

Full Year 2021

FINANCIAL RESULTS

FEBRUARY 2022



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2021 financial results - highlights



Operating revenue growth of 54% to €648.7Mn and EBITDA growth of 115% to €202.9Mn in 2021.



Sales of the heparin franchise increased by 16% to €242.0Mn in 2021.



Sales of Neparvis® increased by 30% to €38.5Mn in 2021.



CMO sales increased by 189% to €264.7Mn in 2021.



For 2022, ROVI is upgrading its 2022 operating revenue guidance from a mid-single-digit growth rate to the range between 15% and 20%.

Milestones achieved – approval of Okedi® and expansion of the long-term collaboration with Moderna



ROVI receives the European Commission's approval of Okedi® as a treatment for schizophrenia

The European Commission has authorised the marketing of Okedi® (Risperidone ISM®) for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone.

This approval is based on the positive results of the pivotal PRISMA-3 study on the efficacy and safety of Risperidone ISM® in schizophrenia patients¹.

The launch of the product in Europe is expected for the second quarter of 2022.



Moderna and ROVI expand long-term collaboration for the manufacture of mRNA medicines

ROVI announced a long-term collaboration with Moderna to increase capacities for the compounding, aseptic filling, inspection, labeling, and packaging of ROVI's facilities located in Madrid, San Sebastián de los Reyes and Alcalá de Henares.

This new agreement, which has a term of ten years, includes a series of investments expected to allow the manufacturing capacity to increase across ROVI's facilities in Madrid, Spain. In addition to producing Moderna's COVID-19 vaccine, ROVI's platform could also be utilized to service future Moderna mRNA vaccine candidates.

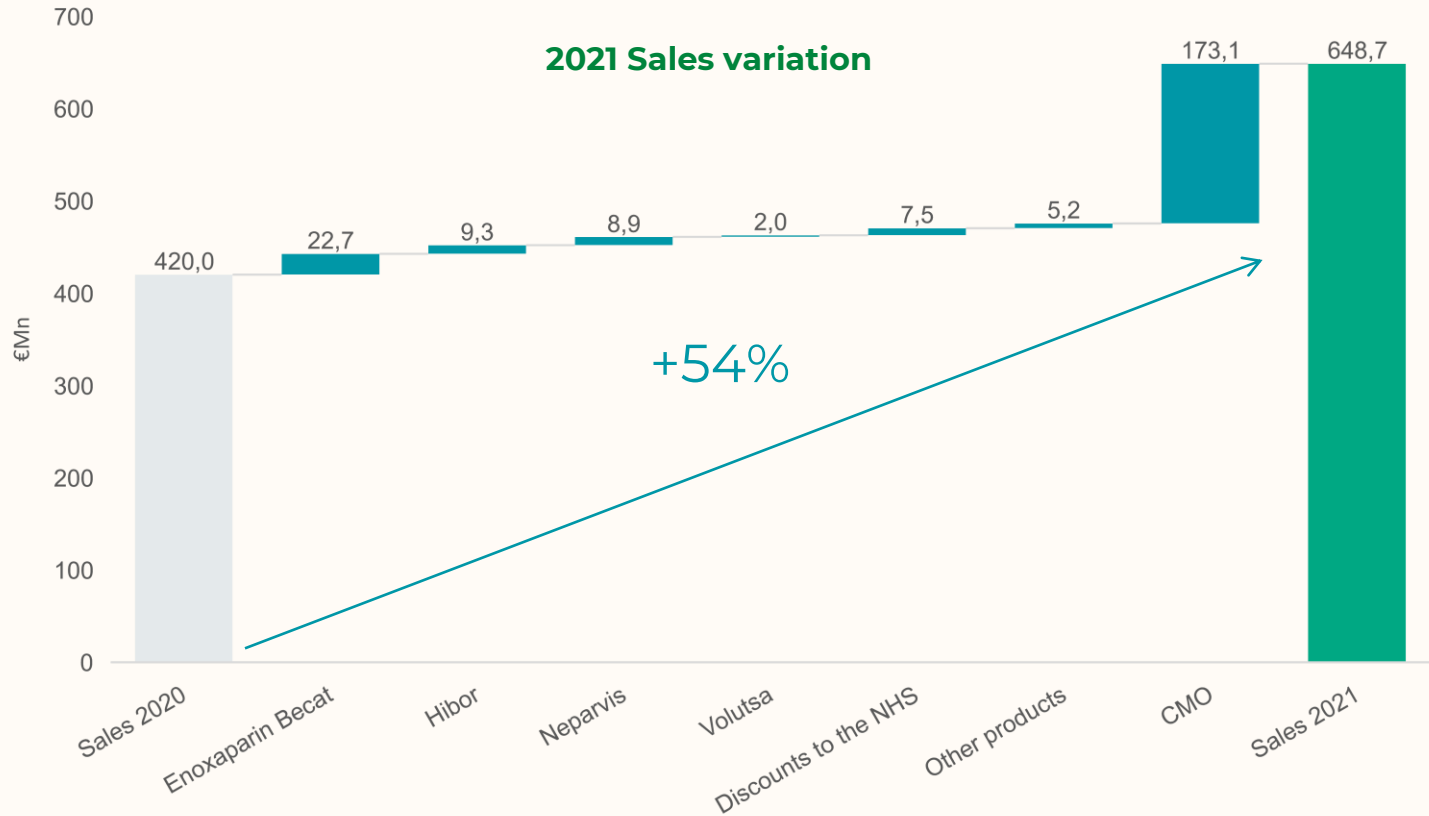


Juan López-Belmonte
Chairman and Chief Executive Officer

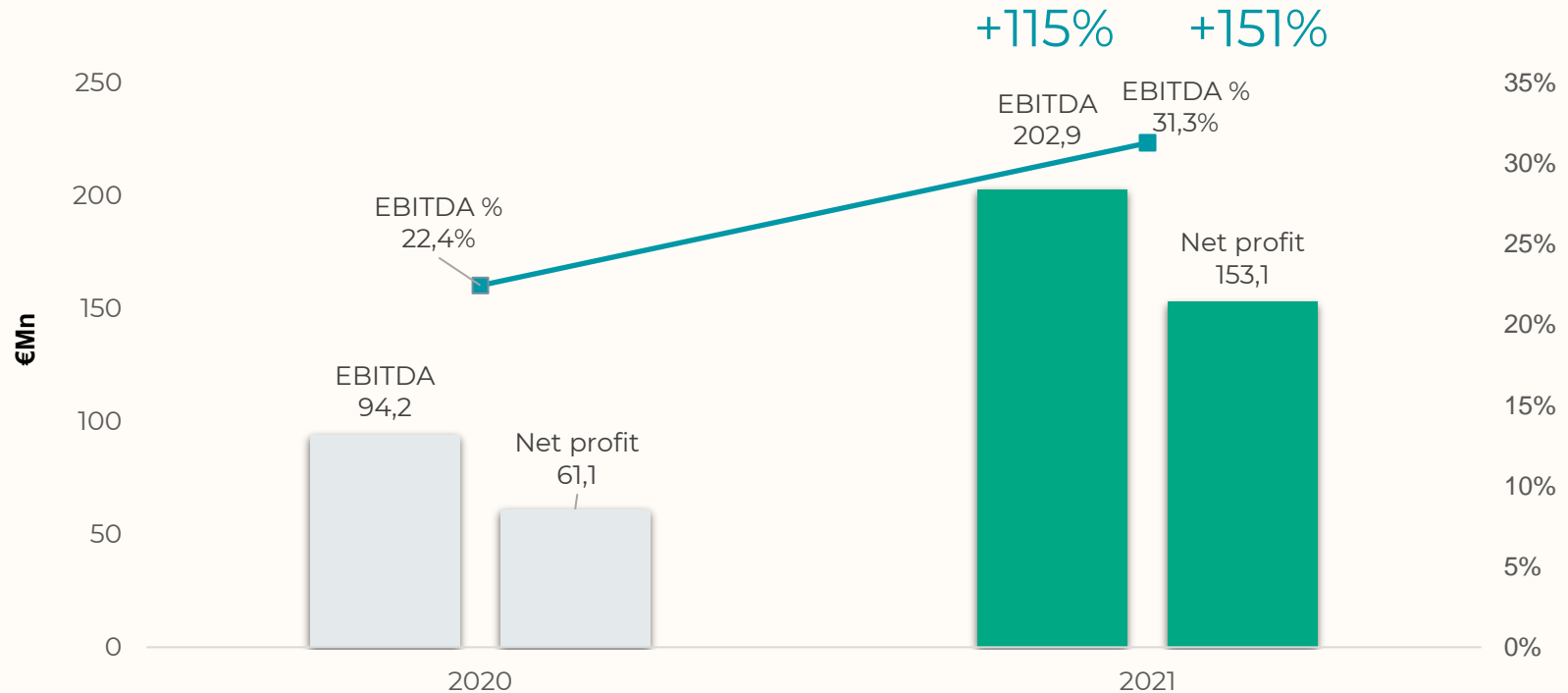
OPERATING RESULTS



Growth driven by CMO and specialty pharma businesses...



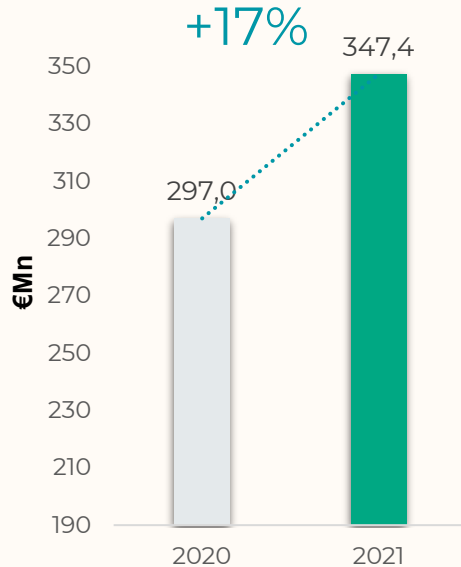
...with high profitability



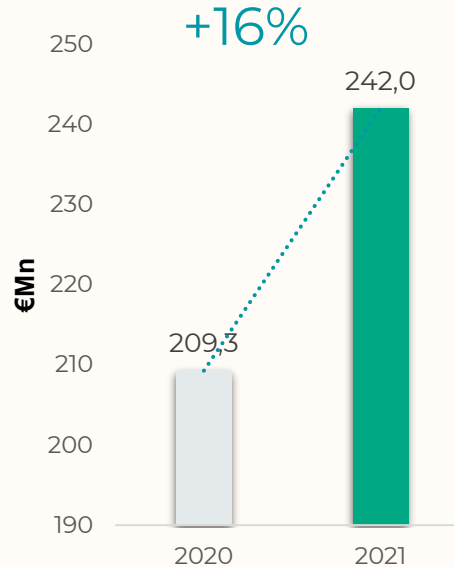
EBITDA increased to €202.9Mn in 2021, a rise of 115% compared to the last year.
Net profit increased by 151%, from €61.1Mn in 2020 to €153.1Mn in 2021.

Heparins, leading the specialty pharmaceutical business

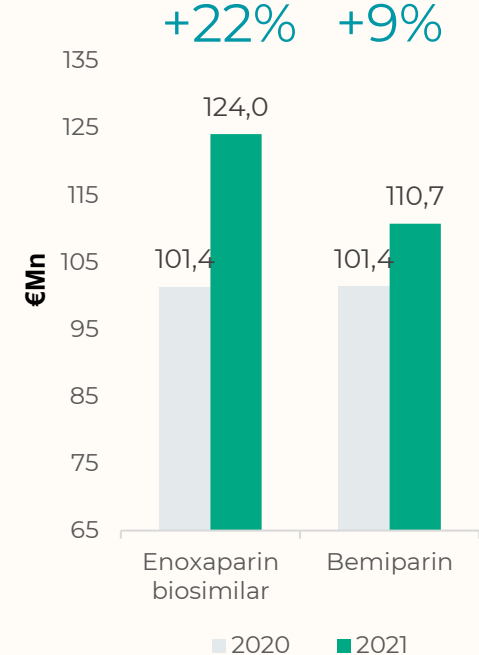
Prescription-based sales



Heparin franchise sales



LMWH sales



Sales of prescription-based pharmaceutical products increased by 17% to €347.4Mn in 2021.

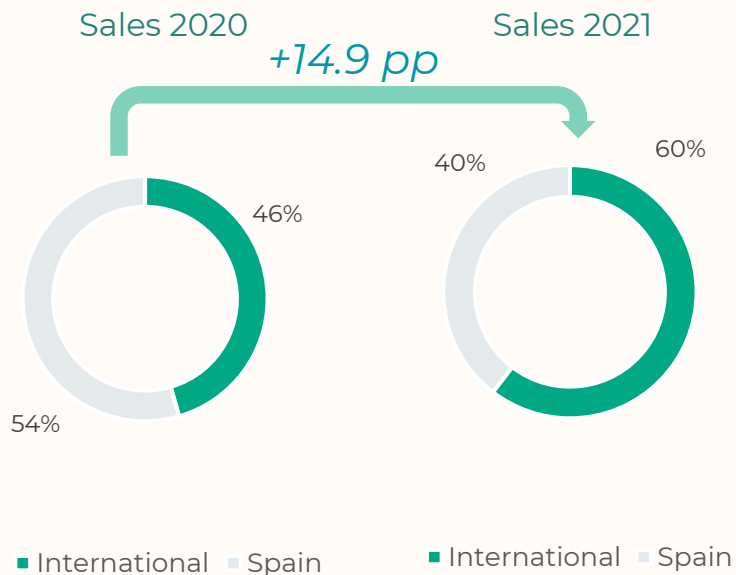
Sales of the heparin franchise increased by 16% to €242.0Mn in 2021.

Heparin sales represented 37% of operating revenue in 2021 compared to 50% in 2020.

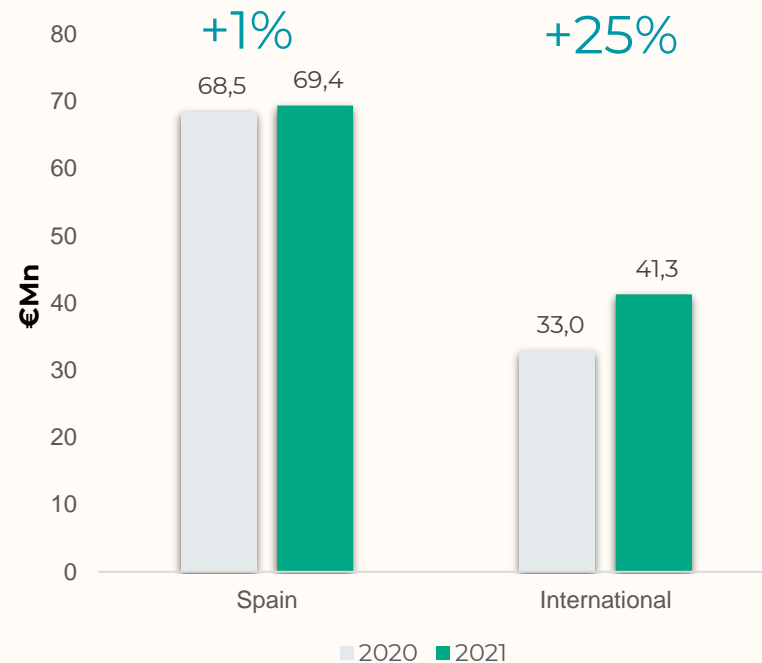
Well positioned to drive long-term leadership in Low Molecular Weight Heparins (LMWH)

Sales of LMWH (Enoxaparin biosimilar and Bemiparin) increased by 16% to €234.8Mn in 2021

Total group sales



Bemiparin sales

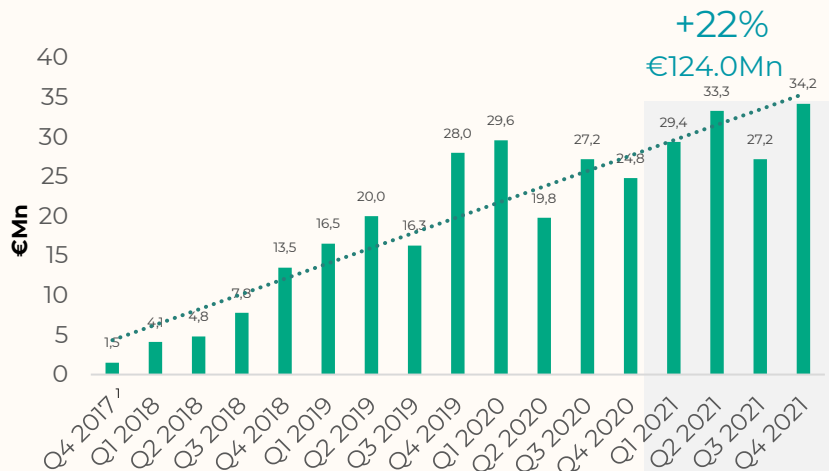


Strong growth potential of Enoxaparin Biosimilar Becat®

Well-Established Network to Minimize Time-to-Market



Enoxaparin Biosimilar Becat® Sales Ramp-up



Commercial Strategy

...the largest enoxaparin market with €1.3bn sales²

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

...which account for c.75% of the European market³

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

50-70%⁴ Market Share

...of the reference product market

ROVI launched enoxaparin in Canada, Malaysia, Albania, North Macedonia, Guatemala, El Salvador, Honduras, Georgia, Bahamas Jamaica, Gabon, Democratic Republic of Congo and Trinidad and Tobago in 2021.



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

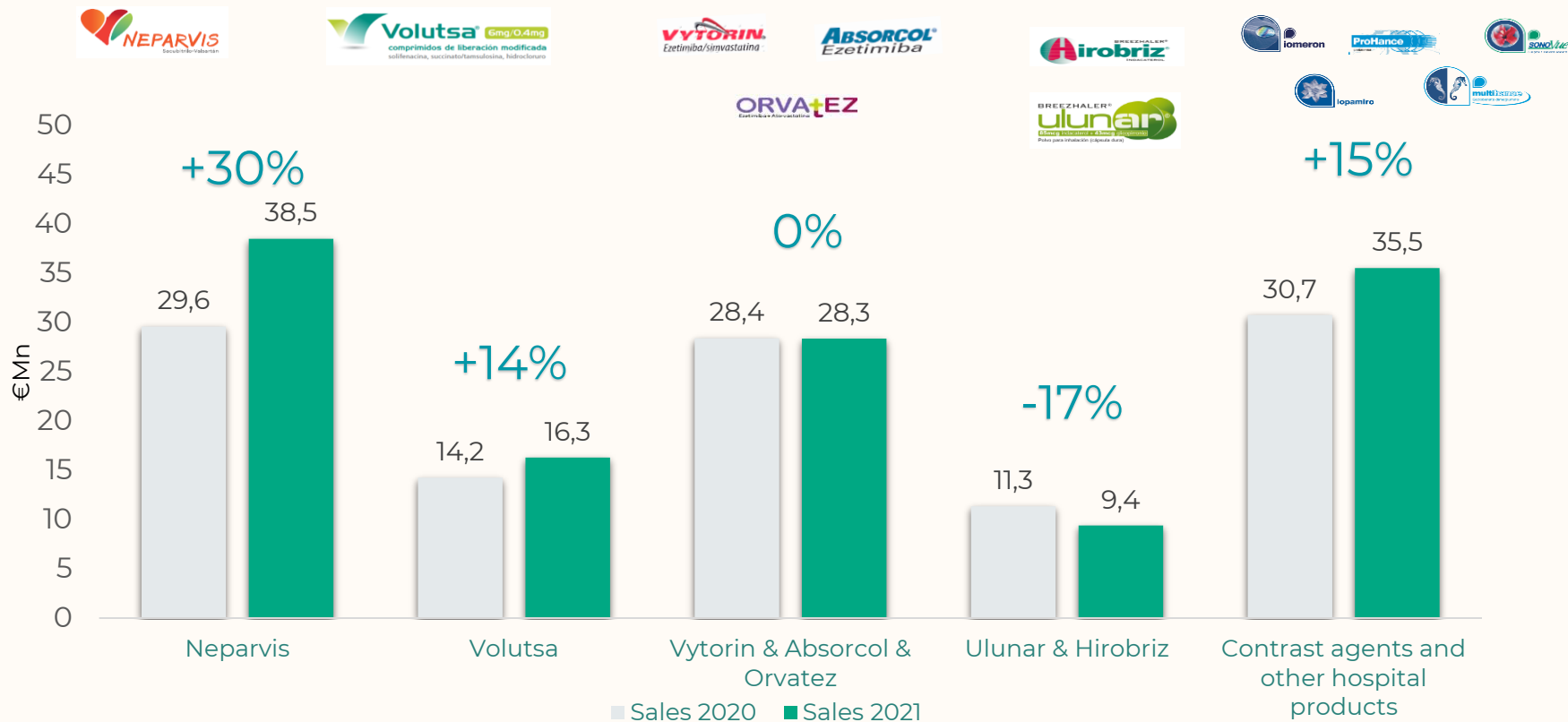
Already Signed Out-Licensed Agreements: > 100 Countries

€0.7bn
Q1 2020 MAT
Market Sales²

1. Becat® 4Q 2017 sales include sales throughout September. As the product was launched that month, sales were negligible.
2. IQVIA MIDAS Q1 2020

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

Neparvis® and Volutsa® leading the growth of the specialty pharma business



Value added CMO services

CMO strategy

ROVI and Moderna will expand long-term collaboration:

- This new agreement, which has a term of ten years, includes a series of investments expected to allow the manufacturing capacity to increase across ROVI's facilities in Madrid, Spain.
- In addition to producing Moderna's COVID-19 vaccine, ROVI's platform could also be utilized to service future Moderna mRNA vaccine candidates.

Packaging Excellence Centre in our Alcalá de Henares plant

State-of-the art installations

2 new blister high speed lines.
7 packaging lines fully dedicated to injectables.
Total 14 packaging lines.

New capacities for our plants

Madrid

1 new state of the art syringe filling line. Total 4 filling lines.
1 new automatic syringe inspection machine. Total 3 lines.

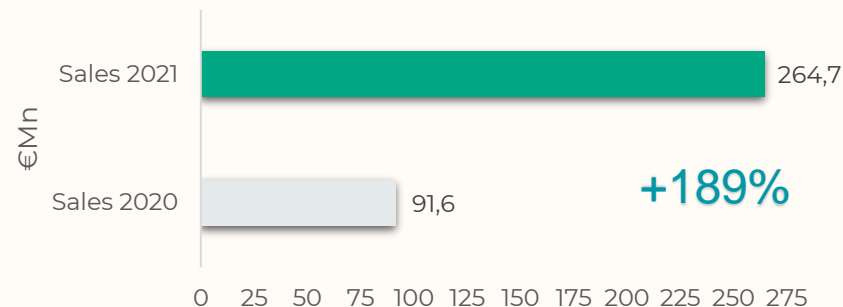
San Sebastián de los Reyes

1 high speed syringe filling line.
3 new state of the art vials filling lines. Total 4 lines.
2 new automatic vials inspection machine. Total 4 lines.
1 new automatic vials packaging machine.

Granada

1 new line supporting production phases of the active substance of the MRNA vaccine.

CMO evolution



CMO sales increased by 189% to €264.7Mn in 2021 as a result of:

- The booking of the income related to the production of the COVID-19 vaccine;
- The booking of the income related to the activities to prepare the plant for the COVID-19 vaccine production under the agreement with Moderna; and
- The redirection of our toll manufacturing activities strategy towards high-value-added products.

In 2022, ROVI expects the CMO business to increase by **between 30% and 40%**, including production of the COVID-19 vaccine.

ISM[®] Platform opens up new avenues of growth for ROVI

Overview

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

Product	Potential Indication	Current Situation	Key Milestones
Risperidone-ISM [®] , monthly	Schizophrenia	Phase III	<ul style="list-style-type: none"> Approved in Europe In approval process in USA
Letrozole ISM [®] Long acting Letrozole	Breast Cancer	Phase I	Phase I started in November 2017
Risperidone, quarterly	Schizophrenia	Non-Clinical	
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 Risperidone-ISM [®] 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 (1-6 months) plasma therapeutic levels from day 1	Rapid onset & sustained clinical effect
5	Vertical Integration	Technological barriers (e.g. power filling) Strong IP Manufacturing capabilities	Protected technology Fully integrated manufacturing plants

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

Outlook 2022



2022 operating revenue growth rate

Upgraded to +15%-20%

The key Growth levers in 2022

Specialty Pharma	CMO
Bemiparin	Spare capacity in the manufacturing plants
Biosimilar of Enoxaparin	New customers to be acquired
Launch of Okedj®	Agreement with Moderna
Existing portfolio of specialty pharmaceuticals	

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 2022.

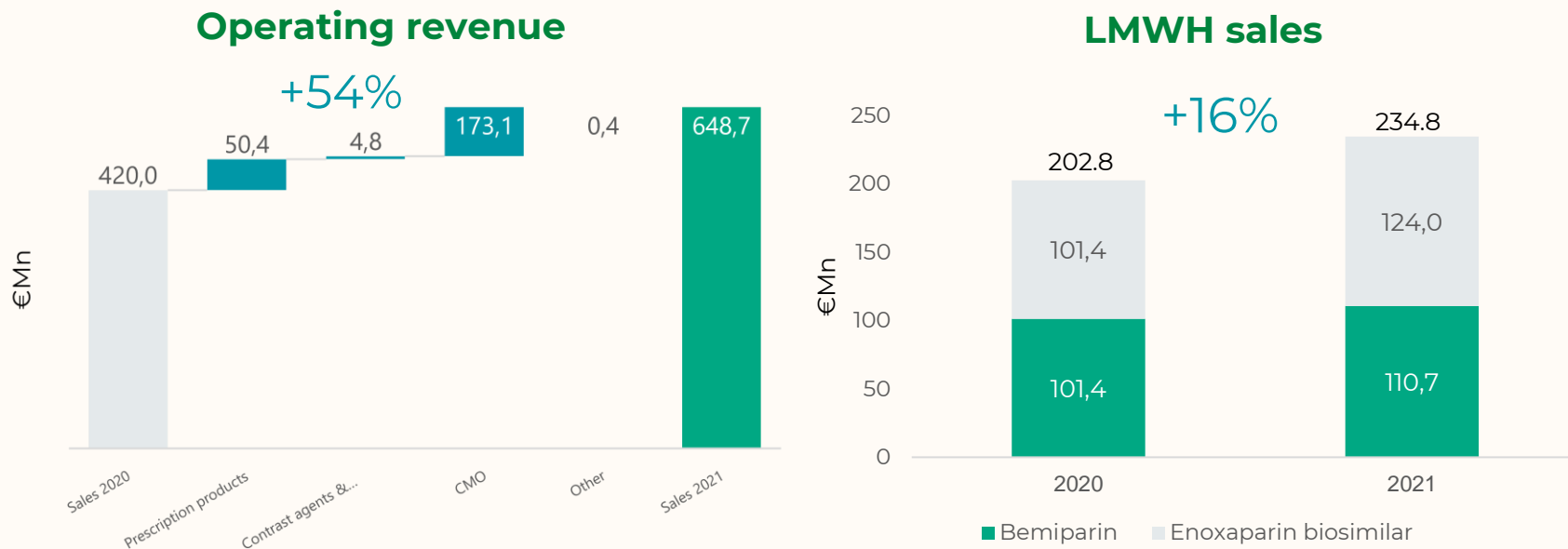


FINANCIAL RESULTS

Javier López-Belmonte
First Vice-President and Chief Financial Officer



Good revenue level with resilient sales growth



Operating revenue increased by 54% to €648.7Mn, achieved on:

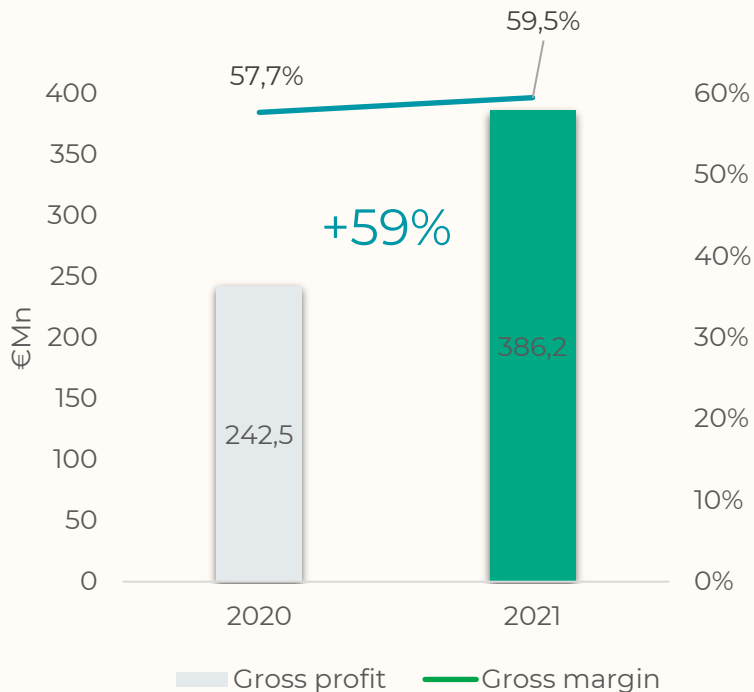
- 189% increase in CMO; and
- 17% growth in prescription-based products.
- Contrast agents and other hospital products increased by 15%.

Sales of **LMWH** increased by 16% to €234.8Mn in 2021.

- **Enoxaparin biosimilar** sales increased by 22% to €124.0Mn and **Bemiparin** sales increased by 9% to €110.7Mn.

Gross margin positively impacted by the CMO division

Gross profit and Gross margin



Gross margin impacts

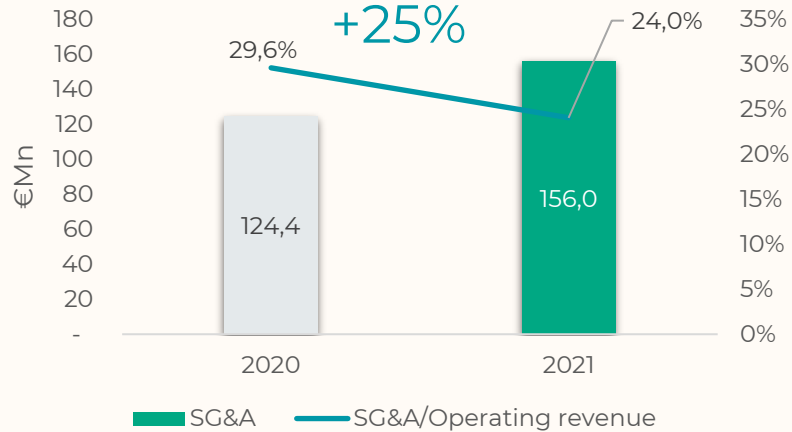
Gross profit increased by 59% to €386.2Mn in 2021, the gross margin showing an increase of 1.8 p.p. from 57.7% in 2020 to 59.5% in 2021, mainly because the increase in the CMO business contributed higher margins to group sales.

This positive impact on the gross margin offset the increase in the LMWH cost of goods sold in 2021 compared to the previous year.

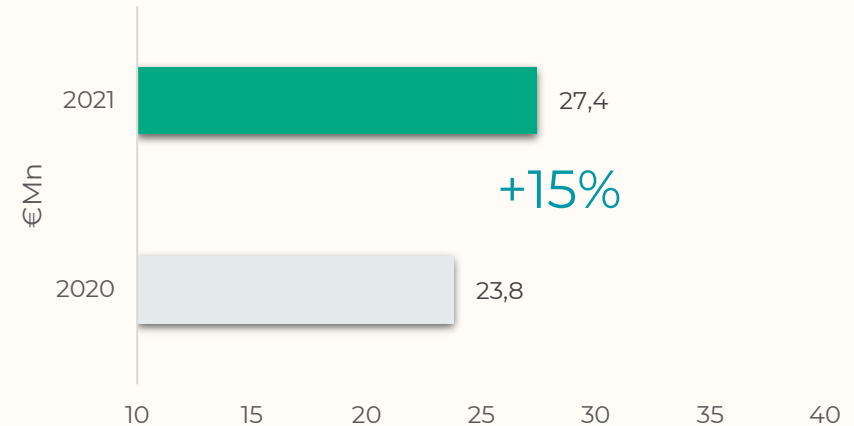
ROVI expects LMWH raw material prices to continue to decline in 2022 as a result of the increase in the pig population in China. Nevertheless, despite the potential decrease in LMWH raw material prices, the impact on the gross margin will continue to be negative because of the long LMWH manufacturing process, in which the raw material currently being used, stocked for several months, was purchased at higher prices.

Cost control along with commitment to R&D

SG&A expenses



R&D expenses



SG&A increased 25% to €156.0Mn in 2021 mainly as a result of:

- An increase in expenses related to the manufacture of the Moderna vaccine; and
- An increase in expenses due to the preparation of the Okedi® launch in Europe.

Excluding expenses related to COVID-19, SG&A would have increased by 28% to 154.4 million euros in 2021, compared to 120.4 million euros in 2020.

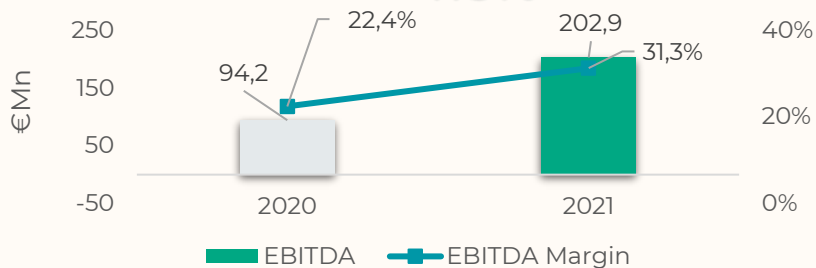
R&D expenses increased 15% to €27.4Mn in 2021. These expenses are related to:

- The repetition of the bioavailability study comparing multiple doses of Risperidone ISM® with oral risperidone, in response to the major observation of the Committee for Medicinal Products for Human Use (CHMP);
- Letrozole-ISM® Phase I trial; and
- Development of a new formulation of Risperidone-ISM® for a 3-monthly injection.

EBITDA, EBIT & Net Profit analysis

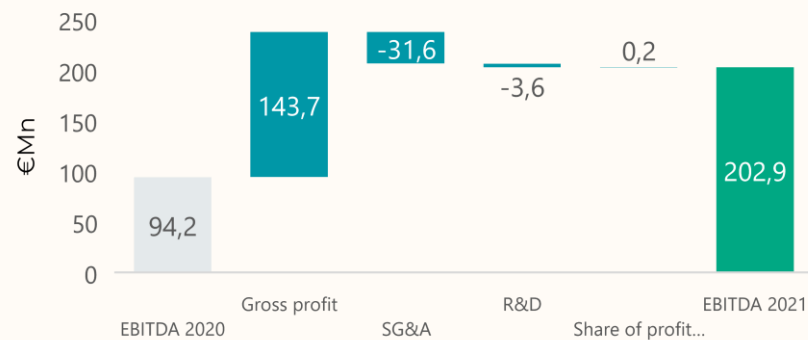
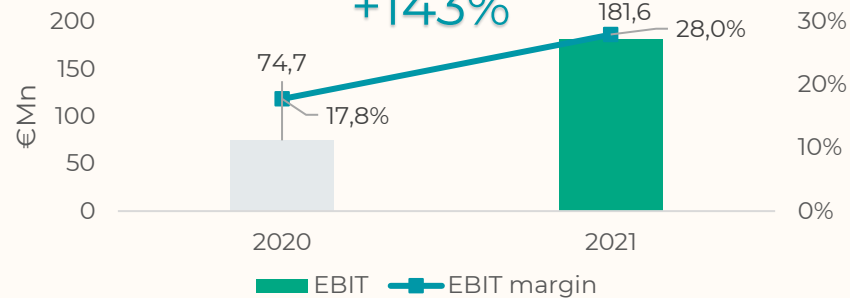
EBITDA

+115%



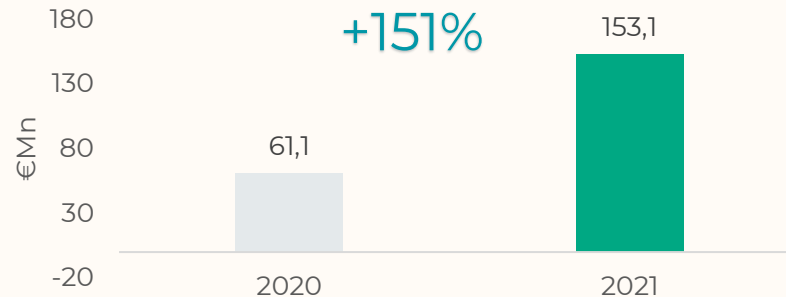
EBIT

+143%

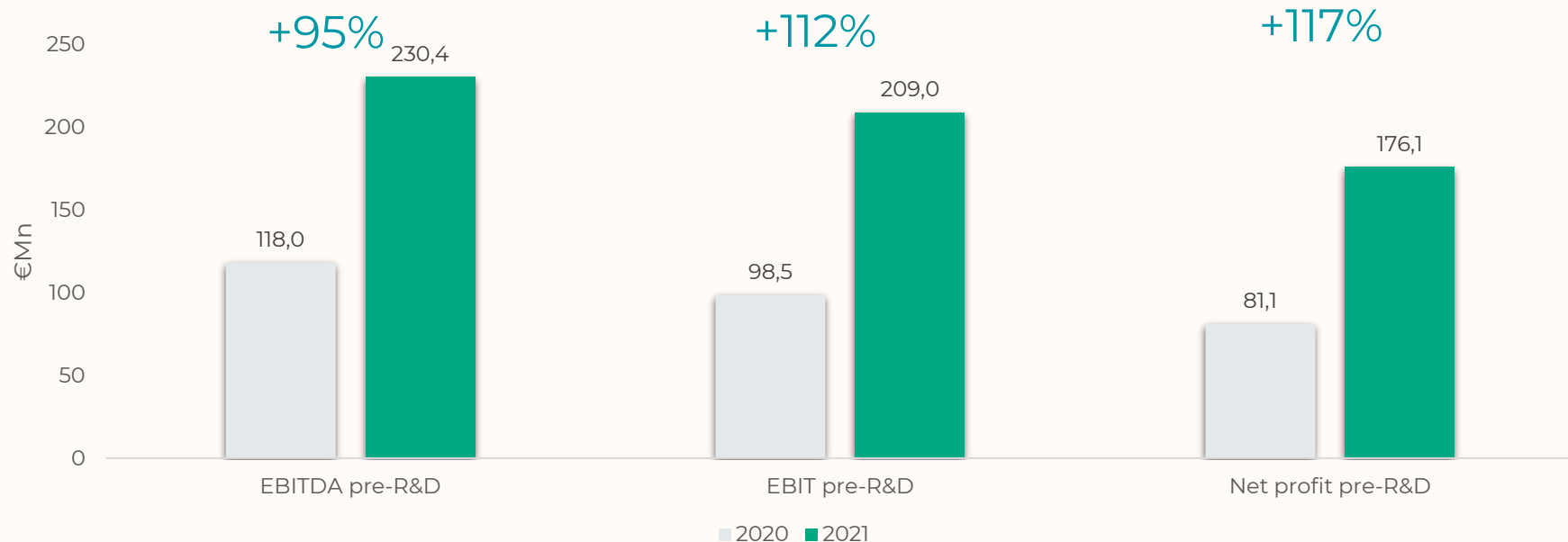


Net Profit

+151%



PRE-R&D analysis



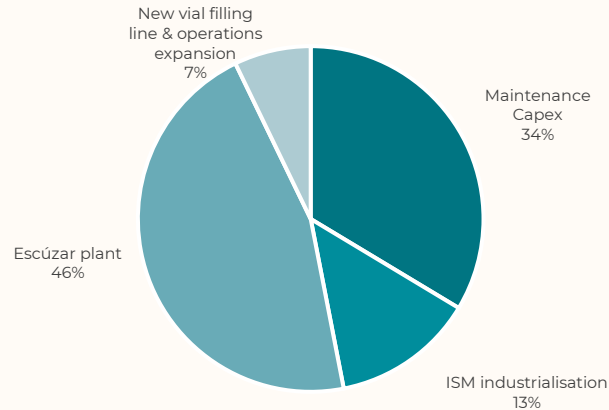
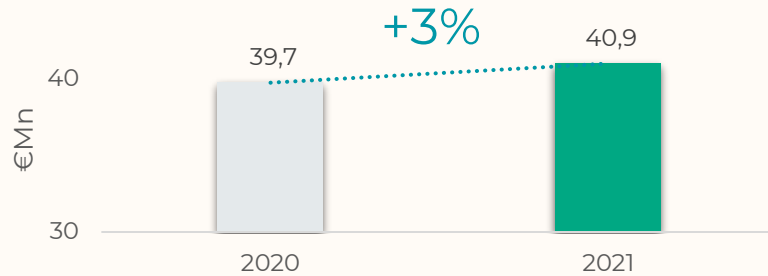
EBITDA “pre-R&D” increased by 95%, from €118.0Mn in 2020 to €230.4Mn in 2021.

EBIT “pre-R&D” increased by 112%, from €98.5Mn in 2020 to €209.0Mn in 2021.

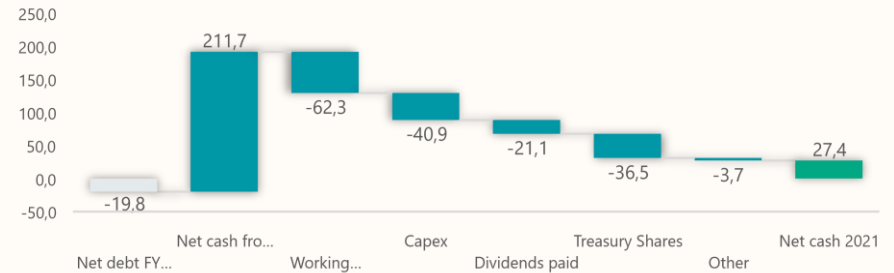
Net profit “pre R&D” increased by 117%, from €81.1Mn in 2020 to €176.1Mn in 2021.

Capital expenditure and Cash Flow

CAPEX Evolution



CF evolution



Cash Flow from operating activities increased to €149.4Mn in 2021 mainly due to:

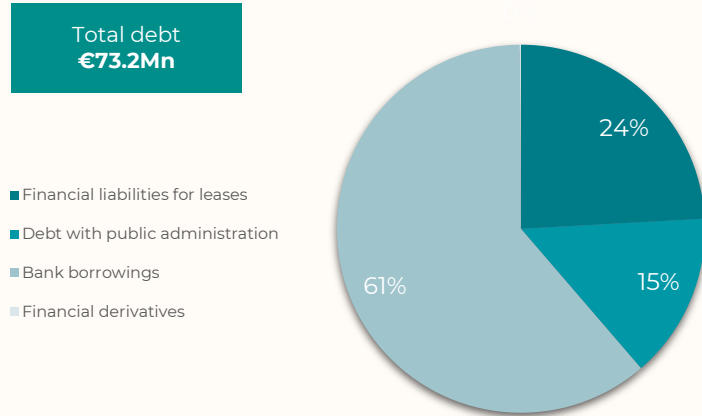
- Increase of €110.0Mn in profit before income tax;
- Decrease of €23.4n in the “inventories” line in 2021 compared to a decrease of €70.4Mn in 2020;
- Booking of €34.4Mn under the “Proceeds from toll manufacturing services” caption in 2021 compared to the €21.6Mn euros recognized in 2020; and
- Increase of €35.4Mn in the “trade and other payables” item in 2021 compared to a decrease of €0.8Mn in 2020.

ROVI **invested €40.9Mn** in 2021 and the 3 main investments projects are:

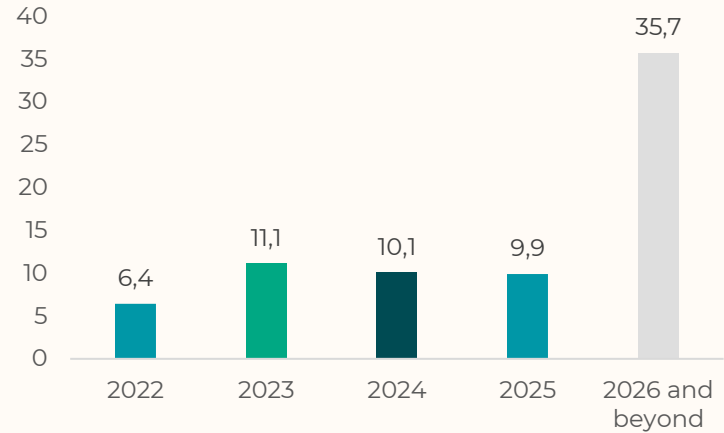
- ISM Industrialization
- Escúzar plant
- New Moderna vaccine lines

Debt analysis

Debt breakdown by source (%)



Debt maturities



Debt with public administration represented **15% of total debt, with 0% interest rate.**

Net cash of €27.4Mn as of 31 December 2021 vs net debt of €19.8Mn as of 31 December 2020.

ROVI will propose to the Shareholders General Meeting a dividend of 0.9556 euros per share with dividend rights on 2021 earnings. This proposed dividend would mean an increase of 151% compared to the dividend on 2020 earnings (€0.3812/share) and represents a 35% pay out.

New ROVI Share Buyback Program

Purpose and scope

To redeem own shares of ROVI (share capital reduction) while, at the same time, increasing the remuneration of ROVI's shareholders by raising earnings per share.

Duration

From today, 23 February 2022, for a **six-month period**.

Maximum monetary amount

Up to **46,000,000 euros**.

Maximum number of shares to be acquired

560,700 shares of the Company, representing approximately 1% of the Company's share capital

News-flow 2022



Specialty pharma

Sales of biosimilar of Enoxaparin

Additional new products to be launched in 2022

Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar outside Europe

CMO

New contracts to be announced
Evolution of Moderna's vaccine manufacturing

ISM® technology platform

Launch of Okedi® in Europe
Marketing authorization for Risperidone ISM® in USA

Discussions with FDA initiated to review Letrozole ISM® phase I results as well as the next steps for continuing the clinical development

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