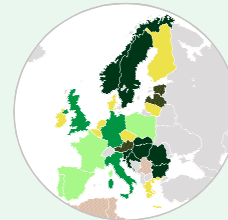
VERY POSITIVE EVOLUTION OF ENOXAPARIN BIOSIMILAR BECAT® SALES SINCE LAUNCH IN 4Q17



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** sales³

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



...which account for **c.75%** of the European market⁴

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

50-70% Market Share⁵

...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 Sales³

11.4%
2018
Market Growth³

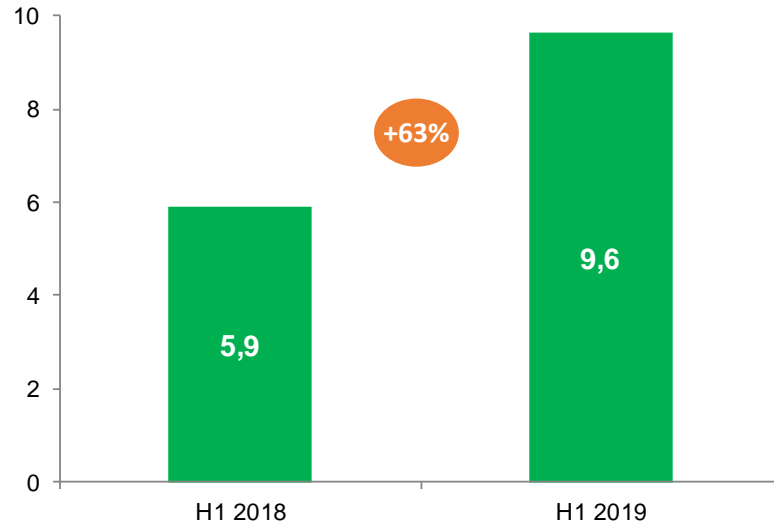
Already Signed Out-Licensed Agreements: **91 Countries**

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.

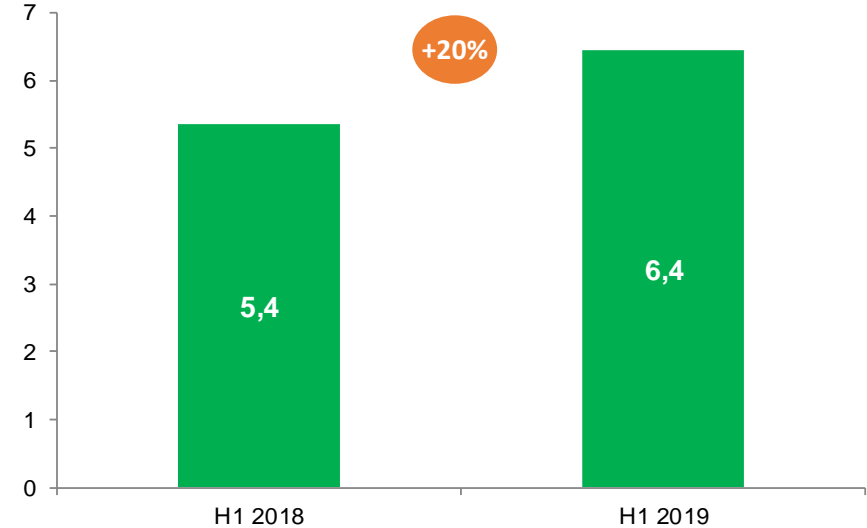
4. QuintilesIMS, 2015.
5. Technavio 2016 biosimilars report.

Strong performance of the product portfolio (1/2)

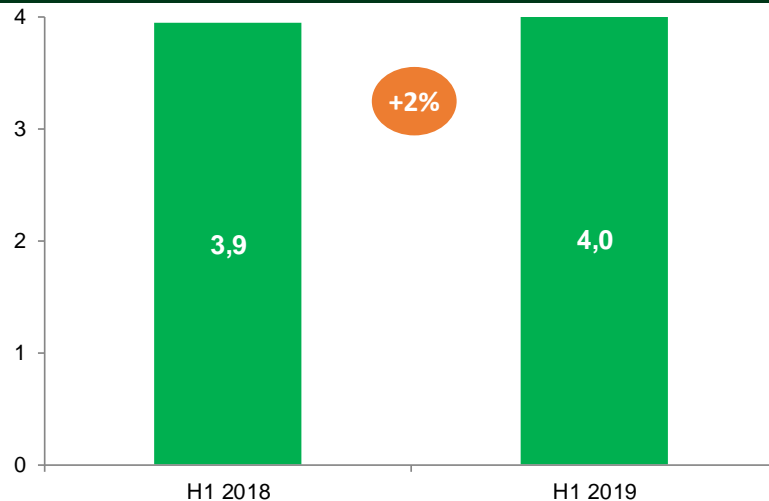
Neparvis sales (€Mn)



Volutsa sales (€Mn)



Medicebran and Medikinet sales (€Mn)



- Sales of **Neparvis**, a specialty product from Novartis launched in December 2016, **increased by 63% to €9.6Mn** in H1 2019, from €5.9Mn in H1 2018.
- Sales of **Volutsa**, launched in Spain in February 2015, **increased by 20%** to €6.4Mn in H1 2019.
- Sales of **Medicebran and Medikinet**, products launched in December 2013 and marketed on exclusivity basis by ROVI in Spain, increased 2% to €4.0Mn in H1 2019.

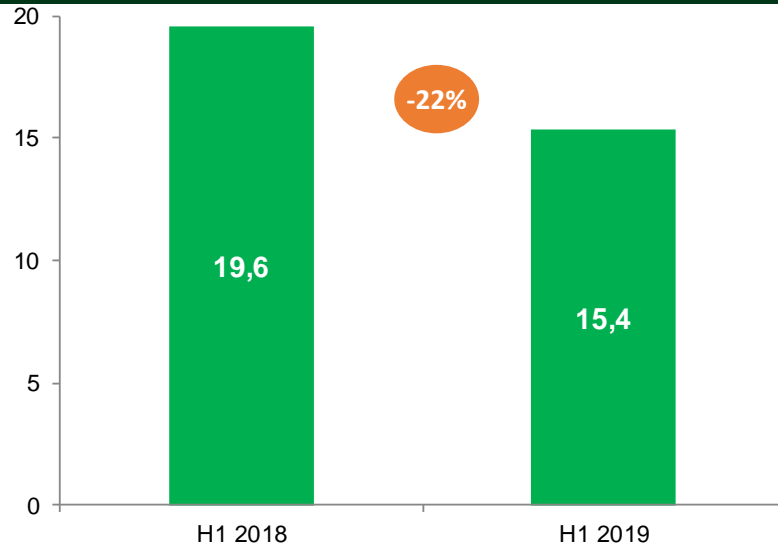
Neparvis is a specialty product from Novartis indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction.

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.

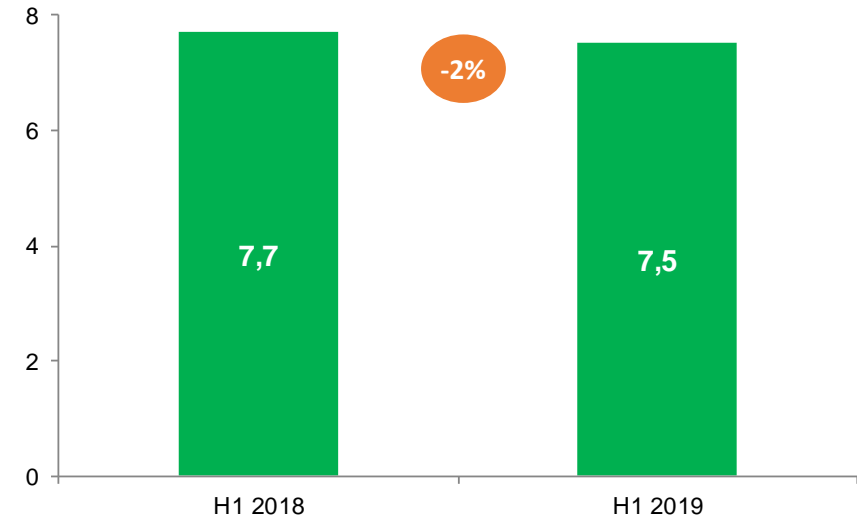
Medicebran and Medikinet are specialty products from Medice indicated for the treatment of ADHD in children and teenagers.

Strong performance of the product portfolio (2/2)

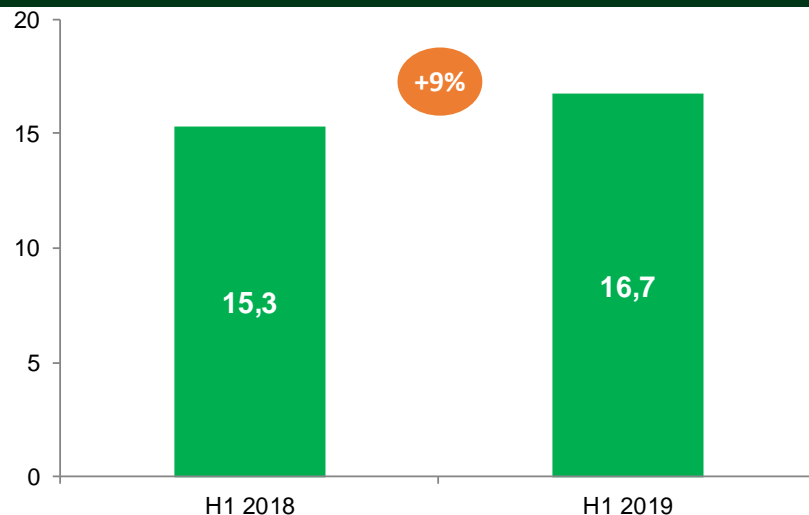
Absorcol, Vytorin and Orvatez sales (€Mn)



Hirobriz and Ulunar sales (€Mn)



Contrast imaging agents sales (€Mn)



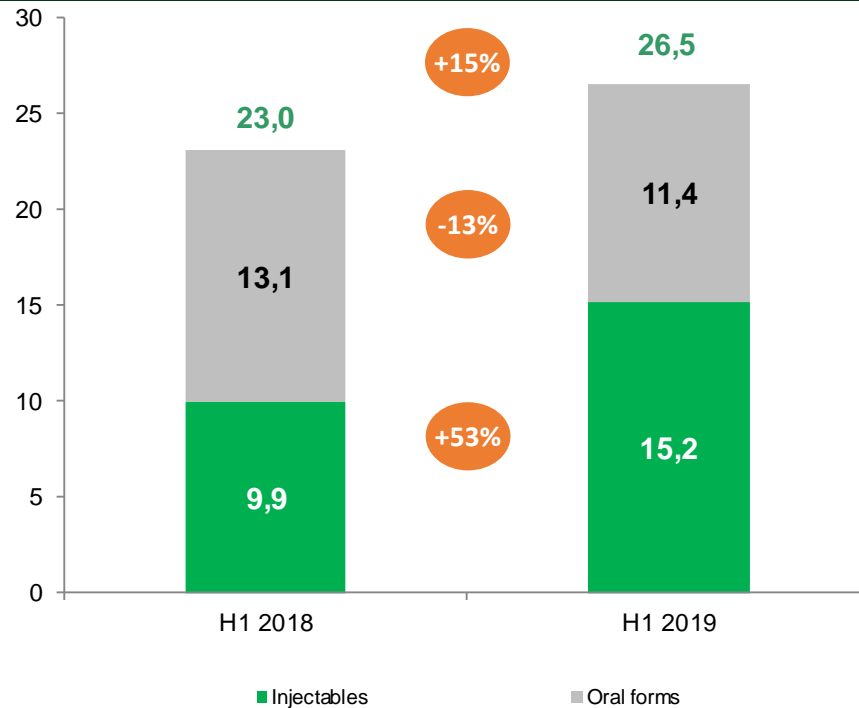
- Sales of **Vytorin**[®], **Orvatez**[®] and **Absorcol**[®] decreased by 22% to €15.4Mn in H1 2019. In 2Q 2018, the active principle ezetimibe went out of patent and the price of Absorcol[®] was reduced. Likewise, generics formulated with ezetimibe and simvastatin were marketed in the same period, so the price of Vytorin[®] was reduced to be competitive. In addition, sales of Orvatez[®] amounted to €12.5Mn in H1 2018, an extraordinary rise of 29% compared to H1 2017.
- Sales of **Hirobriz** and **Ulunar**, both products for patients with COPD, launched in Spain in Q4 2014 decreased by 2% to €7.5Mn in H1 2019.
- **Contrast imaging agents and other hospital products** increased by 9% to €16.7Mn in H1 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 15% to €26.5Mn in H1 2019 because of the good performance of the injectable business, where revenue increased by 53% to €15.2Mn as a result of higher volumes manufactured for some customers.
- Frosst Ibérica plant sales decreased by 13% to €11.4Mn in H1 2019 compared to the same period of the previous year.
- By the end of 2019, ROVI expects the toll manufacturing business to have grown from a high-single-digit rate to a low-double-digit rate.



DORIA®: Positive Results from Phase 3 study

Phase III clinical trial

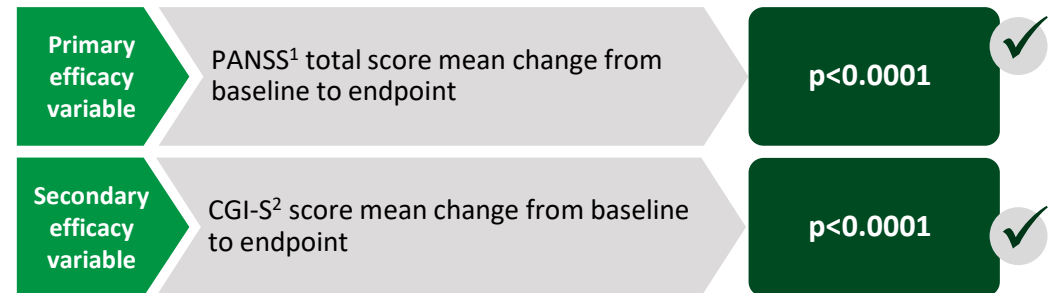
- It is double-blind (+ open-label extension), parallel, multicentre (31 sites/ 2 countries)
- The objectives of Phase III are:
 - Evaluate the efficacy and safety of DORIA® compared to placebo in the treatment of subjects with acute exacerbation of schizophrenia
 - Health Resources Utilization (HRU),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

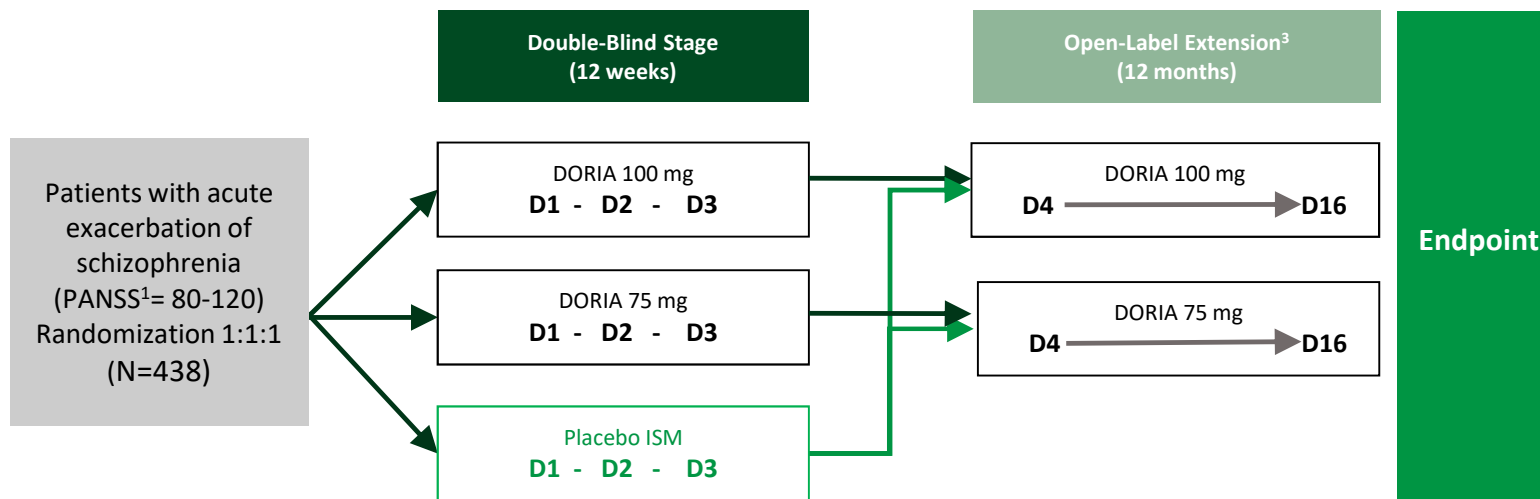
Main efficacy variables achieved

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.

¹ 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.

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

³ 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 Low-double-digit to High-double-digit

THE KEY GROWTH LEVERS IN 2019

Specialty Pharma Business

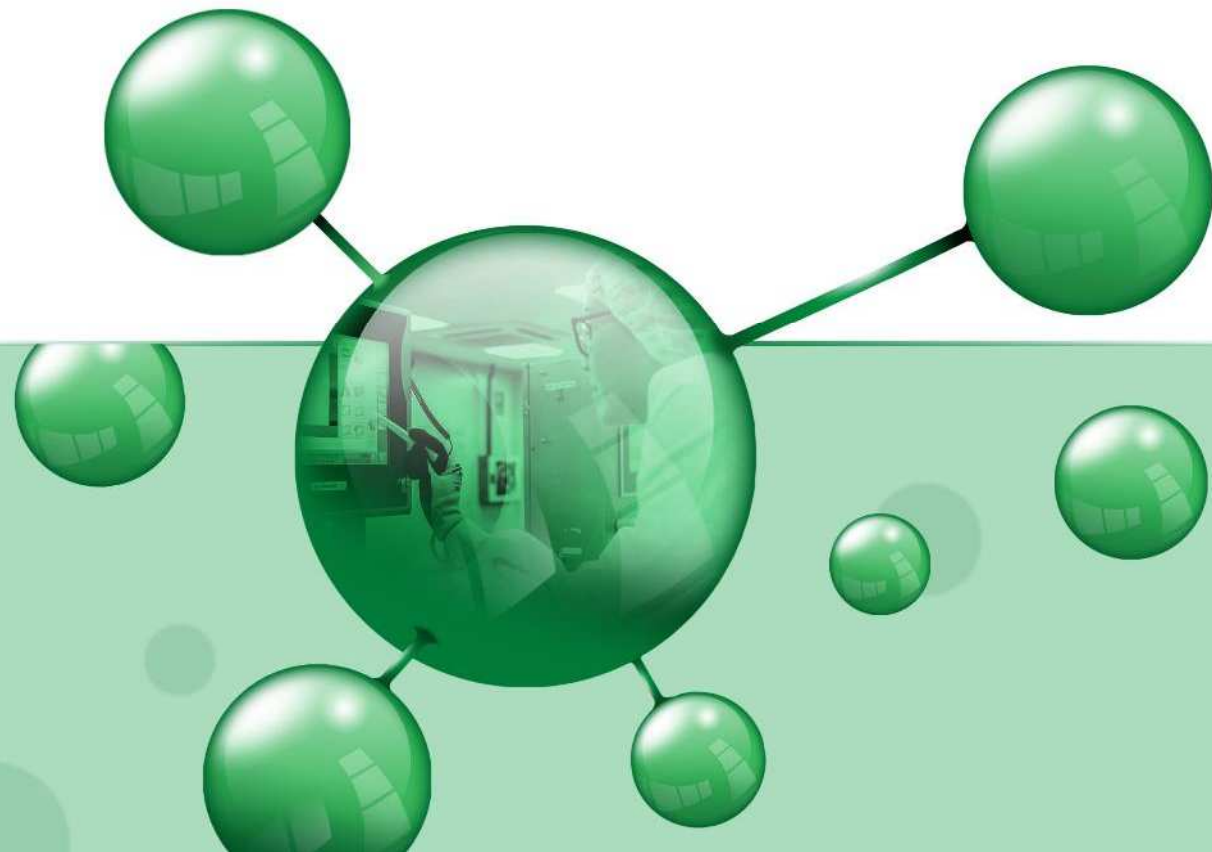
- ✓ Bemiparin
- ✓ Biosimilar of Enoxaparin
- ✓ Latest launches such as Tetridar, Neparvis, Orvatez, Volutsa and Ulunar
- ✓ Existing portfolio of specialty pharmaceuticals
- ✓ New acquisitions (Falithrom and Polaramine)

Toll Manufacturing Services

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

Financial results

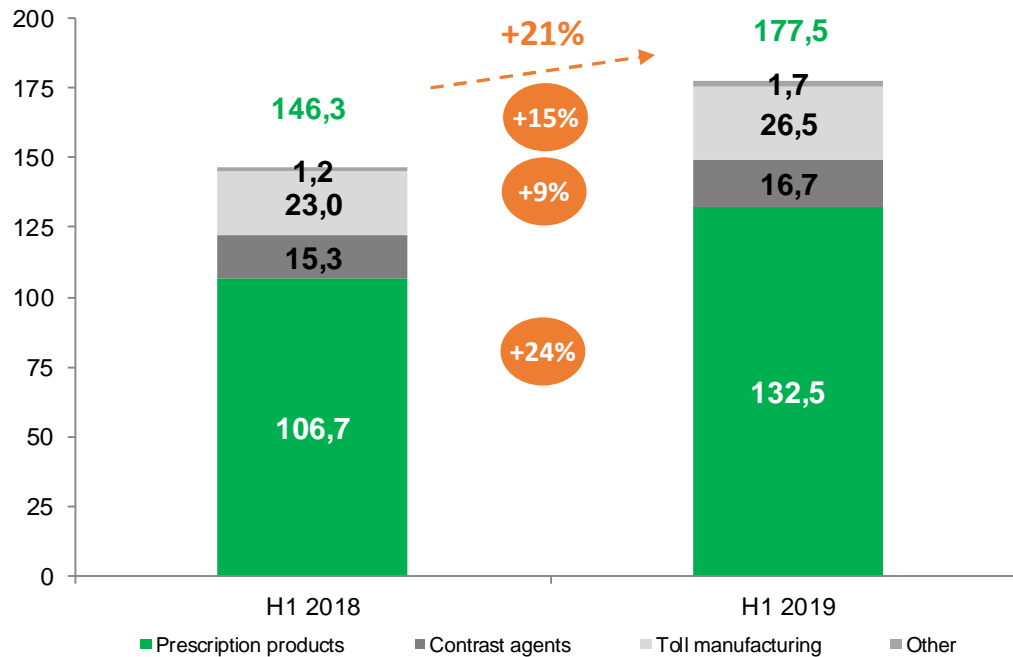
Javier López-Belmonte
Chief Financial Officer



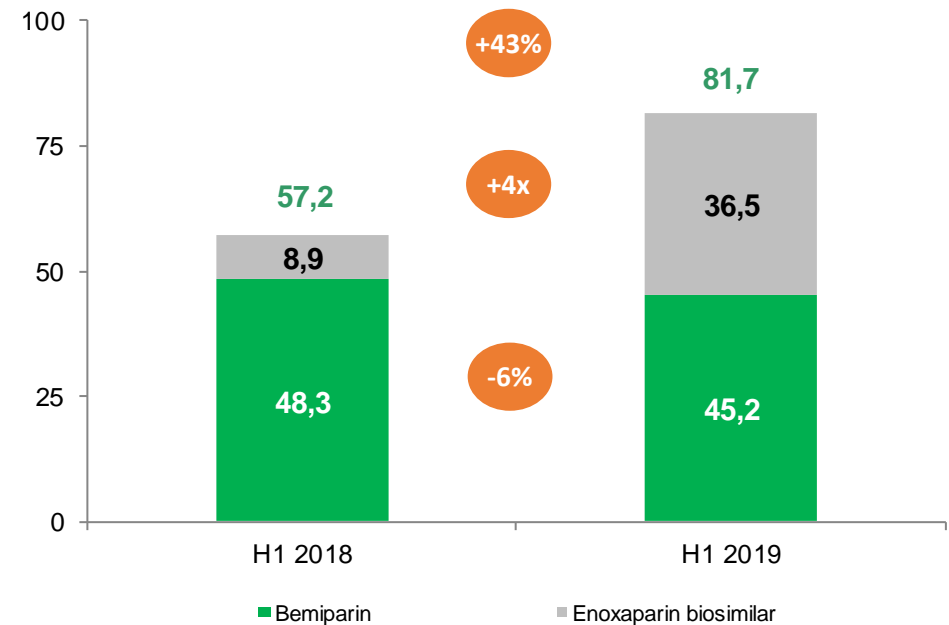


Good revenue level with outstanding LMWH franchise growth

Total operating revenue (€Mn)



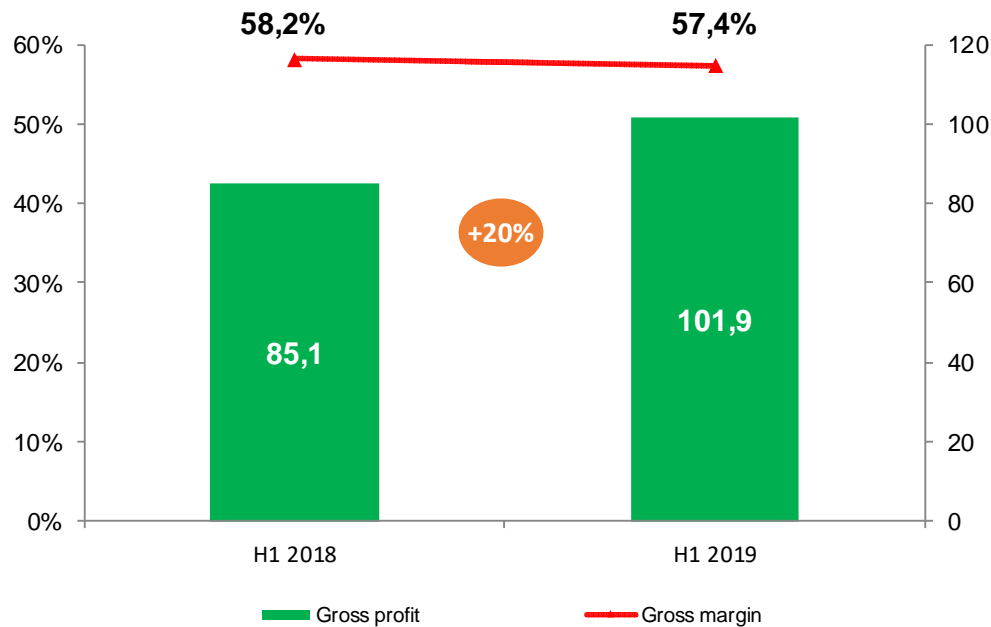
LMWH franchise sales (€Mn)



- **Operating revenue** increased by 21% to €177.5Mn, achieved on:
 - 24% growth in prescription-based products;
 - 9% growth in contrast agents and other hospital products;
 - 15% increase in toll manufacturing; and
 - OTC and other revenues increased by 43%.
- Sales of the **Low Molecular Weight Heparin (LMWH) franchise** increased by 43% to €81.7Mn in H1 2019, representing 46% of operating revenue in H1 2019 vs 39% in H1 2018.
 - **Enoxaparin biosimilar sales increased 4 times to €36.5Mn** and Bemiparin sales decreased by 6%.

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

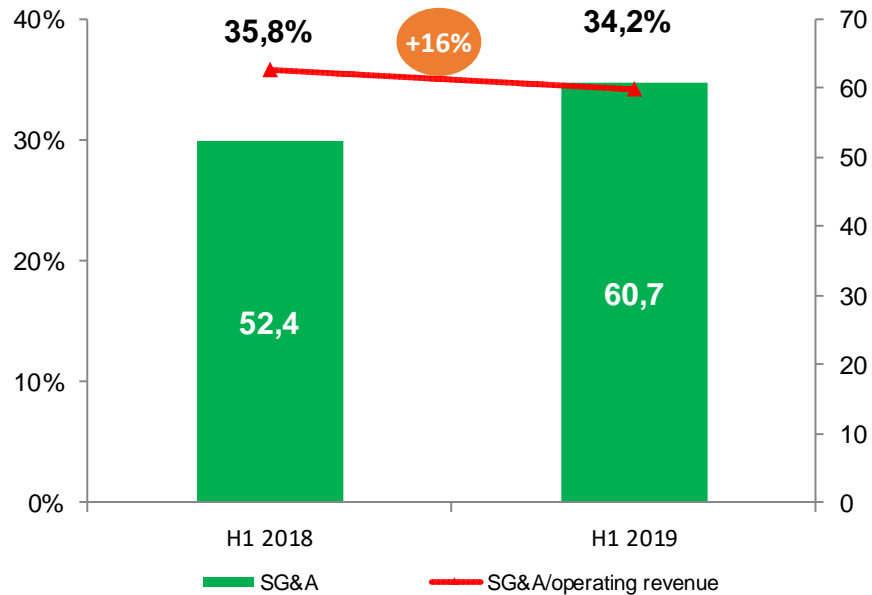
Gross profit (€Mn) and Gross margin (%)



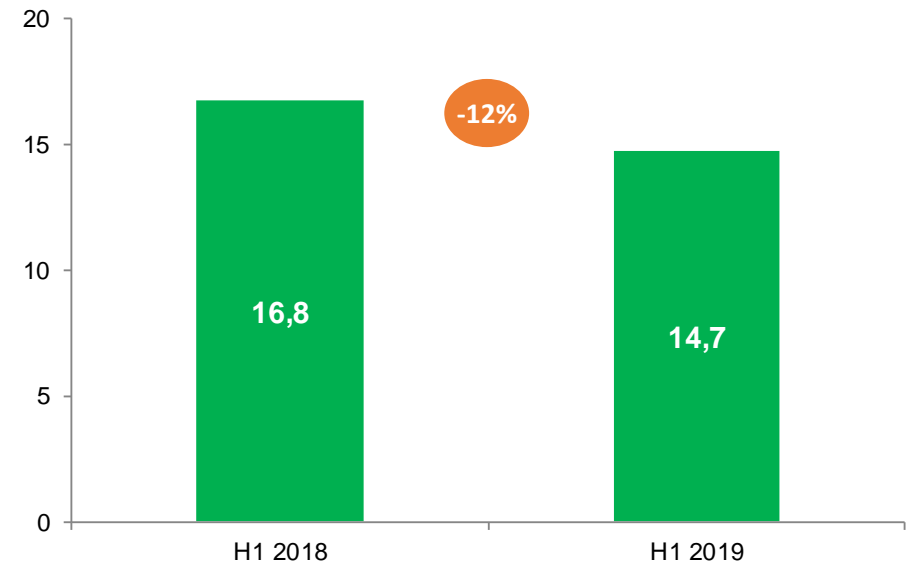
- **Gross profit** increased by 20% to €101.9Mn in H1 2019, the gross margin showing a decrease of 0.8 percentage points from 58.2% in H1 2018 to 57.4%, mainly due to:
 - the increase of Enoxaparin biosimilar sales, which added lower margins in the first half of 2019 after the launch of the product in seven new markets; and
 - the increase in the LMWH raw material prices, which, in the first half of 2019, were running around 35% over first half 2018 prices. ROVI expects this rising trend to continue during 2019.

Cost control along with commitment to R&D

SG&A expenses (€Mn)



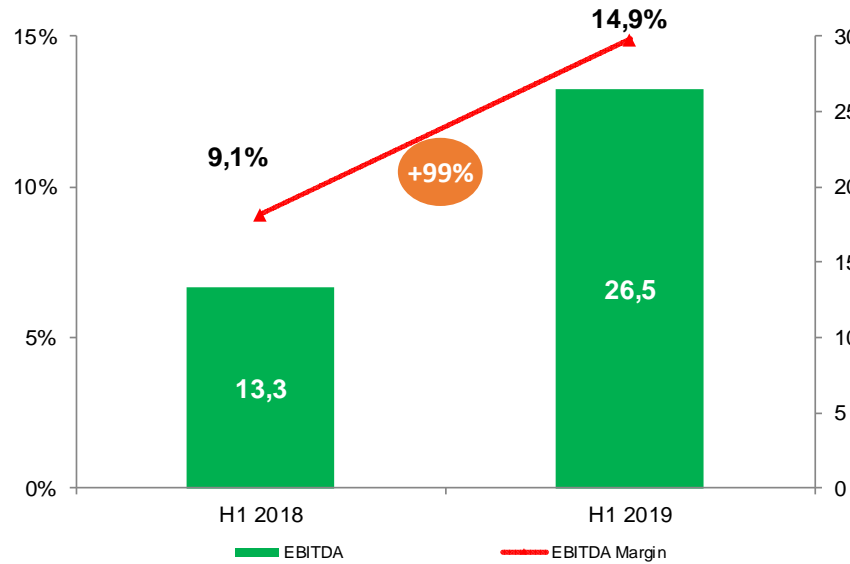
R&D expenses (€Mn)



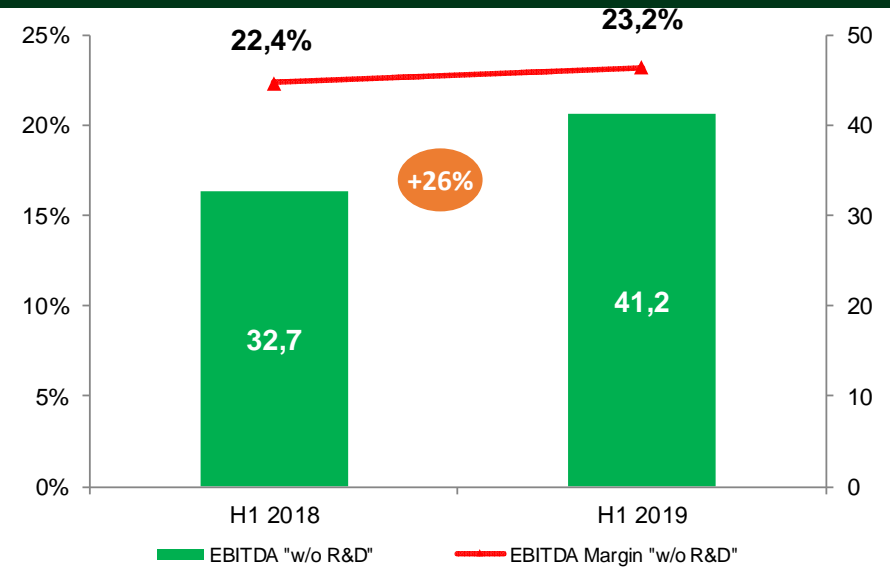
- **SG&A expenses rose 16%** to €60.7Mn in H1 2019 mainly due to:
 - international subsidiaries expenses, which amounted to €4.3Mn compared to €2.6Mn in H1 2018; and
 - a larger volume of enoxaparin biosimilar production.
 - In 2019, expenses related to international subsidiaries are expected to be around 10 million euros.
- **R&D expenses decreased 12%** to €14.7Mn in H1 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 (%)



H1 2019 EBITDA impacts (€Mn)

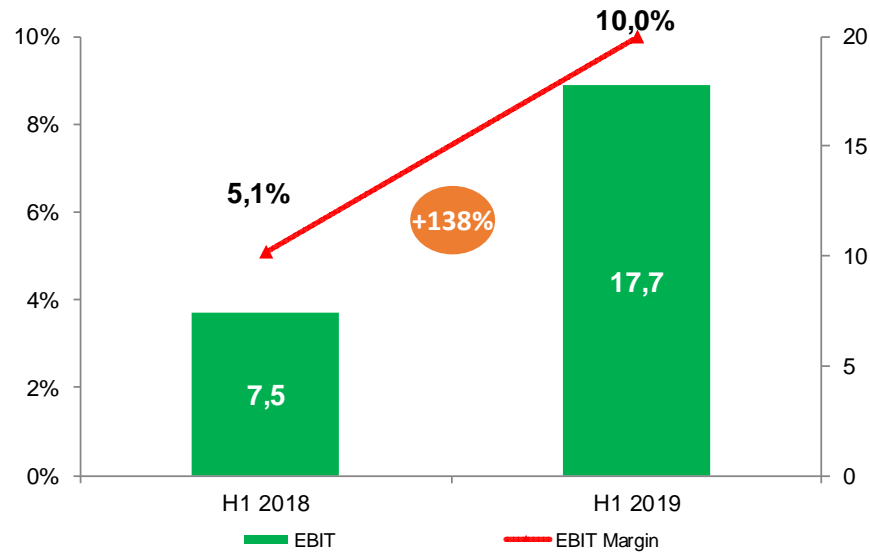


- In H1 2018, EBITDA was affected by non-recurring expenses of €2.6Mn. €1.5Mn of this amount were related to the study and analysis of the capital increase operation carried out in October 2018, while €1.1Mn were linked to a substantial change to Frosst Ibérica employees working conditions.
- **EBITDA** increased by 99% to €26.5Mn in H1 2019, reflecting a 5.8 pp rise in the EBITDA margin, which was up to 14.9% in H1 2019 from 9.1% in H1 2018.
- **EBITDA “pre-R&D”** (w/o R&D and non recurring expenses) increased by 26% to €41.2Mn in H1 2019, reflecting a 0.8 pp rise in the EBITDA margin to 23.2% in H1 2019. Likewise,
 - recognising the same amount of R&D expenses in H1 2019 as in H1 2018 and excluding the impact of the non recurring expenses in H1 2018, EBITDA would have increased by 53% to €24.4Mn, reflecting a 2.8 pp rise in the EBITDA margin to 13.8% in H1 2019.

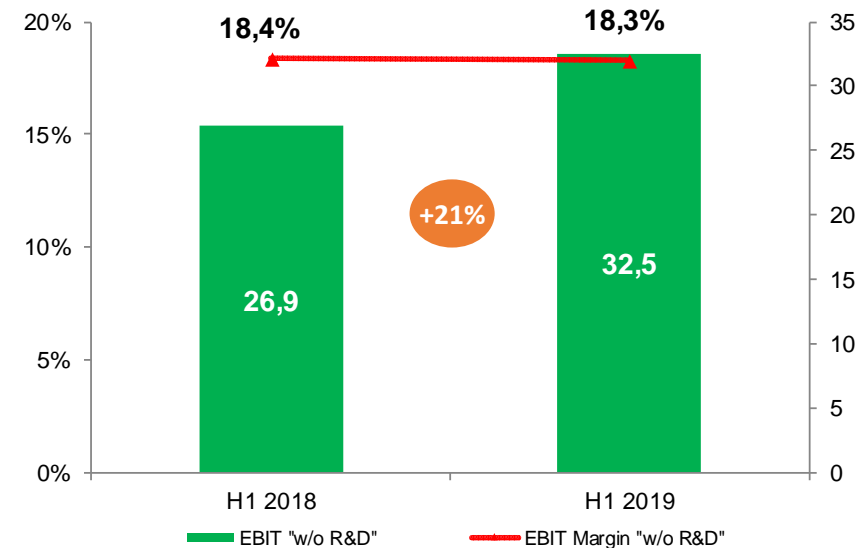
Note: EBITDA “pre-R&D” calculated excluding R&D expenses in H1 2019 and H1 2018 and the impact of non recurring expenses in H1 2018

EBIT

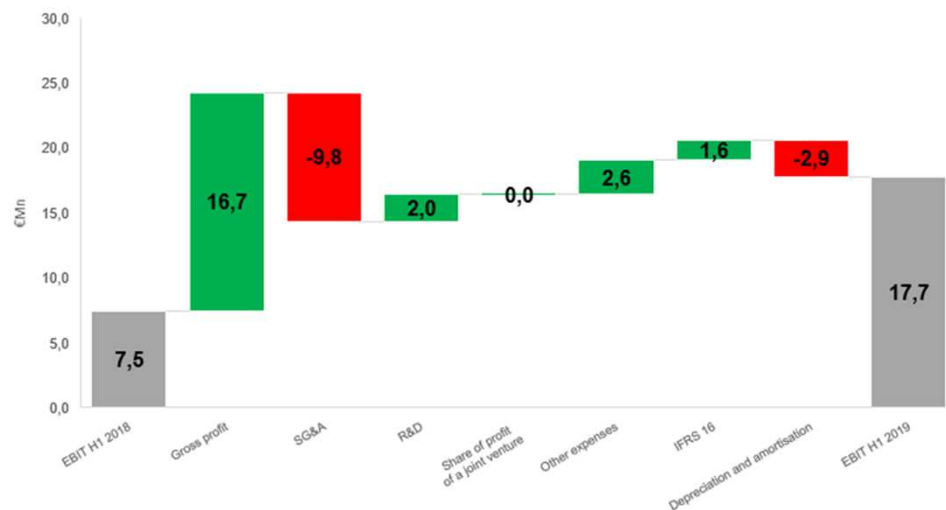
EBIT (€Mn) and EBIT margin (%)



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



H1 2019 EBIT impacts (€Mn)

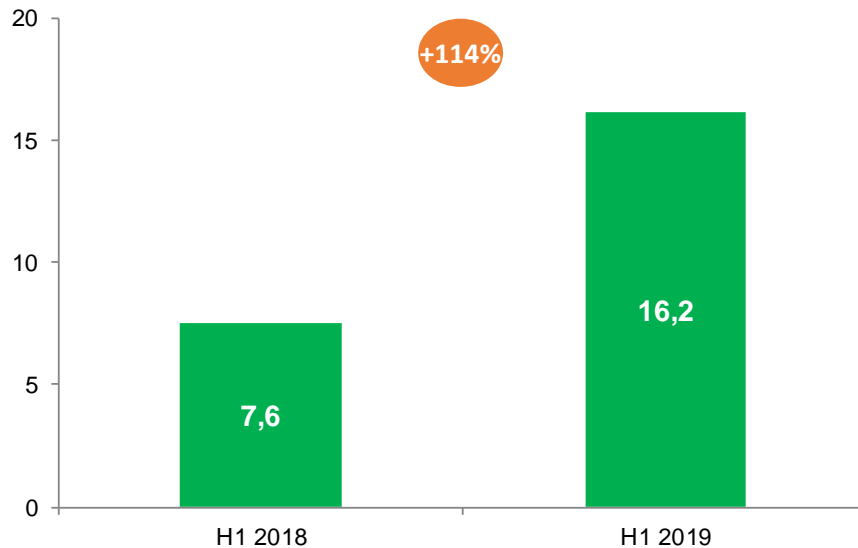


- As a result of the IFRS 16 application and the new PP&E and intangible assets purchases made during the last twelve months, **depreciation and amortisation** expenses increased by 49% to €8.7Mn in H1 2019.
- **EBIT** increased to €17.7Mn in H1 2019, reflecting a 4.9 pp rise in the EBIT margin, which was up to 10.0% in H1 2019.
- **EBIT "pre-R&D"** (w/o R&D and non recurring expenses) increased by 21%, from €26.9Mn in H1 2018 to €32.5Mn in H1 2019, reflecting a 0.1 pp fall in the EBIT margin to 18.3% in H1 2019. Likewise,
 - recognising the same amount of R&D expenses in H1 2019 as in H1 2018 and excluding the impact of the non recurring expenses in H1 2018, EBIT would have increased by 56% to €15.7Mn, reflecting a 1.9 pp rise in the EBIT margin.

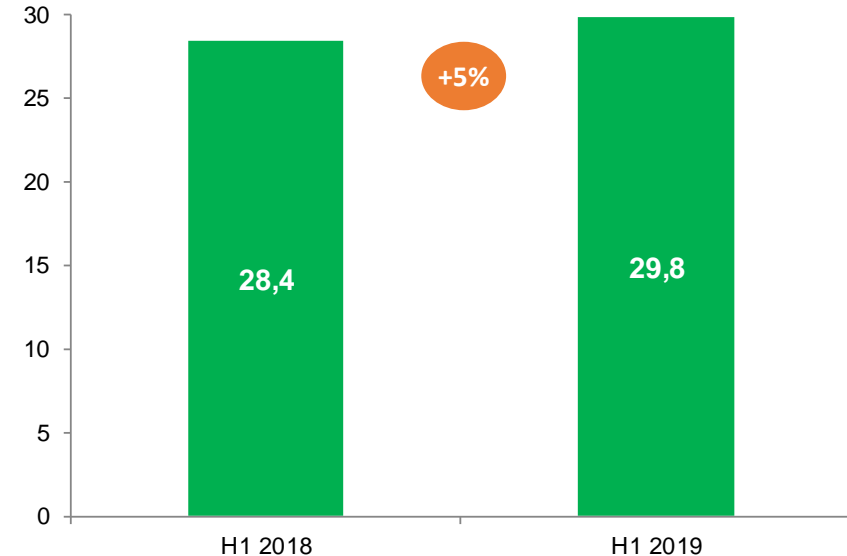
Note: EBIT "pre-R&D" calculated excluding R&D expenses in H1 2019 and H1 2018 and the impact of non recurring expenses in H1 2018

Net profit

Net profit (€Mn)



Net profit “pre-R&D” (€Mn)

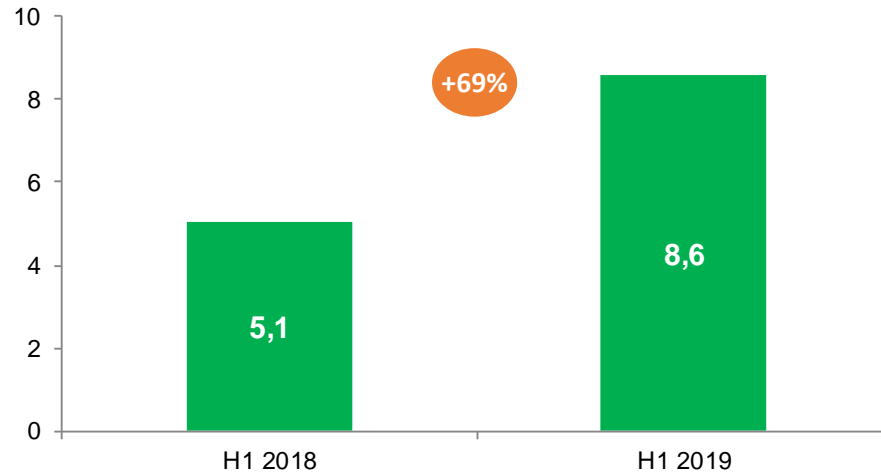


- **Net profit** increased to €16.2Mn in H1 2019, a 114% rise compared to H1 2018.
- **Net profit “pre R&D”** (w/o R&D and non recurring expenses) increased by 5%, from €28.4Mn in H1 2018 to €29.8Mn in H1 2019. Likewise,
 - recognising the same amount of R&D expenses in H1 2019 as in H1 2018 and excluding the impact of the non recurring expenses in H1 2018, net profit would have increased by 37% to €14.3Mn.
- The **effective tax rate** was 7.5% in H1 2019 (negative income tax of €1.3Mn), compared to -7.4% in H1 2018 (positive income tax of €0.5Mn), mainly due to the decrease in R&D expenses in H1 2019, compared to H1 2018, which led to lower R&D tax credits.
- As of 30 June 2019, **negative tax bases** amounted to €36.3Mn, of which €1.4Mn will be used in the 2018 income tax and €1.0Mn in H1 2019.

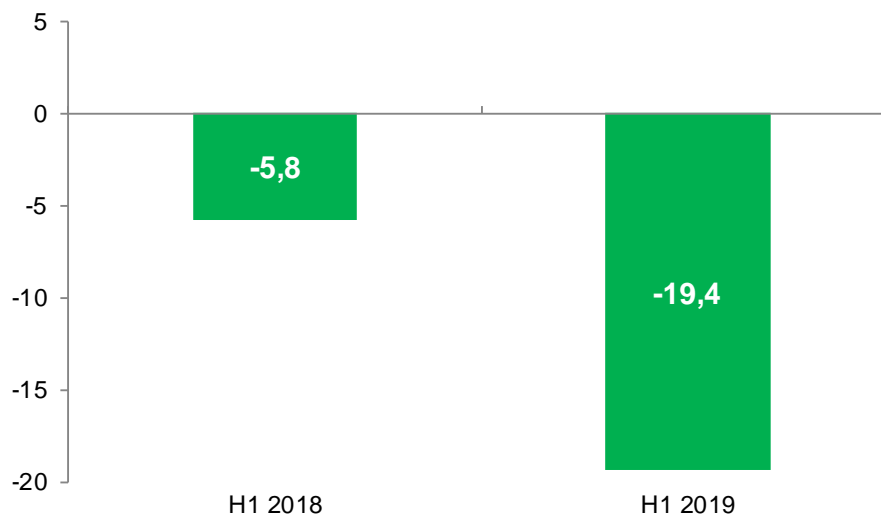
Note: Net profit “pre-R&D” calculated excluding R&D expenses in H1 2019 and H1 2018 and the impact of non recurring expenses in H1 2018. Same effective tax rate as the reported net profit.

Capital expenditure and Free Cash Flow

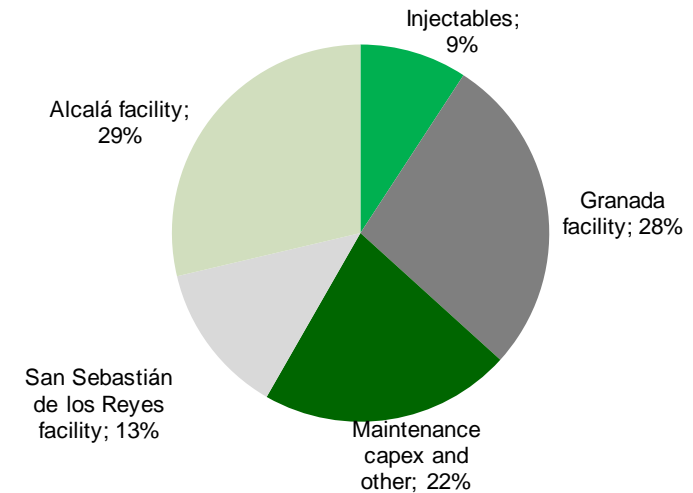
Capex evolution (€Mn)



Free Cash Flow (€Mn)



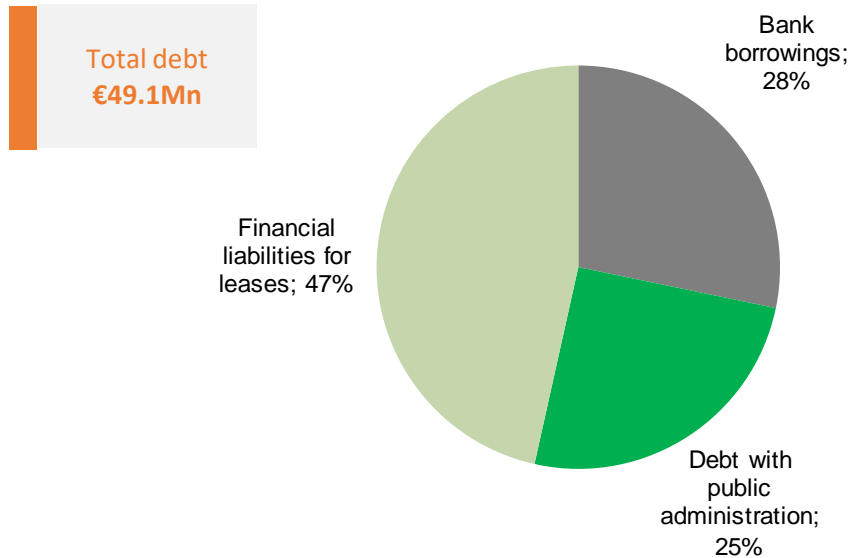
Capex breakdown (%)



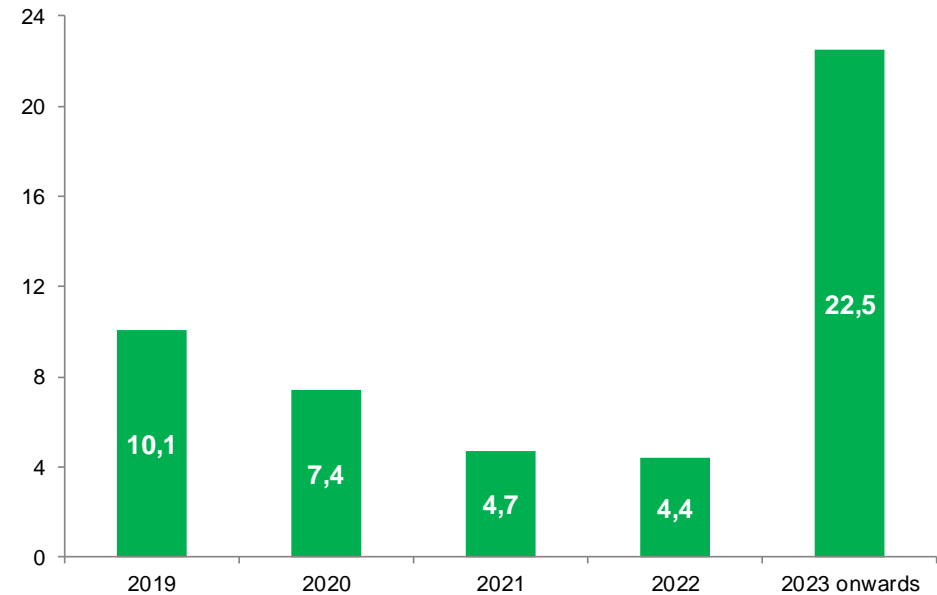
- €8.6Mn of **capex** invested in H1 2019.
 - €0.8Mn of investment capex related to the injectable plant;
 - €2.4Mn of investment capex related to the Granada facility;
 - €2.5Mn of investment capex related to the Alcalá de Henares facility;
 - €1.1Mn of investment capex related to the San Sebastián de los Reyes facility;
 - €1.8Mn of maintenance capex and other capex
- €13.5Mn invested in H1 2019 for the acquisition of Polaramine®.
- **FCF** decreased to €-19.4Mn mainly due to:
 - €17.0Mn increase in capex mainly because of the acquisition of Polaramine®;
 - €26.9Mn increase in “inventories” in H1 2019 vs €15.9Mn increase in H1 2018;
 - €10.0Mn increase in “trade and other receivables” in H1 2019 vs €7.4Mn increase in H1 2018;
 - €21.2Mn increase in “trade and other payables” in H1 2019 vs €18.4Mn increase in H1 2018; and
 - €10.4Mn increase in profit before income tax.

Financial debt

Debt breakdown by source (%)



Debt maturities by year (€Mn)



- **Debt with public administration** represented 25% of total debt, with 0% interest rate.
- As a result of the IRFS 16 application in H1 2019,
 - **Gross cash position of €68.1Mn** as of 30 June 2019 vs €97.0Mn as of 31 December 2018.
 - **Net cash of €19.1Mn** as of 30 June 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



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 85 countries outside Europe
Toll manufacturing	New contracts to be announced
ISM[®] technology platform	Risperidone ISM [®] final Phase III data will be presented in scientific congresses
	Letrozole ISM [®] Phase I ongoing. Next steps to be discussed with regulatory authorities in 2020

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